ANALYSIS OF ALTERNATIVES

and

SOCIO-ECONOMIC ANALYSIS

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and

SOCIO-ECONOMIC ANALYSIS

Legal name of applicant(s):	ENTEK International Limited
Submitted by:	ENTEK International Limited
Date:	18 October 2021
Substance:	Trichloroethylene, EC 201-176-4, CAS 79-01-6
Use title:	Trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries
Use number:	USE 1

CONTENTS

DECLARATION 17

SUMMARY 18

AIMS AND SCOPE OF THE ANALYSIS 19

CONSULTATIONS 20

4 APPLIED FOR "USE" SCENARIO 21

- 4.1 Introduction 21
  - 4.1.2 About the applicant 21
  - 4.1.3 What is a battery? 22
    - *4.1.3.1 Types of batteries* 23
    - *4.1.3.2 What is the function of a battery separator?* 24
  - 4.1.4 Trichloroethylene overview 25
    - 4.1.4.1 Properties 25
    - 4.1.4.2 Known uses of trichloroethylene 27
- 4.2 Market and business trends including the use of the substance 29
  - 4.2.1 ENTEK supply chain 29
    - 4.2.1.1 Upstream supply chain (raw materials) 29
  - 4.2.2 ENTEK battery separator sales 31
    - 4.2.2.1 Downstream supply chain (end users) 31
    - 4.2.2.2 Battery separator market 32
- 4.3 Analysis of the substance function(s) and technical requirement(s) for the product(s) 40
  - 4.3.1 Description of the technical function provided by the Annex XIV substance 40
    - 4.3.1.1 Manufacturing process 41
    - 4.3.1.2 Function of trichloroethylene 43

4.3.2 Description of the product(s) resulting from the use of the Annex XIV substance 49

4.3.3 Description of the technical requirements that must be achieved by the products(s) made with the substance 51

4.3.3.1 Product Specifications 53

4.3.4 Annual tonnage 54

4.4 Remaining risk of the “applied for use” scenario 56

4.4.1 Existing regulatory requirements 56

4.4.2 Exposure and hazard of trichloroethylene 60

4.4.2.1 Exposure 60

4.4.2.2 Hazard 61

4.4.3 Use release summary 63

4.5 Human health impacts of the applied for use scenario 64

4.5.1 Approach for deriving and valuing excess cancer risks 64

4.5.1.1 What types of health impacts are relevant from trichloroethylene exposure? 64

4.5.1.2 What is the excess risk of developing renal cancer from trichloroethylene exposure? 65

4.5.1.3 Derivation and valuation of excess cancer risk 67

Fatal cancer cases 68

Non-fatal cancer cases 69

Estimating benefits of a refused authorisation 70

4.5.2 Trichloroethylene exposure (inhalation) to ENTEK workers 71

What is the risk to ENTEK workers developing cancer? 71

4.5.3 Trichloroethylene exposure (inhalation) to workers in the same industrial estate(s) 73

4.5.4 Trichloroethylene exposure (inhalation and oral) to general population around the Newcastle site 77

4.6 Impact on the environment 82

5 SELECTION OF THE "NON-USE" SCENARIO 83

5.1 Efforts made to identify alternatives 83

5.1.1 Research and development 83

Review of alternatives identified in the original Application for Authorisation 84

5.1.1.1 New alternative solvents 89

Physico-chemical properties 93

Classification and labelling 97

5.1.1.2 Technical feasibility experiments 100

Solubility of process oil and rate of extraction for each alternative solvent 101

Shrinkage of solvent-laden separator upon drying and resulting porosity 106

Impact of trace solvent in the separator on lead-acid electrochemistry: Electrochemical Compatibility 107

Separator Properties: mechanical strength and electrical (ionic) resistance 110

5.1.1.3 Conclusion on solvent alternatives 113

Summary of R&D with solvent alternatives 113

Overall conclusions on alternative solvents 114

5.1.1.4 Alternative technologies 119

[redacted] 120

[redacted] 124

[redacted] 127

[redacted] 131

[redacted] [redacted] 141

5.1.2 Data searches 144

5.2 Identification of known alternatives 144

5.3 Assessment of shortlisted alternatives 145

5.3.1 Alternative 1: Tergo™ MCF 145

5.3.1.1 Substance ID, properties (or Description of alternative technique) 145

5.3.1.2 Technical feasibility of Alternative 1 147

5.3.1.3 Economic feasibility and economic impacts of Alternative 1 149

5.3.1.4 Availability of Alternative 1 152

5.3.1.5 Reduction of overall risk due to transition to Alternative 1 152

5.3.1.6 Conclusions on Alternative 1 157

5.3.2 Alternative 2: Isopar™ G 157

5.3.2.1 Substance ID, properties (or Description of alternative technique) 157

5.3.2.2 Technical feasibility of Alternative 2 159

5.3.2.3 Economic feasibility and economic impacts of Alternative 2 160

5.3.2.4 Availability of Alternative 2 164

5.3.2.5 Reduction of overall risk due to transition to Alternative 2 164

5.3.2.6 Conclusions on Alternative 2 166

5.3.3 Alternative 3: CONFIDENTIAL [redacted] 166

[redacted] [redacted] 166

5.3.3.2 Technical feasibility of Alternative 3 167

5.3.3.3 Economic feasibility and economic impacts of Alternative 3 168

5.3.3.4 Availability of Alternative 3 172

5.3.3.5 Reduction of overall risk due to transition to Alternative 3 173

5.3.3.6 Conclusions on Alternative 3 174

5.3.4 Alternative 4: Cease UK production 175

5.3.4.1 Technical feasibility of Alternative 4 175

5.3.4.2 Economic feasibility and economic impacts of Alternative 4 175

5.3.4.3 Availability of Alternative 4 178

5.3.4.4 Reduction of overall risk due to transition to Alternative 4 178

5.3.4.5 Conclusions on Alternative 4 178

5.3.5 Alternative 5: Cease UK production and relocation outside UK 180

5.3.5.1 Technical feasibility of Alternative 5 180

5.3.5.2 Economic feasibility and economic impacts of Alternative 5 180

5.3.5.3 Availability of Alternative 5 184

5.3.5.4 Reduction of overall risk due to transition to Alternative 5 184

5.3.5.5 Conclusions on Alternative 5 184

5.4 The most likely non-use scenario 185

6 IMPACTS OF GRANTING AUTHORISATION 186

6.1 Human Health and/or Environmental Impacts 186

6.2 Economic impacts 188

6.3 Social impacts 191

ENTEK suppliers 191

ENTEK customers 191

Total number of jobs lost 192

Social Cost of unemployment 192

6.4 Wider economic impacts 193
6.5 Combined assessment of impacts 194
6.5.1 Comparison of impacts 194
6.5.2 Distributional impacts 195
6.6 Uncertainty analysis 196
6.7 Information for the length of the review period 197
6.8 Substitution effort taken by the applicant if an authorisation is granted 199
6.8.1 Introduction 199
6.8.2 Factors affecting substitution 200
6.8.4 Monitoring the implementation of the Substitution Plan 201
6.8.5 Conclusions 201
7 CONCLUSIONS 202
ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS 204
8. REFERENCES 212
APPENDICES 216
Appendix 1 Product specifications – CONFIDENTIAL 216
Appendix 2 Cost break down for substitution to alternatives – CONFIDENTIAL 220

TABLES

TABLE 4.1 SUBSTANCE IDENTIFIERS 26

TABLE 4.2 EU REACH AUTHORISED USES 27

TABLE 4.3 RAW MATERIALS USED IN BATTERY SEPARATOR PRODUCTION PROCESS WITH REPRESENTATIVE COMPOSITION RANGES WHICH DEPEND ON PRODUCT..... 30

TABLE 4.4 LIST OF ENTEK COMPETITORS, THEIR SITES AND SOLVENT USED...... 35

TABLE 4.5 AMOUNT OF BATTERY SEPARATORS PRODUCED AND SOLD (MILLION M^2) BETWEEN 2015-2020 AND FORECAST 2021-2025..... 36

TABLE 4.6 HISTORICAL VOLUME OF BATTERY SEPARATORS PRODUCED AND SOLD OVER THE LAST 5 YEARS (2015-2019) IN NON-EU SITES 38

TABLE 4.7 ANNUAL AVERAGE PRICE OF BATTERY SEPARATORS SOLD (£/M^2) BETWEEN 2015-2019 AND FORECAST 2021-2025..... 38

TABLE 4.8 TURNOVER, COST OF SALES, GROSS AND OPERATING PROFIT (£ MILLION) BETWEEN 2015-2019 AND FORECAST 2021-2025..... 39

TABLE 4.9 ESTIMATED TURNOVER, COSTS AND PROFIT UNDER APPLIED FOR USE SCENARIO OVER 20-YEAR ASSESSMENT PERIOD..... 40

TABLE 4.10 SUMMARY OF ESSENTIAL CRITERIA FOR SUBSTANCE FUNCTION..... 45

TABLE 4.11 'FIT FOR USE' SEPARATOR REQUIREMENTS AND CRITERIA DURING THE BATTERY PRODUCTION PROCESS..... 51

TABLE 4.12 SUMMARY OF TONNAGES..... 54

TABLE 4.13 HARMONISED CLASSIFICATION AND GB MCL OF TRICHLOROETHYLENE..... 56

TABLE 4.14 OCCUPATIONAL EXPOSURE LIMITS (OELS) AS IN ANNEX III OF THE CARCINOGENS AND MUTAGENS DIRECTIVE..... 58

TABLE 4.15 WORKPLACE EXPOSURE LIMITS (WELS) AS SET OUT IN EH40/2005..... 59

TABLE 4.16 TYPE OF RISK CHARACTERISATION REQUIRED FOR WORKERS..... 62

TABLE 4.17 TYPE OF RISK CHARACTERISATION REQUIRED FOR THE GENERAL PUBLIC (MAN VIA THE ENVIRONMENT) 63

TABLE 4.18: VALUES FOR PREVENTING A FATAL CANCER..... 68

TABLE 4.19: VALUES OF PREVENTING A NON-FATAL CANCER IN THE ECONOMIC LITERATURE..... 69

TABLE 4.20: EXCESS RISK AND AVERAGE EXPOSURE AT ENTEK SITE TO TRICHLOROETHYLENE PER WORKER..... 71

TABLE 4.21: ADDITIONAL RENAL CANCER CASES 72

TABLE 4.22: SUMMARY OF THE ESTIMATED TOTAL VALUE OF WORKER HEALTH IMPACTS OF TRICHLOROETHYLENE EXPOSURE (USE 1)..... 73

TABLE 4.23: EXCESS RISK AND AVERAGE EXPOSURE TO TRICHLOROETHYLENE – WORKERS IN THE SAME INDUSTRIAL ESTATE(S)..... 76

Table 4.24: Additional renal cancer cases – workers around the site 76
Table 4.25: Summary of the estimated risk to workers in the same industrial estate(s) to trichloroethylene exposure (nearest £) (based on inhalation only) 77
Table 4.26: Predicted annual mean trichloroethylene concentrations...................................... 78
Table 4.27: Additional renal cancer cases – general population around the site................... 80
Table 4.28: Summary of the estimated risk to the general population around the site to trichloroethylene exposure (nearest £) (based on inhalation only, in order to make an equal comparison across affected groups)... 81
Table 5.1 Summary of findings of the analysis of alternatives for the substances identified in 2014 (with status of risks updated).. 85
Table 5.2 Key physicochemical properties of possible alternatives in comparison to trichloroethylene... 95
Table 5.3 Classification and labelling (C&L)* or other known or potential risks of possible alternatives in comparison to trichloroethylene.. 98
Table 5.4 Rates of oil extraction compared to trichloroethylene 104
Table 5.5 Shrinkage of polyethylene sheet on drying compared to trichloroethylene......... 106
Table 5.6 ECC test data summary 109
Table 5.7 Electrical resistance and resistivity of samples extracted to target 15% residual backweb oil.. 111
Table 5.8 Testing on alternative solvents - summary of outcomes 113
Table 5.9 Overview of alternative solvents.. 116
Table 5.10 Blank 8 142
Table 5.11 Substance identifiers for the Tergo™ MCF constituents 146
Table 5.12: Costs associated with use of Tergo MCF as an alternative to trichloroethylene.. 149
Table 5.13: Total financial costs and benefits to ENTEK of operationalising Tergo MCF 152
Table 5.14 Properties of the constituents of Tergo™ MCF, where available 153
Table 5.15 Summary of feasibility for Tergo™® MCF 157
Table 5.16 Substance identifiers for Isopar™ G, hydrocarbons, C10-C12, isoalkanes, <2% aromatics... 158
Table 5.17 Costs associated with use of IsoparTM G as an alternative to trichloroethylene 161
Table 5.18 Total financial costs and benefits to ENTEK of operationalising IsoparTM G. 163
Table 5.19: Key properties of hydrocarbons, C10-C12, isoalkanes, <2% aromatics.......... 164
Table 5.20 Summary of feasibility for IsoparTM G 166

TABLE 5.21 COSTS ASSOCIATED WITH USE OF BLANK 9 ... 170
TABLE 5.22 BLANK 10 ... 172
TABLE 5.23 BLANK 11 ... 172
TABLE 5.24 BLANK 12 ... 174
TABLE 5.25 COSTS ASSOCIATED WITH CLOSURE OF UK SITE ... 175
TABLE 5.26 TOTAL FINANCIAL COSTS AND BENEFITS TO ENTEK OF CEASING PRODUCTION OF THE UK ... 177
TABLE 5.27 SUMMARY OF FEASIBILITY FOR CLOSURE OF UK SITE ... 178
TABLE 5.28 COSTS ASSOCIATED WITH CLOSURE OF UK SITE AND CREATION OF NEW SITE OUTSIDE OF THE UK (AND EU). ... 181
TABLE 5.29 TOTAL FINANCIAL COSTS AND BENEFITS TO ENTEK FROM RELOCATING OUTSIDE OF THE UK AND EU ... 183
TABLE 5.30 SUMMARY OF FEASIBILITY FOR RELOCATION OF SITE OUTSIDE OF THE UK (AND EU). ... 185
TABLE 5.31 SUMMARY OF AOA ... 185
TABLE 6.1: VALUATION FACTORS FOR MONETISING AVOIDED CANCER CASES, IN 2021 PRICES ... 187
TABLE 6.2: SUMMARY OF HUMAN HEALTH IMPACTS ... 187
TABLE 6.3: COSTS ASSOCIATED WITH CLOSURE OF UK SITE ONLY ... 189
TABLE 6.4: ECONOMIC COSTS TO ENTEK WITHIN THE UK FROM A REFUSED AUTHORISATION ... 190
TABLE 6.5: ESTIMATED NUMBER OF JOBS LOST WITHIN THE UK ... 192
TABLE 6.6 ESTIMATED SOCIAL COST OF UNEMPLOYMENT ... 193
TABLE 6.7: HIGH LEVEL COMPARISON OF KEY BENEFITS AND COSTS OF CONTINUED USE (PV 2021-40) ... 194

FIGURES

Figure 4.1: diagram of Simple battery components ... 22

Figure 4.2: Global market share on lead-acid battery market (B$ 38) (BLANK 46) ... 32

Figure 4.3: BLANK 13 ... 33

Figure 4.4: Global supply of PE battery separators by m^2/year ... 34

Figure 4.5: ENTEK production process diagram, illustrating difference between STD and LR separators drying and subsequent recovery methods (box) ... 42

Figure 4.6: ENTEK equipment photographs and key steps ... 42

Figure 4.7: Schematic drawing of a lead-acid battery and the depiction of a separator envelope surrounding an electrode ... 50

Figure 4.8: Schematic drawing of a lead-acid battery separator profile ... 52

Figure 4.9: Scanning electron micrograph showing the morphology of an ENTEK lead-acid battery separator ... 53

Figure 4.10: Inhalation exposure – dose-response relationship for trichloroethylene - BAuA and ECHA ... 66

Figure 4.11: Step-wise method for estimating the benefits of avoiding cancer ... 70

Figure 4.12: Illustration of the step-wise method for estimating the additional renal cancer cases from inhalation exposure ... 72

Figure 4.13: Air modelling results - Concentrations of TRE around the ENTEK site (2019) ... 74

Figure 4.14: ONS Super Output Area North Tyneside 008B ... 75

Figure 4.15: Air modelling receptor locations ... 78

Figure 5.1: Kamlet-Taft plot of common aprotic solvents ... 90

Figure 5.2: Kamlet-Taft plot of common protic solvents ... 91

Figure 5.3: Kamlet-Taft plot for 'green' aprotic solvents ... 92

Figure 5.4: Kamlet-Taft plot for 'green' protic solvents ... 92

Figure 5.5: Oil solubility check in (left to right) Cyrene™, Augeo® Clean Multi, and Augeo® Clean Plus ... 102

Figure 5.6: Residual oil content (% weight) vs. extraction time (seconds) for various solvents, average of three trials. ... 103

Figure 5.7: Oil concentration (dimensionless) vs time for various extraction solvents. ... 104

Figure 5.8: Schematic diagram of the electrochemical cell used for ECC testing ... 108

Figure 5.9: Cathodic scan for trichloroethylene-extracted separator shows only a small increase in hydrogen overpotential with little change in the charge or discharge peaks. 108

Figure 5.10: Anodic scan for trichloroethylene-extracted separator shows no change in oxygen evolution, or in the charge and discharge peaks. 109

Figure 5.11: Electrical resistivity (mohm-cm) of battery separators extracted with various solvents to ~15% residual oil content. 111

Figure 5.12: Normalised separator puncture strength. 112

Figure 5.13: BLANK 14 [redacted] 120

Figure 5.14: BLANK 15 [redacted] 121

Figure 5.15: BLANK 16 [redacted] .. 122

Figure 5.16: BLANK 17 [redacted] 123

Figure 5.17: BLANK 18 [redacted] 124

Figure 5.18: BLANK 19 [redacted] 125

Figure 5.19: BLANK 20 [redacted] 126

Figure 5.20: BLANK 21 [redacted] 126

Figure 5.21: BLANK 22 [redacted] 128

Figure 5.22: BLANK 23 [redacted] 129

Figure 5.23: BLANK 24 [redacted] 130

Figure 5.24: BLANK 25 [redacted] 132

Figure 5.25: BLANK 26 [redacted] 133

Figure 5.26: BLANK 27 [redacted] 134

Figure 5.27: BLANK 28 [redacted] 134

Figure 5.28: BLANK 29 [redacted] 136

Figure 5.29: BLANK 30 [redacted] 137

Figure 5.30: BLANK 31 [redacted] 138

Figure 5.31: BLANK 32 [redacted] 139

Figure 5.32: BLANK 33 [redacted] 139

Figure 5.33: BLANK 34 [redacted] 140

Figure 5.34: BLANK 35 [redacted] 140

Figure 5.35: BLANK 36 [redacted] 141

Figure 5.36: BLANK 37 [redacted] 151

Figure 5.37: **Financial costs and benefits to ENTEK over time of operationalising IsoparTM G** 163

Figure 5.38: BLANK 38 [redacted] 171

Figure 5.39: Costs and benefits of closing UK site by year (NO DISCOUNTING APPLIED) 177

Figure 5.40: Costs and benefits over time of setting up a new site outside of the UK and EU 183

Figure 6.1: Economic costs to ENTEK of ceasing their UK site 190

LIST OF ABBREVIATIONS

AfA	Applicant for authorisation
AoA	Analysis of Alternatives
C&L	Classification & Labelling
CAS	Chemical Abstracts Service
CEFIC	The European Chemical Industry Council
CLP	Classification, Labelling and Packaging
CMR	Carcinogen, mutagen or reproductive toxin
CSR	Chemical Safety Report
DALY	Disability adjusted life years
DCM	Dichloromethane (methylene chloride)
DNEL	Derived no effect limit
DUs	Downstream users
ECC	Electrochemical compatibility
ECHA	European Chemicals Agency
EEA	European Economic Area
EFB	Enhanced Flooded Battery
eSDS	Extended Safety Data Sheet
EUROBAT	Association of European Automotive and Industrial Battery Manufacturers
ESR	Existing Substances Regulation
EU	European Union
GHG	Greenhouse gas
HSE	Health and Safety Executive
iOEL	Indicative occupation exposure limit
LABS	Lead acid battery separator
ONS	Office for National Statistics
NPV	Net present value
PBT	Persistent, Bioaccumulative, and Toxic
PE	Polyethylene
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
PSIS	Pre-Submission Information Session
QALY	Quality adjusted life year

RAR	Risk Assessment Report
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
SCOEL	The Scientific Committee on Occupational Exposure Limits
SEA	Socio Economic Analysis
SEAC	Socio Economic Analysis Committee
SLI	Starting, lighting, and ignition
SVHC	Substance of Very High Concern
TRI	Trichloroethylene
TWA	Total weight average
UHMWPE	Ultra high molecular weight polyethylene
VSL	Value of statistical life
WEL	Worker exposure level
WTP	Willingness to pay

DECLARATION

The Applicant ENTEK International Limited is aware of the fact that evidence might be requested by HSE to support information provided in this document.

Also, we request that the information blanked out in the “public version" of the Analysis of Alternatives and Socio-economic analysis is not disclosed. We hereby declare that, to the best of our knowledge as of today 18 October 2021 the information is not publicly available or is confidential business information, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature: Director

Date, Place: **October 18th, 2021**
Oregon, USA

SUMMARY

ENTEK International Limited (henceforth, ENTEK) employs approximately 134 people[1] at their site in Newcastle upon Tyne (UK), which produces microporous polyethylene (PE) battery separators. These separators are an integral part of lead-acid batteries which are used for the purposes of starting, lighting and ignition (SLI) for use within automobiles, including cars and light/heavy trucks.

Authorisation is being sought, with a review period of 12 years for continued use of trichloroethylene as a process solvent for the extraction of naphthenic process oil from the PE sheet in the production of PE separators.

The conclusion of the Analysis of Alternatives (AoA) is that there are no alternatives that are suitable and available to the applicant for the replacement of the Annex XIV substance function. The AoA showed that:

- The alternatives identified in 2014 remain not feasible for the applicant, on the basis of technical feasibility, economic feasibility or risk.

- Several possible solvent alternatives have been tested at laboratory scale by ENTEK. Although it was found that for two of the substances (see AoA) there was some potential for the possible replacement of trichloroethylene, a considerable amount of further research would be required to determine the technical feasibility of these substances at a commercial scale. In addition, the customer acceptability of the products manufactured using an alternative would also have to be ensured.

- As well as research on possible solvent substitutes, investigation of the possibilities for manufacture of separators (Blank 39) and separator-free batteries is underway. However, there are many specific technical difficulties to be overcome for these products to be technically feasible and commercially viable.

As set out in Section 6.8 (and Appendix 2) ENTEK has set out a 'substitution plan' setting out what they plan to do to try to substitute away from the use of trichloroethylene if authorisation is granted for the requested 12-year review period. Blank 39a

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[1] Based on 2019 data – Pre COVID-19.

[redacted]

There are a number of challenges (e.g. customer acceptability), whereby at best, it will take ENTEK at least 12 years to implement, assuming none of these challenges are insurmountable.

Section 6.5 summarises the key costs and benefits of a refused authorisation. When comparing the benefits of authorisation (Blank 40) to any potential risks (Blank 41), it is evident that UK society would be better off were authorisation granted. As noted in Section 6.6, the main costs and benefits associated with the continued use of trichloroethylene have been quantified and monetised. Non-quantified impacts are therefore not likely to change the outcome of this SEA. Equally, given the large difference between monetised benefits of continued use vs. monetised costs, any uncertainties in the monetary assessment would not change the outcome of the SEA.

In conclusion, it is recommended that an authorisation is granted for ENTEK's use with a 12-year review period. This is based on the following conclusions:

- The emissions of trichloroethylene have been minimised (as shown in the Exposure Scenario);
- there continues to be no suitable alternatives (nor temporary alternatives) (as shown in the AoA); and
- the benefits of authorisation outweigh the risks by a factor of 8000 (as shown in this SEA).

Further details to justify a 12-year review period are set out in Section 6.7.

AIMS AND SCOPE OF THE ANALYSIS

This report focuses on the efforts undertaken by the authorisation holder to identify alternatives to trichloroethylene for use as a solvent for the extraction of naphthenic process oil from the PE sheet, and to assess the socio-economic impact of the use of the most promising alternatives compared to continued use of trichloroethylene. To this effect the authorisation holder has:

- Updated the current market value of lead-acid battery separators;
- reviewed the alternatives identified in the 2014 Application for Authorisation;
- researched additional alternative solvents and technologies;

- generated initial experimental data to assess the technical performance of the alternatives in comparison to trichloroethylene;
- reviewed the risks associated with trichloroethylene;
- shortlisted the most promising alternatives and reviewed the hazard, risk, technical performance and socio-economic impact of switching to those alternatives; and
- presented a substitution effort scenario with one alternative.

CONSULTATIONS

A consultation was conducted in the 2014 Application for Authorisation in which battery manufacturers were asked about the steps necessary to approve of a battery separator made without trichloroethylene (see 2014 SEA Section 3.2, 3.3 and 3.4).

Several interviews with ENTEK's main downstream users (DUs) and consultation with EUROBAT (the Association of European Automotive and Industrial Battery Manufacturers) were undertaken for the 2014 application. The consultation was used to identify existing alternatives and to acceptability criteria and timings of new products.

In the 2014 consultation, *battery manufacturers indicated that new battery separators would need to be internally tested for a period of at least 4 to 8 months for transportation applications and at least one year for industrial applications. There would also be an additional waiting period to allow the product to advance through the testing queue. After internal testing, the battery manufacturer's customer would then need to test each product, which could take a further 6 months (aftermarket) - 1.5 years (for OEM customers), after some waiting period to advance through the testing queue. EUROBAT members (that also responded to the questionnaire) estimate that this approval process to qualify new battery separators would take longer, at a minimum of 24 months.*

According to ENTEK and confirmed by one battery manufacturer, battery manufactures only approach their customers to test a new product when they have multiple changes to be approved. Any single change, such as a separator made with a new extraction solvent, could potentially have to wait a period of time before the approval process could start. Manufacturers and EUROBAT explained further that they would then gradually phase-in the new product in the market (as there would not be an instant substitute/swap) over a period of at least 2 to 4 years, as the product would have to establish its reputation on the market (in terms of cost effectiveness).

ENTEK has been in dialogue with its customers since the 2014 application to discuss the development of separators using alternative solvents and alternative technologies. A key step in the certification of a new manufacturing method (including using a different solvent for extraction) is partnership with a battery manufacturer. Any new product would need to undergo a series of Battery Council International (BCI) test procedures and each OEM has its own standards and qualification procedures for any component changes. These often follow the VDA 6.3 Process Audit developed by the German trade association for the automotive industry for internal process audits, or for evaluating potential or existing suppliers. It is a framework to ensure compliance, manage risks and to check the plausibility of a plan. ENTEK has attempted to work with battery manufacturers to test new products in batteries, however ENTEK has found that the battery manufacturers are not willing to enter such partnerships. This is assumed to be due to the length and intensity of requirements previously mentioned. It is important to note that ENTEK is not allowed to make batteries themselves to market, because it would breach contract conditions with one of their main customers (‘non-compete’ clause).

ENTEK’s customers have no direct incentive to change separators and price is a key factor in the acceptability of any new product.

4 APPLIED FOR “USE” SCENARIO

4.1 Introduction

4.1.2 About the applicant

ENTEK is a producer of microporous polyethylene (PE) separators used in lead-acid batteries primarily within the automotive industry for the purposes of starting, lighting and ignition (SLI) and in enhanced flooded battery (EFB) for start-stop systems in automobiles, truck, bus, tractors, and motorcycles. These separators are also used in stationary applications technology for end uses in solar, wind, telecommunications, and infrastructure back-up systems.

ENTEK has production sites for PE separators in Newcastle upon Tyne, England (UK), Oregon, (USA), Jakarta (Indonesia) and Tarui (Japan).

Since beginning commercial production of PE separators for SLI lead-acid batteries in 1987, ENTEK’s market share is now estimated to be over 40% of the global PE SLI lead-acid separators market (US, Asia and UK sites combined).

4.1.3 What is a battery?

A battery is an electrochemical device consisting of one or more cells in which energy from a chemical reaction is converted into electricity and used as a source of power. There are many different types of batteries, but generally each consists of: (i) a negative electrode material; (ii) a positive electrode material; (iii) a separator; (iv) an electrolyte that allows ions to move between the electrodes; and (v) terminals that allow electrical current to flow out of the battery (see Figure 4.1). The transfer, or migration, of ions between the negative electrode and the positive electrode, made possible by the electrolyte, takes place through a micro-porous separator. This internal ion transfer is necessary to complete the battery circuit[2].

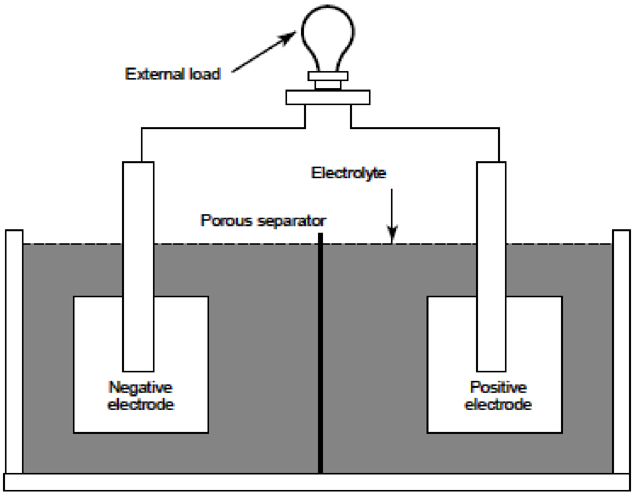

Figure 4.1: diagram of Simple battery components

(Source: engineersedge.com)

Battery separators can be divided into different types depending on their physical and chemical characteristics and application. They can be moulded, woven, non-woven, micro-porous, bonded, papers, or laminates (Arora and Zhang, 2004). A wide variety of properties are required for separators used in batteries, including:

- Minimum electrolyte (ionic) resistance;
- Mechanical and dimensional stability;
- Sufficient physical strength;

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[2] Battery definition and explanations taken from both engineersedge.com and energizer.com accessed April 2021

- Chemical resistance to degradation by electrolyte, impurities, and electrode reactants and products;
- Readily wetted by electrolyte;
- Effective in preventing migration of particles or colloidal or soluble species between the two electrodes; and
- Provide the correct mechanical spacing and electrolyte volume between the electrodes.

4.1.3.1 *Types of batteries*

Among the different varieties, batteries can be categorised in the broadest terms as primary (not rechargeable) or secondary (rechargeable) batteries. Within rechargeable, there are many different types, including:

- Lead-acid;
- lithium ion;
- nickel cadmium; and
- nickel metal hydride.

Battery separators produced by ENTEK at their production site in Newcastle are only used within lead-acid batteries.

There are two different types of commercially available lead-acid battery designs: **flooded cell** and the **recombinant cell**, both of which are used in many automotive and industrial (e.g., forklift) applications. Both types include adjacent positive and negative electrodes that are separated from each other by a porous battery separator, as shown in Figure 4.1.

The first type of lead-acid battery, the flooded battery, has only a small portion of the electrolyte absorbed into the separator. The remaining portion of the acid between the electrodes is in a continuous liquid state. Flooded battery separators typically include porous derivatives of cellulose, polyvinyl chloride, rubber, and polyolefins.

A sub-category of the flooded lead-acid battery is the dry-charged battery. This battery is built, charged, washed and dried, sealed, and shipped without electrolyte. It can be stored for up to 18 months. Before use, liquid electrolyte (acid) is added, and the battery is given a conditioning charge. Batteries of this type have a long shelf-life. Motorcycle batteries are typically dry charged batteries. The acid between the electrodes and the separator is in a continuous liquid state.

The second type of lead-acid battery, the recombinant battery, or valve-regulated lead-acid battery, typically has an absorptive glass mat (AGM) separator composed of microglass fibres. While AGM separators provide high porosity (>90%), low ionic resistance, and uniform electrolyte distribution, they are relatively expensive and still do not offer precise control over oxygen transport rate or the recombination process. Furthermore, AGM separators exhibit low puncture resistance that is problematic for two reasons: (1) the incidence of short circuits increases, and (2) manufacturing costs are increased because of the fragility of the AGM sheets. In some cases, battery manufacturers select thicker, more expensive separators to improve the puncture resistance, while recognising that the ionic resistance increases with thickness. These batteries have an elevated cost compared to flooded lead-acid batteries and are used in luxury vehicles. As indicated in the previous application, the applicant does not manufacture AGM separators at the Newcastle site (nonetheless, the technology has been developed into research of alternative separators for lead-acid batteries, as reported in Section 5.1.1.3).

The separators produced at the ENTEK Newcastle facility, and the focus of this application are used in flooded lead-acid batteries.

4.1.3.2 What is the function of a battery separator?

The battery separator provides a critical function within a lead-acid battery. For efficient operation, a battery requires electricity, i.e. electrons, to flow through an external device (e.g. starter motor) from negative to positive plates. If these plates physically touch, this creates a short circuit, and the battery fails. The lead-acid battery separator (LABS) provides a robust physical barrier between these plates. The battery separator also has to allow the ions to flow between the plates and therefore needs to be porous. If a solid sheet of polyethylene was used, electricity would not flow, and the battery would not function. This porosity is created by the oil and trichloroethylene. A LABS's porosity, consisting of microscopic "holes" which the ions can flow through, is created by having oil in the first phase of the production process which is later removed with a solvent. Removal of the majority of the process oil and evaporation of the trichloroethylene in ENTEK's process creates the "holes" for the ions to flow through. LABS are produced in a variety of different shapes and sizes based upon the type of lead-acid battery made, however, they all have the physical barrier and porosity characteristics that are critical to making a long-lasting, reliable lead-acid battery.

More specifically, microporous polyethylene separators are commonly used because of their ultrafine pore size, which inhibits dendritic growth while providing low ionic resistance, high puncture strength, good oxidation resistance, and excellent flexibility. These properties facilitate sealing of the battery separator into a pocket or envelope configuration into which a positive or negative electrode can be inserted.

Most flooded lead-acid batteries include polyethylene separators. The term "polyethylene separator" is a misnomer because these microporous separators require large amounts of precipitated silica to be sufficiently acid wettable. The volume fraction of precipitated silica and its distribution in the separator generally control its ionic permeability, while the volume fraction and orientation of polyethylene in the separator generally control its mechanical properties. The porosity range for commercial polyethylene separators is generally 50%-65%.

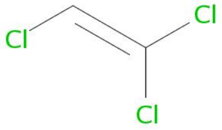
A more detailed explanation of lead-acid battery functionality and product specifications are presented throughout Section 4.3.

4.1.4 Trichloroethylene overview

4.1.4.1 Properties

Trichloroethylene is a clear colourless liquid (at normal temperature and pressure) with a relatively high vapour pressure and low water solubility. It is non-flammable and not explosive. These properties make it ideal for the applicants use.

Table 4.1 Substance identifiers

EC number:	201-167-4
EC name:	trichloroethylene
CAS number (EC inventory):	79-01-6
CAS name:	1,1,2-trichloroethene
IUPAC name:	1,1,2-trichloroethene
CLP Annex I index number:	602-027-00-9
EU REACH Annex XIV entry: **Structure**	15 
Molecular formula:	C_2HCl_3
Molecular weight range:	131.3883

Sources: ECHA[3] and Pubchem[4]

Trichloroethylene is classified in the EU under the CLP Regulation (EC) No 1272/2008 and is present on the GB mandatory classification and labelling (GB MCL)[5] list as a carcinogen, is suspected of causing genetic defects, is harmful to aquatic life with long lasting effects, causes skin and eye irritation and may cause drowsiness or dizziness. The substance is included on the EU REACH Authorisation list (Annex XIV) because of its carcinogenic

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[3] https://echa.europa.eu/substance-information/-/substanceinfo/100.001.062 accessed April 2021

[4] https://pubchem.ncbi.nlm.nih.gov/compound/6575#section=DSSTox-Substance-ID accessed April 2021

[5] https://www.hse.gov.uk/chemical-classification/classification/harmonised-classification-self-classification.htm accessed April 2021

properties (category 1B meeting the criteria of Article 57 a). A corresponding UK Authorisation list is not available at the time of writing the report.

Further information on the properties of trichloroethylene is presented in Section 4.1.4, and in the properties CSR.

4.1.4.2 Known uses of trichloroethylene

Trichloroethylene is registered under EU REACH[6] at 10,000 to 100, 000 tonnes per annum. The registered uses include manufacture of the substance itself, formulation, industrial use as an intermediate, industrial uses including use in the synthesis of vulcanisation accelerating agents for fluoro-elastomers; surface cleaning in closed systems, uses as a heat transfer fluid; use as an intermediate (including under strictly controlled conditions), industrial use in textile scouring. Since the substance has been subject to the requirement for authorisation for placing the substance for use on the EU market since 2014 all uses (apart from manufacture) are authorised. The existing granted authorisation applications give more detail on the specific uses of trichloroethylene, specific applied for uses are summarised in Table 4.2.

Table 4.2 EU REACH Authorised uses[7]

Use	Applicant
Use of trichloroethylene as a solvent for the removal and recovery of resin from dyed cloth	Vlisco Netherlands BV
Use of trichloroethylene as a solvent in a process to recover and purify resin from process water	Vlisco Netherlands BV
Trichloroethylene used as degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries	Microporous GmbH
Use of trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin	ROQUETTE Frères
Use of trichloroethylene as a process solvent for the manufacturing of modules containing hollow fibre gas separation membranes	Parker Hannifin Manufacturing Netherlands (Filtration & Separation) BV

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[6] Information from ECHA website accessed April 2021. Information for GB REACH is not available.

[7] https://echa.europa.eu/applications-for-authorisation-previous-consultations (accessed April 2021)

Use	**Applicant**
Industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil	DOMO Caproleuna GmbH
Industrial use as a process chemical in caprolactam purification	Grupa Azoty S.A.
Use as an extraction solvent in caprolactam production	SPOLANA a.s.
Use of trichloroethylene as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers	A.L.P.A.-AZIENDA LAVORAZIONE PRODOTTI AUSILIARI S.P.A.; CAFFARO INDUSTRIE S.P. A
Use of trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist	Blue Cube Germany Assets GmbH & Co. KG
Industrial use as process chemical (enclosed systems) in Alcantara Material production	Blue Cube Germany Assets GmbH & Co. KG
Use of trichloroethylene in packaging	Blue Cube Germany Assets GmbH & Co. KG
Use of trichloroethylene in formulation	Blue Cube Germany Assets GmbH & Co. KG
Use of trichloroethylene as Extraction Solvent for Bitumen in Asphalt Analysis	Blue Cube Germany Assets GmbH & Co. KG
Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems	Blue Cube Germany Assets GmbH & Co. KG
Use of trichloroethylene in formulation	Richard Geiss GmbH
Use of trichloroethylene in packaging	Richard Geiss GmbH

ENTEK’s granted application has been transferred (grandfathered) to UK REACH and is no longer valid in EU REACH. Further details on the use of trichloroethylene in the production of lead-acid battery separators can be found in Section 4.3.1 of this report as well as the exposure CSR.

4.2 Market and business trends including the use of the substance

Approximately 95% of production from the Newcastle plant is used within lead-acid car batteries. Using the same technology, the plant can produce separators for heavy duty industrial batteries, such as forklifts and golf carts in addition to industrial stand-by power stations for submarines, boats, and cellular towers/data centres. These products are sold worldwide, and not just within the European Union.

All vehicle types, including electric vehicles (EVs) with large lithium batteries, have a lead-acid battery. As is detailed in Section 4.2. Market and business trends including the use of the substance, the global market for electric vehicles (EVs) is increasing, particularly rapidly in Europe. Therefore, the market for lead-acid batteries (also used in EVs) is growing and is likely to continue to for the foreseeable future as measures such as the banning of sales of internal combustion engine automotive vehicles by 2035 in the UK result in EVs being the only options for independent automotive transportation (GOV.UK, 2021).

4.2.1 ENTEK supply chain

Establishing and 'mapping' the supply chain is a fundamental component of the SEA process as it establishes the life cycle of trichloroethylene; the individuals involved in its use, use of articles derived from it, and the overall size of the market.

4.2.1.1 Upstream supply chain (raw materials)

In order for ENTEK to make PE separators, a number of raw materials are used (excluding electricity and natural gas (for energy) and steam/water). As detailed in Table 4.3, the raw materials used are: silica; process oil; ultra-high molecular weight polyethylene (UHMWPE); trichloroethylene; a stearate-based lubricant; antioxidant; and colourant. The quality of the raw materials is integral to the integrity of the lead acid battery separator, for example, producers require separators to be manufactured from UHMWPE as this gives the separator the required physical properties (strength, oxidation resistance, long-term life). Further details are presented throughout Section 4.3. The materials percentage (%) presence in the final product (battery separator) is also included in Table 4.3.

Based on internal communications with ENTEK (Feb 2021), around 76% of these materials are purchased from within the EU.

Table 4.3 Raw materials used in battery separator production process with representative composition ranges which depend on product

Material	Basic function	Mass % of product per m^2
Silica	Provides wettability of the pore structure within the battery separator. The quality and type of silica is critical to the battery's acid-wettability (i.e. allowing the flow of acid through the separator to the lead plates in the battery). The volume fraction of precipitated silica and its distribution in the separator controls electrical (ionic) properties, while the volume fraction and orientation of UHMWPE in the separator control mechanical properties.	(Blank 42)
Ultra-high molecular weight polyethylene (UHMWPE)	UHMWPE serves as a binder for the silica that is dispersed throughout the separator, and it is responsible for the mechanical properties (e.g. puncture strength and stiffness) of the separator.	(Blank 42)
Naphthenic process oil	Process oil is required for the extrusion of UHMWPE and creation of the pore structure within the separator. A residual amount of oil is left in the finished separator to help with the long-term life of the separator (oxidation resistance) within the battery.	(Blank 42)
Colourants	Carbon black additive that imparts grey colour to the separator for better contrast in vision system used to identify defects (e.g. pinholes)	(Blank 42)
Antioxidant	Additive that is used to minimize degradation of the UHMWPE polymer during extrusion	(Blank 42)
Stearate	A release agent that prevents the oil-filled	(Blank 42)

Material	Basic function	Mass % of product per m²
	sheet from sticking to the calendar rolls	
Sodium alkyl sulfosuccinate	A surface-active molecule that grafts to UHMWPE and improves wettability	(Blank 42)

Source: ENTEK chief technology officer

ENTEK's upstream supply chain is as follows: seven raw materials (including trichloroethylene) are purchased and used to produce a battery separator. However, the trichloroethylene and process oil removed during the production of the battery separator are recycled in a continuous process. The battery separators are bought and integrated into SLI lead-acid batteries by battery manufacturers. In 2019 ENTEK's Newcastle site manufactured (Blank 42) million m^2 battery separators, worth approximately (Blank 43) million in terms of sales value.

See Section **4.3.4 Annual tonnage** for the volume of trichloroethylene that ENTEK uses.

4.2.2 ENTEK battery separator sales

4.2.2.1 Downstream supply chain (end users)

The separators made in the Newcastle site are sold to around (Blank 44) customers each year. ENTEK estimates that in 2020, around 90% of the separators produced at the Newcastle site was sold within the EU. This is because the new Jakarta plant supplies the vast majority of its Asian market with a small amount exported to Asia from the UK and US sites.

The applicant's main customers include[8]:

- (Blank 45)
- (Blank 45)
- (Blank 45)
- (Blank 45)

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[8] Source: questionnaire completed by ENTEK issued in March 2021.

As shown in Figure 4.2, the applicant's main customers are some of the main global lead-acid battery manufacturers, where the global lead-acid battery market is estimated to be worth around $38 billion (£27.6 billion[9]).

[redacted]

Figure 4.2: Global market share on lead-acid battery market (B$ 38) (Blank 46)

Source: AVICENNE ENERGY, 2020

(Blank46)

(Blank46)

(Blank46)

(Blank46)

[redacted][10]

4.2.2.2 Battery separator market

All lead-acid batteries require battery separators. The lead-acid battery separator market is ~60% dominated by automotive vehicles, in terms of sales. Perhaps less well known, is that all vehicle types, including EVs with large lithium batteries, have a lead-acid battery. Based on internal market research (by ENTEK), the global supply of and demand for PE battery separators in 2021 is estimated to be:

- Global Demand: ~1.06 billion m^2 / year - shown in Figure 4.3
- Global Supply: ~1.165 billion m^2 / year - shown in Figure 4.4

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[9] Converted using: https://www.fx-exchange.com/usd/gbp-38-exchange-rates.html accessed 13 April 2021.

[10] Source: questionnaire completed by ENTEK, issued March 2021.

ENTEK is estimated to have (Blank 47) market share of the global PE separator market. Assuming ENTEK's UK lead-acid separator price is representative for the global market, the global PE separator market is estimated to be worth (Blank 47) [11] (rounded to the nearest £1 million).

[redacted]

Figure 4.3: [redacted]

[redacted] (Blank 47)

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[11] Converted from USD to GBP at BOE exchange rate of 0.7731

[redacted]

Figure 4.4: Global supply of PE battery separators by m²/year

Notes:

[redacted]

(Blank 48)

The global battery separator market is expected to significantly grow over the next 5-10 years (see Verified Market Research[12], Market Data Forecast[13] and Data Bridge Market Research[14]). However, there is a notable difference between lithium-ion battery separators (with a predicted 12-13% compound annual growth rate (CAGR)) and lead-acid battery separators (with a predicted 2-3% CAGR). The larger increase in lithium-ion battery separators is a result of increasing numbers of electric vehicles (EVs) in the automotive fleet. Conversely, there is no notable change in the lead-acid battery market which is why a steadier 2-3% increase is expected.

Whilst there will be with continued demand for all types of lead-acid batteries (since vehicles have a long lifespan), it is likely there will be also be greater growth over the next 20 years from those vehicles (new and existing) using start-stop technology, and for hybrid vehicles (HVs), and electric vehicles (EVs).

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[12] https://www.verifiedmarketresearch.com/product/battery-seperator-market/

[13] https://www.marketdataforecast.com/market-reports/market-of-battery-separators

[14] https://www.databridgemarketresearch.com/reports/global-battery-separator-market

Number of battery separator manufacturers

ENTEK is one of the leading suppliers of PE SLI battery separators (by volume of battery separators produced), but competes with companies in the EU, and globally. ENTEK estimates it accounts (Blank 49) of the global PE SLI lead-acid separators market by volume of battery separators produced. ENTEK's largest competitor (Daramic), that accounts for approximately (Blank 50) of the global market, use hexane as a solvent instead of trichloroethylene at their French and USA sites. However, at their other sites (and notably, in the most recent three sites built) trichloroethylene was chosen as the solvent used. It should be noted that the battery separator manufacturing process that requires trichloroethylene as a solvent is the same type of extraction process used by Daramic with the solvent hexane (although the properties of hexane mean that the handling and safety structures and operations are quite different (see below)). Table 4.4 lists ENTEK's other competitors, their sites and solvent used during production of battery separators.

Table 4.4 List of ENTEK competitors, their sites and solvent used.

Competitor	Location of site(s)	Solvent used
Daramic	France (Selestat) USA Owensboro, Kentucky	Hexane
	China – Dongli District Thailand – Prachinburi India	Trichloroethylene
Microporous	Austria - Feistritz USA – Piney Flats, Tennessee	Trichloroethylene
Anpei	China – One site	Trichloroethylene
BFR	China (Baoding)	Trichloroethylene
Tiger Membranes	Chines One site	Trichloroethylene
Associated Batteries	India	Trichloroethylene

Notes: Data presented in this table was provided by ENTEK as a response to a questionnaire issued March 2021.

As is detailed above, one major competitor uses hexane at some of its manufacturing sites, instead of trichloroethylene, to manufacture battery separators. This is not feasible for ENTEK's Newcastle site for two key reasons; firstly, hexane cannot be used in the continuous process that ENTEK operates in the Newcastle site, this would require a large capital cost to switch to another extraction process. Secondly, hexane is highly flammable (so presents control difficulties due to its high volatility), is a neurotoxin and reproductive toxin so is likely to come under further regulatory pressure in the future. Further justification can be found in the previous Application for Authorisation Analysis of Alternatives document in Section 5.1 which details why hexane is not a suitable alternative for ENTEK.

Table 4.5 sets out the volume (million m^2) of battery separators produced and sold by ENTEK between 2015 and 2019 with the predicted values from 2021 and 2025. The year 2020 was not included in the study as the numbers would likely be misleading due to the vast impact of the Covid-19 pandemic. Despite expected growth in demand for battery separators over time, the predicted volume of battery separators produced [redacted] (Blank 51) and ENTEK do not intend to expand their production in the UK. [redacted] (Bank 52)

Table 4.5 Amount of battery separators produced and sold (million m^2) between 2015-2020 and forecast 2021-2025

	Actual					**Predicted**				
	2015	2016	2017	2018	2019	2021	2022	2023	2024	2025
Amount of battery separator produced (million m^2)	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53
Amount of battery separator sold (million m^2)	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53	[redacted] Blank 53

Notes:

1. Figures have been rounded to nearest million m^2.
2. Production and sales values for 2015 – 2019 are those reported by ENTEK as part of an AfA questionnaire while forecasted revenue for 2021 – 2025 are based a predicted average production and sales volumes for each year.
3. [redacted] (Blank 53)
4. The year 2020 was not included in the study as the numbers would likely be misleading due to the vast impact of the Covid-19 pandemic.

Battery separators are made to meet detailed customer specifications and are generally shipped within the same year. Therefore, production volumes and sales volumes are generally closely matched (i.e. limited production is stock-piled). For the period 2026-2040, for modelling purposes, it is assumed (Blank 54) are both produced and sold each year reflecting the maximum site capacity despite continued growth in the global market. This is a reasonable assumption as ENTEK has a more recent production site in Asia that is more likely to be expanded to meet increasing global demand.

The battery separator market is very competitive, and customers demand a very competitive price for these products (the market is price sensitive). The manufacturing process used is critical to ENTEK's competitive cost structure. In addition, the majority of ENTEK customers fix their product designs via a Production Part Approval Process (PPAP) specification agreed with the Original Equipment Manufacturers (OEMs), such as Ford, GM, Renault, Volkswagen etc. The OEMs issue major penalties for product switches, which include separator solvent usage as a fineable change of raw materials, that are not validated according to the PPAP specification process. These restrictions place constraints on the battery producer, which are extended to ENTEK as well as other separator manufacturers, who abide by the design standards via quality and commercial supply agreements.

Of the applicant's other production sites, the Oregon site is larger and currently produces (Blank 55) more separators (m2) than the Newcastle site (based on 2019 figures). While the Jakarta site is smaller, producing (Blank 56) fewer separators (m2) than the Newcastle site (based on 2019 figures). The Oregon site predominantly supplies the American (South and North) market while the new Jakarta site exclusively supplies the Asian market. ENTEK established a Joint Venture with PT Separindo in Indonesia in August 2017 to service the growing market in Asia. Table 4.6 presents sales data for these two sites.

Table 4.6 Historical volume of battery separators produced and sold over the last 5 years (2015-2019) in non-EU sites

Actual	**2015**	**2016**	**2017**	**2018**	**2019**
Amount of battery separator produced (million m^2)					
Oregon site - USA	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)
Jakarta site - Asia	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)
Tarui site – Asia	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)
Amount of battery separator sold (million m^2)					
Oregon site - USA	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)
Jakarta site - Asia	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)
Tarui site – Asia	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)	(Blank 57)

Notes:

1. Figures have been rounded to nearest million.
2. The discrepancy between total battery separators produced and total sold can be accounted for by imports from other ENTEK sites (e.g. the UK) and partially by existing stock.

Table 4.7 sets out ENTEK's annual average sales price achieved both historically and predicted up to 2025 from the Newcastle site. Prices are expected to broadly increase over time (e.g. due to increases in energy costs, labour, raw material prices and rent). The prices from 2015-2019 are taken from the ENTEK Annual Reports while the predicted purchases are based on internally gathered information which estimated the 2021 price of a battery separator (£/m^2) and is then uplifted in line with UK five-years inflation forecasts thereafter (2022-2040); this method is used to avoid potential optimism bias. The year 2020 was not included in the study as the numbers would likely be misleading due to the vast impact of the Covid-19 pandemic.

Table 4.7 Annual average price of battery separators sold (£/m^2) Between 2015-2019 and forecast 2021-2025

	Actual purchases					**Predicted purchases**				
	2015	2016	2017	2018	2019	2021	2022	2023	2024	2025
Sales price of battery separator sold (£/m^2)	Blank 58	Blank 58	Blank 58	Blank 58	Blank 58	Blank 58	Blank 58	Blank 58	Blank 58	Blank 58

Notes:

1. Sales price for 2015 – 2019 were calculated using sales revenue as reported in financial reports (ENTEK 2015; 2016; 2017; 2018; 2019) and sales volume data provided by ENTEK in AfA questionnaire while forecasted prices post 2021 are assumed to rise in line with the UK five-year inflation forecast (Blank 58)

Table 4.8 details ENTEK's turnover, cost of sales, gross and operating profit (£ million) between 2015 and 2025. The figures between 2015 and 2019 are from ENTEK's Annual Reports (2015, 2016, 2017, 2018 and 2019) while the predicted values (between 2021 and 2025) are calculated from predicted battery separators sales and predicted cost per m^2 battery separator[15]. There has been no discounting rate applied to these predicted values.

Table 4.8 Turnover, cost of sales, gross and operating profit (£ million) between 2015-2019 and forecast 2021-2025

	Actual					**Predicted**				
	2015	2016	2017	2018	2019	2021	2022	2023	2024	2025
Turnover (£ million)	38	44	45	44	51	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59
Cost of sales (£ million)	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59
Gross profit (£ million)	10	11	11	11	11	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59
Operating profit (£ million)	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59	Blank 59

Notes:

1. Figures have been rounded to nearest million.
2. The figures between 2015 and 2019 are from ENTEK's Annual Reports (2015, 2016, 2017, 2018 and 2019) while the predicted values (between 2021 and 2025) are calculated from predicted battery separators sales and predicted cost per m^2 battery separator.

Table 4.9 summarises the financial information under the applied for use scenario over a 20-year period (2021-2040) with and without discounting, which is applied at 3.5% as per the UK HM Treasury Green Book Guidance (HM Treasury, 2020).

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[15] Predicted Turnover is generated by sales price of battery separator and amount of battery separators produced (source: ENTEK Annual reports and questionnaire question 'k' completed by ENTEK, issued March 2021). Predicted Cost of sales applies a ratio of cost of sales to turnover (source: ENTEK Annual reports).

Table 4.9 Estimated turnover, costs and profit under applied for use scenario over 20-year assessment period

Using discount rate of 3.5%	Total (2021-2040) £million (undiscounted)	Total (2021-2040) £million in Present Value
Turnover	Blank 60	Blank 60
Cost of sales	Blank 60	Blank 60
Gross profit	Blank 60	Blank 60
Operating profit	Blank 60	Blank 60

4.3 Analysis of the substance function(s) and technical requirement(s) for the product[16](s)

The intention of this section is to detail:

1) the production process specific to ENTEK's Newcastle site, in which trichloroethylene is used to make lead-acid battery separators;
2) the function of trichloroethylene in the manufacture of lead-acid battery separators;
3) an overview of the function of separators within batteries, which complements what is presented in Section 4.1.3;
4) the technical specifications of the lead-acid battery separators manufactured through the use of trichloroethylene; and
5) the annual volume of trichloroethylene used in this application.

4.3.1 Description of the technical function provided by the Annex XIV substance

This section initially sets out the process in which trichloroethylene is used to manufacture lead-acid battery separators and then details the technical function of trichloroethylene within that process. The manufacturing process is centred on the properties of trichloroethylene and has been developed and adapted to efficiently recapture and reuse it.

Since the original Application for Authorisation was submitted, the Newcastle plant has started the production of Low Resistance (LR) separators, in addition to the Standard

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[16] See How to develop use descriptions in applications for authorisation, Chapter 2.1

(STD) battery separators. The STD separator is used in traditional lead acid batteries, whereas the LR separator was developed for use with 'start-stop' engine technology (extended flooded batteries) – the form and function of the products are the same.

The products have some differences: due to the increased load on a start-stop battery, the LR separator has a higher porosity, modified pore size distribution, greater puncture strength and a 35-50% lower electrical resistance (ER) compared to STD separator.

Production of LR separator began in April 2014, with no substantive changes required to production process, but with changes to the solvent drying and recovery processes. A summary of the manufacturing process will be presented in the next section and more details can be found in the Exposure CSR.

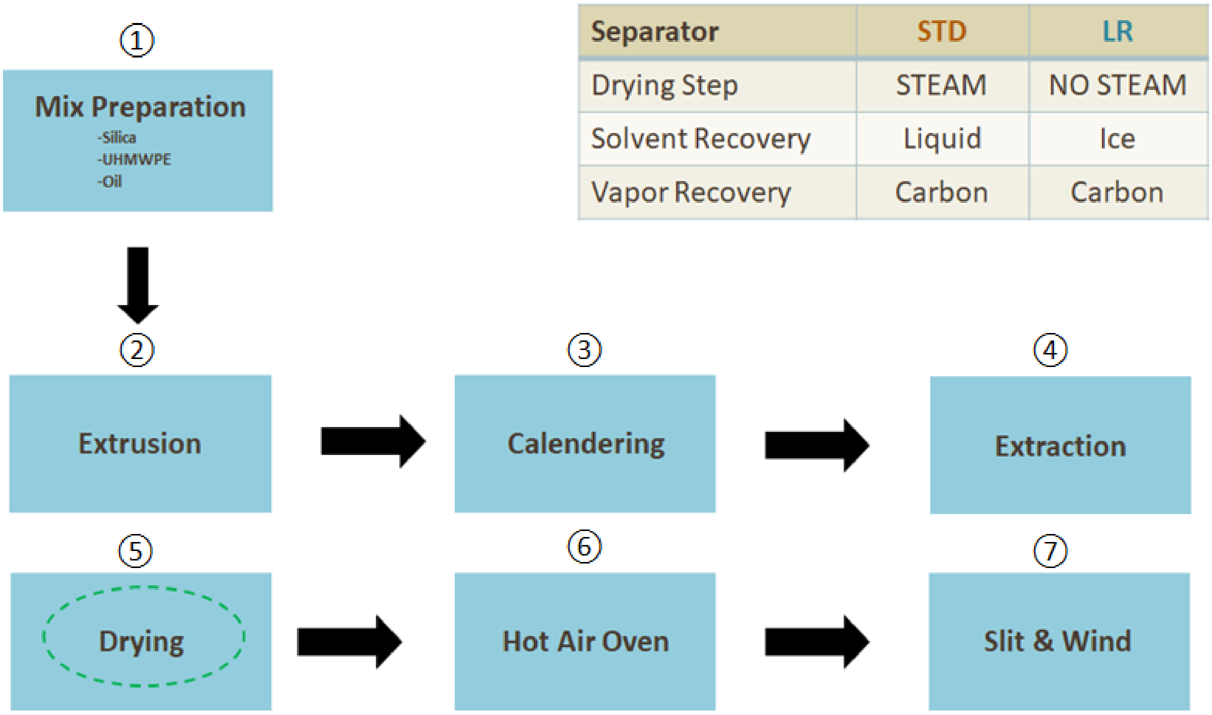
4.3.1.1 Manufacturing process

ENTEK utilises a continuous manufacturing process that starts with raw materials and ends with finished goods in roll form. At the Newcastle factory battery separators are made continuously on four production lines and production is carried out all year around (except for maintenance shutdowns). A key economic benefit of a continuous process is that there is minimal down time in production, maximising the production capacity available.

Polyethylene (PE) separators are microporous and require large amounts of precipitated silica to be sufficiently acid-wettable (i.e. to fill the pore space in the separator and present a continuous volume of acid through the separator and between the lead plates in the battery).

As shown in Figure 4.5 during the manufacture of ENTEK's polyethylene separators, precipitated silica and ultrahigh molecular weight polyethylene (UHMWPE) are combined with process oil and various minor ingredients (listed in Table 4.3) to form a mixture that is extruded at elevated temperature to form an oil-filled sheet. The oil-filled sheet is calendered (rolled out) into the desired thickness and embossed with a rib pattern, followed by extraction of the majority of the process oil with trichloroethylene. The solvent-laden sheet is then passed through a 'dryer' to remove the trichloroethylene and leave behind the interconnected pore structure of the separator.

A process flow diagram for the ENTEK production process is shown in Figure 4.5 and equipment photographs at key steps are shown in Figure 4.6.



Separator	STD	LR
Drying Step	STEAM	NO STEAM
Solvent Recovery	Liquid	Ice
Vapor Recovery	Carbon	Carbon

Figure 4.5: ENTEK production process diagram, illustrating difference between STD and LR separators drying and subsequent recovery methods (box)

STD = standard battery separators and LR = low resistance battery separators.

Step 1: Mix Preparation:
Filler, Polymer, Plasticizer

Step 2: Extrusion
Formation of sheet

Step 3: Calendering
Formation of sheet

Step 4: Extraction and Drying
a) Extraction of oil with TCE
b) Drying: Removal of TCE using steam
c) Hot air oven: Removal of residual TCE and moisture

Step 5: Slitting

Step 6: Winding

Figure 4.6: ENTEK equipment photographs and key steps

Depending upon the final product, the solvent is removed from the sheet by two different processes (illustrated in Figure 4.5):

1. In the production of **standard (STD)** separator, **steam** is used to evaporate the trichloroethylene. The resultant gaseous mixture is then largely condensed into liquid using cooling coils at the bottom of the dryer. The liquid trichloroethylene and water are easy to separate and re-use since they form two immiscible layers. Next, the sheet is passed through a hot air oven where any residual trichloroethylene is evaporated and sent as vapour to an activated carbon bed system. The trichloroethylene adsorbs to the carbon and is eventually recovered when the carbon beds are 'desorbed' (See ES Section 9.1.1 ' Carbon Beds – Solvent Laden Air (SLA) Treatment').

2. In the production of **low resistance (LR)** separator, hot air only is used to evaporate trichloroethylene from the sheet and the solvent laden vapour is then passed through a heat exchanger operating at low temperatures (approximately minus 38°C) such that trichloroethylene "ice" is formed. A duplex system allows for the trichloroethylene "ice" to be recovered as liquid after warming back to room temperature. In this system, a small amount of residual trichloroethylene vapour still travels to the activated carbon bed system where it is recovered. This process imparts higher porosity and a slightly larger average pore size in the LR separator such that it has lower ionic resistance compared to the STD separator.

After either of the above trichloroethylene removal processes, the sheet is then inspected for defects with an on-line vision system and then cut at multiple positions to form separator rolls that have the appropriate profile for customers' battery designs. The term "profile" refers to the width, backweb thickness, number of ribs, rib height, and shoulder design of the separator (further details are provided in Section 4.3.2 and 4.3.3) used in a customer's battery design.

4.3.1.2 Function of trichloroethylene

A critical step in the manufacturing process is the extraction of a controlled amount of process oil from the sheet and subsequent removal of the extraction solvent to form a microporous separator. ENTEK uses the trichloroethylene as its extraction solvent. The purpose and function of the trichloroethylene in this use is to perform the extraction of process oil by displacing the majority of the oil in the sheet. This is followed by evaporation of the trichloroethylene to leave behind interconnected pores in the finished separator.

Solvent in the ENTEK process must meet the following criteria:

1. Hazard rating: non-flammable.
2. High degree of solvency for the process oil.
3. Reasonable vapour pressure for effective evaporation.
4. Low surface tension to prevent pore collapse (resulting from capillary forces exerted during evaporation of the solvent from the sheet).
5. Condensable in a steam atmosphere.
6. Minimal solubility in water.
7. Reversible recovery of high purity solvent using distillation and vapour adsorption/desorption onto activated carbon in a continuous process.
8. Low environmental, health, and safety risk when exposure is managed within acceptable limits.
9. Chemical stability under the conditions used for extraction, drying, and recovery.
10. Available in required quantity at reasonable cost.
11. Produces a finished separator that meets customer requirements for battery production and performance.

These selection criteria have guided ENTEK's choice of trichloroethylene as its extraction solvent. First and foremost, ENTEK believes that it is prudent to use a non-flammable solvent to ensure the safety of its workforce and capital investment. The use of any flammable solvent is currently not compatible with ENTEK's continuous separator manufacturing process (raw materials to finished separator rolls). The requirement for a non-flammable solvent quickly consolidates the potential solvent options.

A high degree of solvency for the ENTEK process oil is important because it ultimately determines the residence time that is required in the extractor and the size of the extractor.

The solvent also needs to have a vapour pressure that is compatible with recovery in distillation and drying steps. The current processes allow recovery of the majority of the solvent as a water-trichloroethylene mixture, which is a much less energy intensive option compared to using hot air to evaporate the solvent from the separator sheet and then sending 100% of it to carbon beds in vapour form.

Finally, solvent cost and availability are important to ensure that the ENTEK separator manufacturing process remains profitable.

The functions of trichloroethylene as a process solvent for the extraction of process oil from polyethylene sheet remain the same as identified in 2014 and are set out above. Table 4.10 below is a summary of the essential criteria with a short explanation/comment to justify why that is the case; however, the detailed arguments are set out in the subsequent sections.

Table 4.10 Summary of essential criteria for substance function

Essential criterion for substance function	**Justification/explanation**
1. Task performed by Annex XIV substance	Trichloroethylene is used to remove (extract) naphthenic process oil from polyethylene/silica sheet during the manufacture of battery separators for onward use in lead-acid batteries in automobiles. The use of trichloroethylene maintains fire and explosion safety in ENTEK's continuous manufacturing process. It also enables effective recovery and reuse of trichloroethylene by distillation or carbon adsorption/desorption. Lead acid battery separators are primarily composed of UHMWPE, precipitated silica and oil. UHMWPE is a polymer that requires a large percentage of process oil to be extruded in sheet form. This polymer imparts the necessary mechanical properties for handling in the manufacturing process. It also imparts high puncture strength demanded by customers. There is significantly less oil in the finished product than the amount of oil required for manufacturing separators; therefore, a solvent is required to remove the majority of the oil from the extruded sheet.. After removal of the required amount of oil, the solvent must then be evaporated from the sheet. This step leaves behind the required amount of porosity to enable ion transport in a battery. The solvent must be highly miscible with the process oil and non-flammable in the ENTEK continuous separator manufacturing process. After removal of the process oil the oil/solvent mixture must be distilled into its separate components for reuse in the manufacturing process. The solvent is also recaptured after evaporation from the separator sheet in both vapour and liquid form. The vapour is recovered through adsorption/desorption in a carbon bed system and the liquid is phase separated from the condensed steam/solvent mixture formed in the dryer or from warming trichloroethylene "ice" to room temperature.
2. What critical properties and quality criteria must the substance fulfil?	A non-flammable solvent is critical to worker and equipment safety. Additionally, this characteristic makes it compatible with the ENTEK continuous manufacturing process.

Essential criterion for substance function	**Justification/explanation**
Non-flammability	
A high degree of solvency with process oil	The solvent must have a high degree of solvency for the process oil so that the oil can be extracted efficiently.
Reasonable vapour pressure for effective evaporation	The vapour pressure determines the ability of the solvent to be evaporated and recovered from the continuous process, enabling recycling of the substance.
Condensable in a steam atmosphere A reversible recovery of solvent using distillation and high surface area carbon	The recovery processes require a solvent that can be condensed in a steam atmosphere, phase separated from water, and that can be captured on carbon and subsequently released and recovered.
3. Function conditions Ambient/room temperature processing	Effective extraction of oil from the sheet in closed solvent baths allows efficient use of energy and control and capture of solvent vapour. The recovery of process oil is accomplished through distillation of the oil/trichloroethylene mixture removed from the extractors.
Recovery of process solvent and process oil	Trichloroethylene is recovered in both vapour and liquid form at different points in the manufacturing process. Liquid trichloroethylene is recovered via distillation of the oil/trichloroethylene mixture and from phase separation of the water/trichloroethylene mixture condensed during the drying stage or from warming trichloroethylene "ice" to room temperature. Finally, trichloroethylene vapour is recovered through adsorption/desorption in the carbon beds. The recovered trichloroethylene is then reused in the ENTEK continuous separator manufacturing process.
4. Process and performance constraints Product	Upon evaporation of the solvent, the finished separator must have sufficient porosity and wettability to provide low electrical (ionic) resistance.

Essential criterion for substance function	**Justification/explanation**
Performance of the separator in lead-acid batteries and acceptance of product by customers.	It is essential that the separator provides mechanical integrity so that the separator can be enveloped at high speeds and to prevent grid wire puncture during battery assembly or operation. It is also essential that any trace amount of the solvent that may be left in the separator will not negatively affect the electrochemical performance of the lead-acid batteries.
Compatibility with the process equipment for making polyethylene separators.	Trichloroethylene is stable and non-reactive with the grade of Stainless Steel used throughout the ENTEK plant for equipment that handles solvent (e.g. piping, valves, fittings, carbon beds, extractor and dryer).
5. Is the function associated with another process that could be altered so that the use of the substance is limited or eliminated?	There are two main processes involving trichloroethylene: 1) The extraction of process oil from the separator sheet to reduce the oil content from about (Blank 61) by weight to about (Blank 62) by weight in the finished product. 2) The recovery and recycling of the trichloroethylene that allows reuse of the solvent with a high degree of efficiency. Both processes allow battery separators to be manufactured efficiently in a continuous process with good control of releases. Both processes are interdependent and specifically designed for the use of trichloroethylene. The possibilities for using an alternative substance are analysed and the associated process changes considered in this document. It is found that it is not currently possible for the applicant to use an alternative. Research concludes that it will be at least 12 years before an alternative could be commercially acceptable.

Essential criterion for substance function	**Justification/explanation**
6. What customer requirements affect the use of the substance in this use? Key separator characteristics	The lead-acid storage battery includes positive and negative electrodes that are separated from each other by a porous battery separator. There are five major requirements for the battery separator, it must: 1) be an electrical insulator to prevent shorting between the electrodes; 2) be composed of materials that can provide chemical and oxidation resistance; 3) be porous to allow for ionic conduction through the separator as the battery is discharged; 4) provide the correct mechanical spacing and electrolyte volume between the electrodes; and 5) run effectively through the separator enveloping line during battery manufacture. Trichloroethylene enables the above key separator characteristics by: • controlled quantitative extraction of process oil from the extruded separator sheet to leave behind the required pore size distribution and percent porosity; • evaporation of solvent from the separator sheet to leave behind the required pore size distribution and percent porosity; • not negatively impacting battery performance even if trace amounts of residual solvent remain in the finished product; and • closed loop recycling allows for efficient and safe reuse of the solvent in the manufacturing process and delivery of the separator to the customer at a competitive price.
Security of supply	Separators are a critical component in lead-acid batteries used throughout Europe. Security of supply is of critical importance for battery manufacturers. Each supply location plays a critical role in the security of supply for the battery manufacturers. Each supplier is expected to have robust processes to ensure timely delivery of this critical component. For example, annual analysis and reporting on risks to continuous operation and mitigation efforts for these risks, for example, fire safety, may be contractually required.

Essential criterion for substance function	Justification/explanation
7. Are there particular industry sector requirements or legal requirements for technical acceptability that must be met and that the function must deliver?	Battery Council International (BCI), Society of Automotive Engineers (SAE), and European Norm (EN) specifications must be met for both separators and lead-acid batteries.

4.3.2 Description of the product(s) resulting from the use of the Annex XIV substance

An overview of batteries is presented in Section 4.1.3. This section focuses on the function and characteristics of separators within lead-acid batteries.

The PE separator in a lead-acid battery provides mechanical integrity for highspeed enveloping and prevents sharp grid wires or plates from shorting the battery during assembly. The separator produced by ENTEK is further processed by downstream users ready for assembly into batteries: the separator is fed to a machine that forms 'envelopes' by cutting the separator material, inserting an electrode, and sealing its edges (see Figure 4.7). The electrode is either a positive or negative grid that is pasted with electrochemically active material.

The battery separator provides a critical function within a lead-acid battery. It physically separates the positive and negative electrodes (plates) so that a short circuit cannot form, its pore structure allows for ionic conduction through the acid between the electrodes. The porosity is created by the extraction of oil by trichloroethylene followed by the evaporation of the solvent. If a solid sheet of polyethylene was used, ions and electrons would not flow, and the battery would not function. The porosity of a lead-acid battery, provided by microscopic 'holes' through which ions can flow, is created by phase separation of the oil and polymer in the first phase of the production process. The subsequent displacement of the majority of the oil with trichloroethylene, followed by its evaporation, results in the pore structure ('porosity') that allows for ion flow between the electrodes . Separators are produced in a variety of different shapes and sizes; however, they all have the physical barrier and porosity characteristics that are critical to making a long-lasting, reliable lead-acid battery.

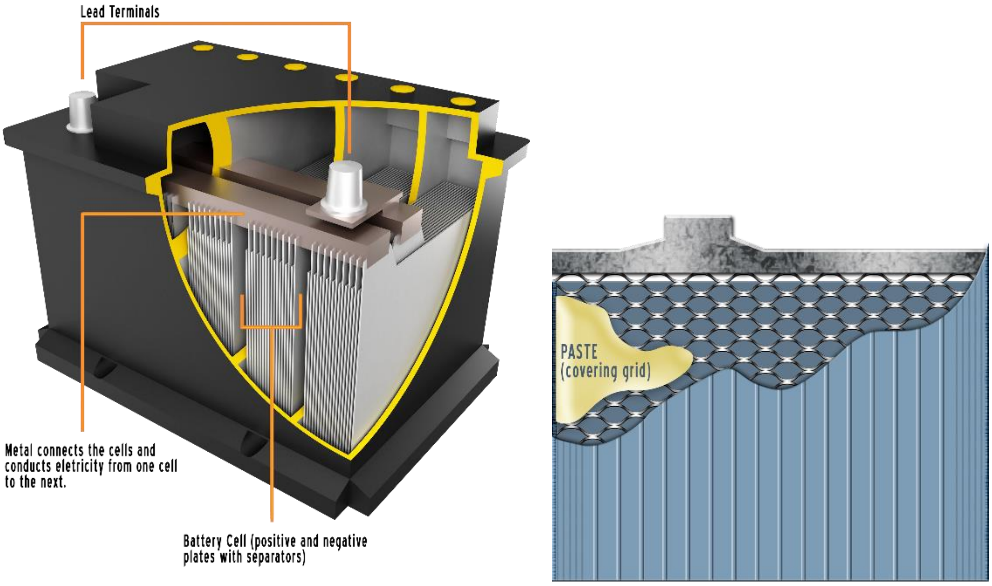


Figure 4.7: Schematic drawing of a lead-acid battery and the depiction of a separator envelope surrounding an electrode

An electrode package is formed once the positive or the negative electrode is inserted into the separator envelope. The electrode package is then alternated with the other electrode (positive or negative) type to form a stack in which the separator acts as a physical spacer and an electronic insulator between the electrodes (i.e., plates). After making series and parallel connections between the electrodes and 2V cells, an electrolyte (i.e. sulphuric acid) is then introduced into the assembled battery to facilitate ionic conduction within the battery. Finally, the battery goes through an electrochemical formation step.

Separator rolls must meet a number of criteria, described as 'fit for use', in order for downstream users to further process the separators at an industrial scale, as described above. Table 4.11 summarises the 'fit for use' requirements and criteria that ENTEK's separators must meet. These requirements form part of the technical product specifications outlined in the next section.

Table 4.11 'Fit for Use' separator requirements and criteria during the battery production process

Enveloping	Acid filling	High Voltage (High Potential test (HiPot))	Formation
Low skew	Uniform porosity	No pinholes	Low hot acid shrinkage
No wavy edge	Good wettability	Controlled pore size distribution	Minimal oil dissolution
Roll tension	Fixed Overall dimension	Low moisture	High durability
Fixed width	No folded ribs		Controlled amount and type of wetting agent
Minimal shoulder width variation			
Easy to cut			
High puncture strength			
Good Sealability			

4.3.3 Description of the technical requirements that must be achieved by the products(s) made with the substance

This section details the separator characteristics and the product technical requirements.

In order to do that the separator properties outlined in Section 4.1.3, the raw materials outlined in Section 4.2.1.1, as well as the manufacturing process, characteristics of separators, and the function of trichloroethylene outlined in the previous sections, are brought together in this section.

As already indicated elsewhere, UHMWPE is the material widely chosen for lead-acid battery separators because it can impart excellent mechanical properties while serving as a "binder" for the large quantities of precipitated silica necessary to provide wettability. The repeat unit of polyethylene is shown below:

$(-CH_2CH_2-)x$

where x represents the average number of repeat units in an individual polymer chain. In the case of polyethylene used in many film and moulded part applications, x equals about 10^3-10^4 whereas for UHMWPE x exceeds 10^5. This difference in the number of repeat units is responsible for the higher degree of chain entanglement and the unique properties of UHMWPE.

A specific desired property is the ability of UHMWPE to resist material flow even when heated above its crystalline melting point (135°C). This phenomenon is a result of the long relaxation times required for individual chains to slip past one another, and therefore, UHMWPE is not a true thermoplastic. It requires a plasticizer such as a naphthenic process oil to assist in solubilising and disentangling the polymer chains under the high temperature and shear conditions inside a twin screw extruder. After the extrudate passes through the die and between the calender rolls that emboss a rib pattern (see Figure 4.6), the sheet is cooled so that the oil phase separates from the polymer to form regions that will eventually become pores after removal of the oil.

A separator profile consists of its backweb thickness, overall thickness and width plus the design and layout of the ribs. Each profile gives different performance and use characteristics. Figure 4.8 illustrates the profile of a general lead-acid battery separator.

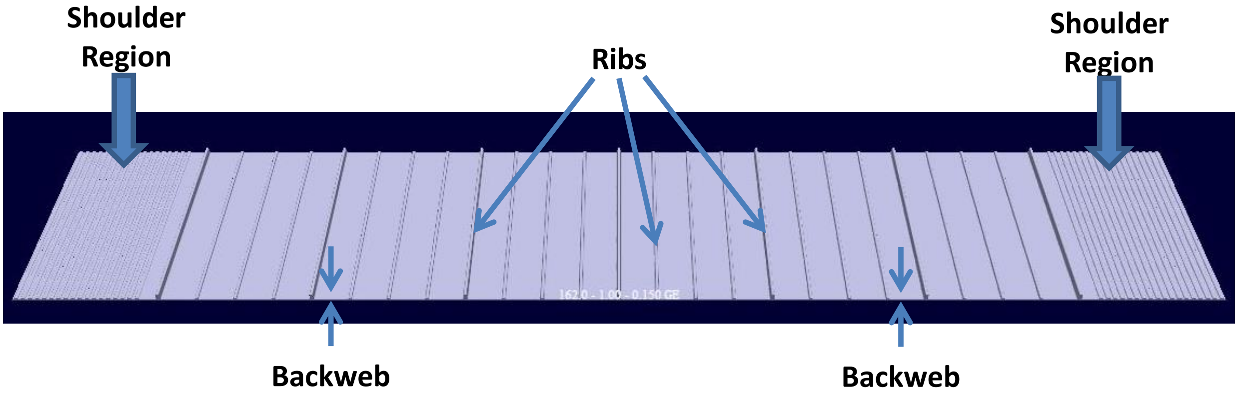


Figure 4.8: Schematic drawing of a lead-acid battery separator profile

There is always a controlled amount of oil left in the finished separator because it has a positive impact upon the oxidation resistance of the separator. The residual oil is believed to reside within the UHMWPE fibrils that are dispersed throughout the separator. In this case, the oil serves as a reactive species for scavenging oxygen and other oxidizing agents that can attack the long polymer chains and cause embrittlement of the separator.

As indicated elsewhere, polyethylene separators are microporous and require precipitated silica to be sufficiently acid-wettable. The volume fraction of precipitated silica and its distribution in the separator determine its ionic resistance, and the volume fraction and orientation of polyethylene in the separator determine its mechanical properties. Figure 4.9 shows the typical structure of a microporous separator.

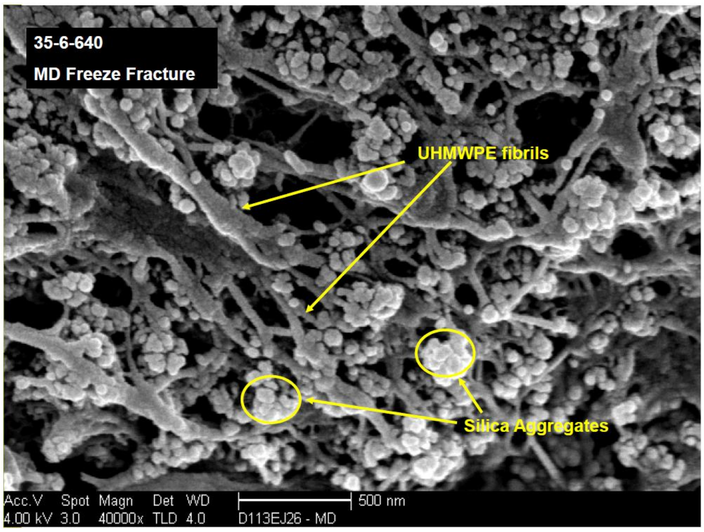


Figure 4.9: Scanning electron micrograph showing the morphology of an ENTEK lead-acid battery separator

Battery manufacturers require microporous polyethylene separators with a material composition that provides good puncture resistance, high oxidation resistance and low electrical (ionic) resistance. All these characteristics are critical for the separator to function properly both during and after formation of the battery. Puncture strength, stiffness, tensile strength, and elongation-at-break are a measure of the separators' mechanical properties: a separator must be strong enough to maintain integrity during the further processing by battery manufacturers.

4.3.3.1 Product Specifications

Key characteristics and their tolerances are usually outlined in mutually agreed-upon specifications with individual customers. An example of confidential ENTEK Global specifications for its STD and LR separator products are shown in Appendix 1, Tables A1-1 and A1-2, respectively.

ENTEK measures the key characteristics outlined in the previous section and uses them for statistical process control during the manufacturing process.

4.3.4 Annual tonnage

The use tonnages assumed in the original application, along with the current use tonnages and the expected future use tonnages are summarised in Table 4.12.

Table 4.12 Summary of tonnages

Year	Tonnage consumed (tonnes/year)[a]	% Reduction from previous year	Comment
2009	207	-	Original application
2010	188	-9	Original application
2011	189	0	Original application
2012	162	-14	Original application
2013	42	-74	Original application
2014	10-100 tonnes per annum Blank 63	Blank 63	Review report
2015	10-100 tonnes per annum Blank 63	-34% - purchased -31% - consumed	Review report
2016	10-100 tonnes per annum Blank 63	+68% - purchased +55% - consumed	Review report
2017	10-100 tonnes per annum Blank 63	+5% - purchased -16% - consumed	Review report
2018	10-100 tonnes per annum Blank 63	-33% - purchased -24% - consumed	Review report
2019	10-100 tonnes per annum Blank 63	-16% - purchased -7.3% - consumed	Review report
2021	10-100 tonnes per annum Blank 63		Estimated future annual purchase of trichloroethylene
2022	10-100 tonnes per annum Blank 63		Estimated future annual purchase of trichloroethylene
2023	10-100 tonnes per annum Blank 63		Estimated future annual purchase of trichloroethylene

Year	Tonnage consumed (tonnes/year)[a]	% Reduction from previous year	Comment
2024	10-100 tonnes per annum Blank 63		Estimated future annual purchase of trichloroethylene
2025	10-100 tonnes per annum Blank 63		Estimated future annual purchase of trichloroethylene

Note: a) The tonnage purchased each year is used to replace the tonnage consumed (or lost) from the process. In some years the amount purchased is slightly different to the amount consumed and these are indicated in the Table. The site holds a stock of trichloroethylene and these differences between the purchased amount and the consumed amount translate to a small increase or small decrease in the total amount of trichloroethylene held at the site.

A strategic business objective at the ENTEK Newcastle upon Tyne (UK) facility is minimisation of trichloroethylene usage. Substantial investment has been made in new carbon beds, enclosures and extraction systems, a comprehensive trichloroethylene monitoring system and a full time Environmental manager position. The reduction in trichloroethylene use in Table 4.12 reflects the operation of new equipment to reduce fugitive trichloroethylene losses. The exposure assessment presents the improvements made at the plant to reduce emission.

The applied for use is a continuous process and the trichloroethylene in the system is continuously recycled and reused. The resident trichloroethylene in the system is ≤50 Blank 63a tonnes, but this is reprocessed continually as the trichloroethylene used to extract the oil from the separator sheet is recycled. The total volume that is *processed* in a year is the volume that is recycled and reused within the system; this total use volume was ≤115,000 Blank 63a tonnes per year in the original application and ≤90,000 Blank 63a tonnes per year in 2019. The volume of substance that is *purchased* within a year is the volume that is required to replace the volume of substance that is lost from the system; there are yearly small differences between the actual volume purchased and the actual volume consumed (lost from the system) and this translates into small yearly fluctuations in the total volume held at the site. The volume consumed was approximately 42 in the original application and ≤50 Blank 63a in 2019 (the amount purchased in 2019 was ≤45) Blank 63a. In terms of efficiency of reprocessing, the recycling of trichloroethylene at the ENTEK site was estimated to be ≤99.99% Blank 63a efficient in the original application, since ≤45 Blank 63a was the amount lost from a total use of ≤115,000 Blank 63a processed. A similar calculation for the 2019 data (≤50 Blank 63a tonnes loss from a total use ≤90,000 Blank 63a processed) gives an estimated ≤99.99% Blank 63a efficiency for the recycling process.

4.4 Remaining risk of the "applied for use" scenario

The intention of this section is to set out the potential risks from continuing to use trichloroethylene in the "applied for use" scenario and to explain the current regulatory requirements that apply to ENTEK's use of trichloroethylene and how those risks are controlled. A detailed assessment and documentation of how the risks are managed is presented in the Exposure Scenario (part of the CSR).

4.4.1 Existing regulatory requirements

The human health classification and labelling of trichloroethylene determines much of the regulatory obligations for the substance. The harmonised classification and labelling of trichloroethylene (under Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)) and the GB Mandatory Classification and Labelling is set out in Table 4.13.

Table 4.13 Harmonised classification and GB MCL of trichloroethylene

Hazard Class and Category Codes	Hazard phrase	Hazard Code
Skin Irrit. 2	Causes skin irritation	H315
Eye Irrit. 2	Causes eye irritation	H319
STOT SE 3	May cause drowsiness or dizziness	H336
Muta. 2	Suspected of causing genetic defects	H341
Carc. 1B	May cause cancer	H350
Aquatic Chronic 3	Harmful to aquatic life with long lasting effects	H412

The 2014 AfA identified the relevant UK and EU regulatory requirements for the applied use scenario of trichloroethylene. These remain the same, with the addition of UK REACH obligations. These are summarised here:

- EU REACH (European Parliament and Council Regulation (EC) No 1907/2006) and UK REACH. This regulation and its amendments up to 31 December 2020 are retained in UK law.
- Carcinogens and Mutagens Directive - Directive 2004/37/EC of the European Parliament and the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC).)
- Chemical Agents Directive - Directive 98/24/EC - on the protection of the health and safety of workers from risks related to chemical agents at work, insofar as it relates to risks to health from exposure to substances other than asbestos or lead.
- Control of Substances Hazardous to Health (COSHH) – UK Legislation - Control of Substances Hazardous to Health Regulations 2002 – note that in the UK COSHH implements Council Directive 2004/37/EC, on the protection of workers from risks related to exposure to carcinogens at work, insofar as it relates to carcinogens other than asbestos; and Council Directive 98/24/EC, on the protection of the health and safety of workers from risks related to chemical agents at work, insofar as it relates to risks to health from exposure to substances other than asbestos or lead.
- Environmental permitting - Environmental Permitting (England and Wales) Regulations 2010 SI 2010 No. 675 (the Regulations), implementing European Community (EC) Directive 2008/1/EC. Also, UK Water Industry Act 1991 for control of discharges in wastewater to the foul sewer.

The following paragraphs summarise the regulatory requirements of trichloroethylene

- EU REACH and equivalent UK REACH

Under EU and UK REACH trichloroethylene is considered as an SVHC (Substance of Very High Concern) because of its classification as a carcinogen (Carc. 1B). and is listed in Annex XIV of the EU REACH. Its status has not changed since the last application.

- Carcinogens and Mutagens Directive

The function of the directive is the protection of workers from the risks related to exposure to carcinogens or mutagens at work. In early 2019 binding and limit values as well as skin notation have been added to Annex III of the directive and are presented in Table 4.14.

Table 4.14 Occupational Exposure Limits (OELs) as in Annex III of the Carcinogens and Mutagens Directive

Long-Term Exposure Limit (LTEL) values		**Short-Term Exposure Limit (STEL) values**		**Skin Designation**
mg/m^3	**ppm**	**mg/m^3**	**ppm**	
54.7	10	164.1	30.0	Yes

Note: mg/m^3 is milligrams per cubic metre of air at 20 °C and 101.3 kPa

The previous Occupational Exposure Value (OEL) was set by the Scientific Committee on Occupational Exposure Limits (SCOEL) at 10 ppm 8-hour time weighted average.

In the UK these limit values are transposed as WELs in the Health and Safety Executive (HSE) publication EH40/2005 Workplace exposure limits. The requirement to comply with Workplace Exposure Limits (WEL) is set out in Regulation 7(7) of the Control of Substances Hazardous to Health Regulations (COSHH), see below.

- Control of Substances Hazardous to Health (COSHH)

REACH and COSHH are similar in that both require a risk assessment taking into account the hazards of substances used in the workplace and the possible exposure of workers to hazardous substances. In COSHH it is the employer’s responsibility to conduct the risk assessments for all substances that may be hazardous to health and to impose site-specific and process-specific measures to control exposure. COSHH relies somewhat on UK WEL and the objective is to keep exposure to workers below the relevant WEL. REACH information is complimentary to this; in REACH, application of the risk management measures (RMM) in the extended Safety Data Sheet (eSDS) indicates likely compliance with the derived no effect limit (DNEL) (the safe level for humans, in this case workers). In COSHH, the use of good control practice (set out in guidance from the UK HSE) indicates likely compliance with WEL. Normally, good practice under COSHH and RMM under REACH are complimentary, but if assessment in either regime calls for extra controls, these need to be applied. The WELs set out in EH40/2005 Workplace exposure limits are higher than the OELs in the carcinogens directive and are presented in Table 4.15.

Table 4.15 Workplace Exposure Limits (WELs) as set out in EH40/2005

Long-Term Exposure Limit (LTEL) values (8-h TWA reference period)		**Short-Term Exposure Limit (STEL) values (15-min TWA reference period)**		**Notations**
mg/m^3	**ppm**	**mg/m^3**	**ppm**	Carc and Sk
550	100	820	150	Yes

Carc = Capable of causing cancer.
Sk = Can be absorbed through the skin. Assigned to substances for which there are concerns that dermal absorption will lead to systemic toxicity.
mg/m^3 is milligrams per cubic metre of air at 20 °C and 101.3 kPa

- Environmental Permitting

Emissions of trichloroethylene from the ENTEK plant at Newcastle are subject to Environmental Permits issued by the Environment Agency and Northumbrian Water to control emissions. These were reported in the previous Application for Authorisation and are repeated here.

Emissions to air are covered under the Environmental Permitting (England and Wales) Regulations 2010. ENTEK's permit (EPR/WP3434LT) is issued by the Environment Agency. According to this permit a new single stack from Carbon bed Absorbers 1-4 has a limit of 100 mg/m^3 (100 mg per cubic meter at normal temperature and pressure). There is also a fugitive emissions reduction programme in the permit, which details the measures to be used to control fugitive emissions of halogenated solvent (trichloroethylene). Potential sources of fugitives must be identified along with a review of the controls in place to prevent, or where this is not possible, minimise emissions. The plan must identify improvements that can be made. This was effective from 1 January 2010 and then is to be updated every two years thereafter.

Emissions to wastewater are covered under the UK Water Industry Act 1991. ENTEK operates under a Discharge of Trade Effluent Consent (No: N1378) issued and monitored by Northumbrian Water. Any wastewater from the process that contains trichloroethylene is treated via distillation prior to discharge to trade effluent. The amount of trichloroethylene in the trade effluent discharge is set by the trade effluent discharge consent. The current limit set is 1.2 mg/l. Daily release rates are reported in the exposure scenario as 2.8E-3 kg/day and the local predicted environmental concentration is 2.9E-8 mg/L.

4.4.2 Exposure and hazard of trichloroethylene

4.4.2.1 Exposure

Potential exposure to trichloroethylene arises from fugitive emissions from the separator manufacturing process, where trichloroethylene is used as a solvent for the removal of process oil from polyethylene sheet.

Uncaptured trichloroethylene is released to the atmosphere via a stack with a permit set limit at 100 mg/m^3 (17 ppm). There is an internal site operating limit for the stack set at 12 ppm.

All of the operations involving trichloroethylene are undertaken within enclosures. The solvent extraction takes place in an enclosed unit and the four production lines (2 pairs) are housed in additional enclosure areas with negative air pressure to reduce fugitive emissions. The air from each enclosure is extracted and passes to the carbon beds for solvent capture / recovery. Workers are excluded from the enclosures apart from when undertaking essential process checks and any engineering or maintenance activities. For essential process checks, a worker would typically spend less than 10 minutes within the enclosure during a 12-hour shift and longer for any engineering/maintenance activity . Access to the enclosures is, however, controlled in relation to use of respiratory protective equipment and maximum time that a worker can spend within enclosure. More details on the operations and a copy of the Standard Operating Procedures can be found in the exposure CSR.

In addition to the enclosures around the operations involving trichloroethylene, the winder area where workers are regularly working, are in enclosures which are also under negative pressure with fresh air being blown in onto the workers and any "end of line" emissions from the oven drawn back into the oven enclosure. These enclosures were added in 2019 in an effort to further reduce worker exposure.

Outside the enclosure, workers are exposed to background or fugitive emissions of trichloroethylene (listed in the exposure CSR) and to a few point emissions sources: carbon bed discharge stack, oil coalescing filter discharge stacks and dust bag.

The releases to atmosphere from the facility, the stack and from other fugitive emissions give the possibility for exposure of the general public and the environment to trichloroethylene from aerial emissions. This and the limited release to wastewater result in exposure of the general public to trichloroethylene via food and water intake.

The assessment is based on risk to human health for workers and for the general public (i.e. man via the environment).

4.4.2.2 Hazard

As stated in Section 4.4.1, trichloroethylene is included on the REACH Authorisation list (Annex XIV) and equivalent UK legislation because of its carcinogenic properties (category 1B meeting the criteria of Article 57 a). As indicated from the classification of the substance, the substance does have other hazards both to humans (trichloroethylene is an eye and skin irritant as well as mutagenic), and it is also indicated as harmful to aquatic life. However, the main focus of this and the previous application is the properties of the substance that cause it to be listed as an SVHC, i.e. its carcinogenic properties.

For the assessment of trichloroethylene there is a need to consider the status of the substance as a threshold or non-threshold carcinogen. The hazard conclusions for systemic effects for human health contained in the last submitted version of the EU Lead Registrant REACH dossier are presented as Derived No Effect Levels (DNELs) for threshold effects, which in turn are based on the 8-hour Time Weighted Average (TWA) long-term and 15-minute short term exposure limits for workplace exposure as determined by the EU Scientific Committee for Occupational Exposure Limits (SCOEL)[17]. In the context of this exposure assessment, it is appropriate to retain the short-term DNELs from the registration dossier and also the qualitative conclusions for local effects on skin and eyes which are based on existing classifications for these endpoints.

The long-term inhalation DNEL for an 8-hour shift is based on an 8-hour TWA iOEL of 10 ppm (53.71 mg/m^3 at 25°C); while the long-term inhalation DNEL for a 12-hour shift is derived from a pro-rated 12-hour TWA iOEL of 6.7 ppm (23.99 mg/m^3 at 25°C).

However, the exposure levels can also be assessed without comparison to safe levels, and in the context of a non-threshold carcinogen these levels can also be compared to the dose-response cancer risk curve as communicated by ECHA's Risk Assessment Committee[18]. In the context of cancer risk as set out in ECHA's approach to assessment of trichloroethylene, the worker risk estimates are based on the assumption of 8-hour exposure for 5 days/week over 40 years. This is a 40-hour week over 40 years. At ENTEK the shifts are 12 hours, of which 10.67 hours are on the factory floor. Each factory floor worker works a 42-hour week based on 3.5 shifts; of this 42 hours, some 37.33 hours are spent on the factory floor.

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[17] Scientific Committee on Occupational Exposure Limits (SCOEL) Report No. SCOEL/SUM/142

[18] ECHA 10 April 2014, RAC/28/2014/07 rev 2 Final. Application for Authorisation: Establishing A Reference Dose Response Relationship For Carcinogenicity of Trichloroethylene

The *de facto* Derived Minimal Effect Level (DMEL) for the long-term inhalation route, as calculated by ECHA based on the dose-response curve for kidney cancer risk, is 33 mg/m^3 (6 ppm), for which the excess cancer risk is calculated to be 4*10-4. Likewise, a DMEL value of 4.72 mg/kg bw/day is calculated for long-term dermal exposure. For the purposes of this application, assessment of risk is based on the DMEL values presented in Table 4.16, which are more conservative than the conventional DNELs present in the EU REACH registration dossier.

Tables 4.16 and 4.17 below show the safe levels that have been derived for trichloroethylene for workers and for the general public.

Table 4.16 Type of risk characterisation required for workers

Route	**Type of effect**	**Risk characterisation type**	**Hazard conclusion**
Inhalation	Systemic effects - long term	Semi-quantitative	DMEL (Derived Minimum Effect Level) = 33 mg/m^3
	Systemic effects - acute	Quantitative	DNEL (Derived No Effect Level) = 164.1 mg/m^3
	Local effects - long term	Not needed	No hazard identified
	Local effects - acute	Quantitative	DNEL (Derived No Effect Level) = 164.1 mg/m^3
Dermal	Systemic effects - long term	Semi-quantitative	DMEL (Derived Minimum Effect Level) = 4.72 mg/kg bw/day
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	Qualitative	Medium hazard (no threshold derived)
Eye	Local effects	Qualitative	Medium hazard (no threshold derived)

Table 4.17 Type of risk characterisation required for the general public (man via the environment)

Route of exposure and type of effects	**Risk characterisation type**	**Hazard conclusion**
Inhalation: Long term, Systemic	Semi-quantitative	DMEL (Derived Minimum Effect Level) = 6.2 mg/m³
Inhalation: Long term, Local	Not needed	No hazard identified
Oral: Long term, Systemic	Semi-quantitative	DMEL (Derived Minimum Effect Level) = 0.92 mg/kg bw/day

Note: Although ECHA quantified a dermal hazard, in the exposure scenario and in this assessment, dermal exposure is not considered to be a relevant exposure route for the general population and therefore is not characterised.

In the exposure scenario there is a comparison of the DNELs to exposure measured and estimated in the Newcastle facility and also calculations of the excess cancer risk for workers and general public at the estimated exposure levels.

4.4.3 Use release summary

The facility at Newcastle is very efficient at trichloroethylene recovery it processes ≤90,000 Blank 63b tonnes of trichloroethylene per year. In terms of efficiency of reprocessing, the recycling of trichloroethylene at the ENTEK site is estimated to be ≤99.99% Blank 63b efficient, since ≤50 Blank 63b tonnes was the amount lost from a total use of ≤90,000 Blank 63b tonnes processed in 2019.

A summary of the ≤50 Blank 63b tonnes 'lost' trichloroethylene during processing is set out as follows:

- Volume released to atmosphere via point source emissions = ≤25 Blank 63c tonnes
- Volume released to atmosphere as fugitive emissions = ≤25 Blank 63c tonnes
- Volume assumed to be residual in product = ≤0.4 Blank 63c tonnes
- Volume released to wastewater = <0.001 tonnes

Of the volume released to air some will end up in the soil near to the site. Of the volume released to wastewater some will end up in surface water and some in sewage sludge that may then be spread on land.

4.5 Human health impacts of the applied for use scenario

This section covers the potential human health impacts associated with the inhalation of trichloroethylene. Specific focus is given to three groups of people; workers at the ENTEK plant, those who work in neighbouring businesses and those who live in close proximity to the ENTEK site. Section 4.5 is broken down into the following sub-sections:

- **4.5.1 Approach for deriving and valuing excess cancer risks**– This section sets out the different approaches to deriving excess cancer cases and the associated monetary values.
- **4.5.2 Trichloroethylene exposure (inhalation) to ENTEK workers** – This section sets out health impacts on ENTEK workers from the exposure to trichloroethylene.
- **4.5.3 Trichloroethylene exposure (inhalation) to workers in the same industrial area(s) -** This section sets out the health impacts on other workers within close proximity of the ENTEK site from exposure to trichloroethylene.
- **4.5.4 Trichloroethylene exposure (inhalation and oral) to general population around the Newcastle site -** This section sets out the health impacts on those living within close proximity of the ENTEK site.

This section quantifies and monetise risk per population group, whilst the aggregate estimates for the impacts on human health are presented in Section 6.1.

4.5.1 Approach for deriving and valuing excess cancer risks

4.5.1.1 What types of health impacts are relevant from trichloroethylene exposure?

Various epidemiological studies have examined the potential health impact risks from trichloroethylene exposure. The most relevant reports (in 2013) were prepared by the

German Federal Institute for Occupational Safety and Health (BAuA)[19] and their Committee on Hazardous Substances (AGS)[20].

AGS (2013) reports available evidence related to trichloroethylene, assessing potential risks from long-term exposure to trichloroethylene for three types of cancer: renal (kidney), hepatic tumours (liver) and non-Hodgkin lymphomas (NHL).

The AGS (2013) suggests that it is "*doubtful whether TRI [trichloroethylene] can also cause hepatic cancer and non-Hodgkin lymphomas in humans*". The dose-response analyses indicates that risk for renal tumours is triggered at lower exposure levels than adverse effects on other organs. The evidence of risk associated with other organs is also less consistent. Therefore, renal cancer remains the main endpoint of concern associated with trichloroethylene exposure.

As set out in the exposure scenario of the CSR, it is not necessary to assess any potential risks associated with dermal exposure to trichloroethylene for ENTEK workers.

4.5.1.2 What is the excess risk of developing renal cancer from trichloroethylene exposure?

ECHA's dose-response relationship is used for inhalation exposure, which determines how many additional cancer cases might occur for a given level of exposure to trichloroethylene. It is expressed as the percentage of excess cancer risk per unit concentration. This approach is based on and consistent with the risk-based approach for carcinogenic substances, as developed by BAuA (2013).

Specifically for trichloroethylene, based on the work by AGS (2013), ECHA developed different dose-response curves to determine the renal cancer risk at different exposure levels. For a long-term exposure of trichloroethylene up to 75 ppm (410 mg/m^3), BAuA reports evidence of carcinogenicity[21] (an excess risk of 5%) and use this to propose a linear relationship between exposure and renal cancer incidences.

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[19] BAuA (2013) – "The risk-based concept for carcinogenic substances developed by the Committee for Hazardous Substances - From limit-value orientation to an action-oriented approach". Available at: http://www.baua.de/de/Publikationen/Broschueren/A85.pdf?__blob...v=4

[20] AGS (2013) – "Exposure-risk relationship for trichloroethylene" - Available at: http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/pdf/910/910-trichloroethylene.pdf?__blob=publicationFile&v=2

[21] AGS (2013) reference: POD; German epidemiological studies of kidney cancer

BAuA also sets a threshold concentration (also referred to as a 'point of departure') at 6 ppm (33 mg/m^3), below which there is no relevant 'cancer–enhancing effect' to the kidney (nephrotoxicity). BAuA suggests that below 6 ppm, the risk is lower by an order of magnitude compared to the linear extrapolation. Two dose response curves are therefore established:

1. Based on an excess risk of renal cancer of 5%, 1% and 0.4% related to average exposure of 75 ppm, 15 ppm and 6 ppm (respectively) extrapolated through the origin (see the black dashed line in Figure 4.10); and
2. A sub-linear curve based on the break-point at 6 ppm (33 mg/m^3), at which 0.04% excess risk is estimated and extrapolated downward to the origin and upward to the point of departure at 75 ppm (see the red solid line in Figure 4.10).

Based on the conclusions from AGS (2013) and ECHA, this SEA takes the non-linear relationship as the basis for estimating risks (i.e. used for the best estimate).

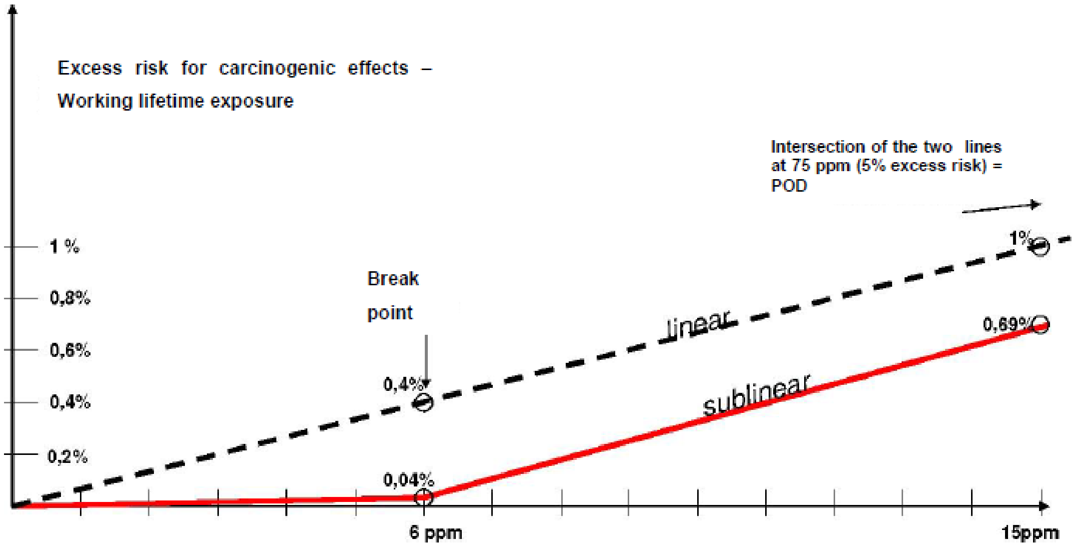

Figure 4.100: Inhalation exposure – dose-response relationship for trichloroethylene - BAuA and ECHA

Source: BAuA (2013) Exposure-risk relationship for trichloroethylene in BekGS 910

The non-linear equation for inhalation exposure risk is set in a tiered way (by AGS and ECHA) as follows:

- Excess risk (%) for the first 6 ppm = 0.0067 x concentration (ppm); and

- Excess risk (%) for the range of ppm beyond 6 ppm = 0.0720 x concentration (ppm).

Box 4.1 shows the dose-response relationships derived by ECHA. Due to lack of valid data for risks to the general population, ECHA uses different factors, such as the duration of exposure and breathing volume of the person, to account for the derivation relative to the worker inhalation dose response curve. ECHA uses "route-to-route" extrapolation from the worker inhalation dose-response curve to derive the oral general population dose response curve.

Box 4.1: ECHA Dose Response Relationships

Worker inhalation exposure

At 33 mg/m^3 and above:
Excess risk = 1.3 × 10^{-4} (mg/m^3)-1 × concentration (mg/m^3) – 0.0039
Below 33 mg/m^3:
Excess risk = 1.2 × 10^{-5} (mg/m^3)-1 × concentration (mg/m^3)

General population inhalation exposure

At 6.2 mg/m^3 and above:

Excess risk = 6.9 × 10^{-4} (mg/m^3)-1 × concentration (mg/m^3) – 0.0039
Below 6.2 mg/m^3:
Excess risk = 6.4 × 10^{-5} (mg/m^3)-1 × concentration (mg/m^3)

General population oral exposure

At 0.92 mg/kg bw/d and above:
Excess risk = 4.66 × 10^{-3} (mg/kg bw/d)-1 × dose (mg/kg bw/d) – 0.0039
Below 0.92 mg/kg bw/d:
Excess risk = 4.32 × 10^{-4} (mg/kg bw/d)-1 × dose (mg/kg bw/d)

Source: ECHA (2014)

4.5.1.3 Derivation and valuation of excess cancer risk

The first step to monetising the additional cancer cases is to determine the renal cancer mortality rate. Data on UK-specific incidence and mortality rates for renal cancer by gender were obtained from the IARC database[22]. The probability that a cancer is fatal for males

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[22] IARC database: http://globocan.iarc.fr.

and female combined[23] is 43%[24] for the UK (and therefore 57% of renal cancers are not fatal).

Fatal cancer cases

For fatal cancers, there are alternative ways of estimating a monetary value. One approach is to measure the effect of the cancer on an individual in terms of the number of years lost due to the disease (as quality-adjusted life year (QALY), or disability-adjusted life year (DALY)) and assigning a monetary value to it, based on the willingness to pay (WTP) to gain an additional QALY/DALY. Alternatively, a value of a statistical life (VSL)[25] can be applied, by means of the productivity lost or the WTP to avoid the risk of fatality. The approach applied in this SEA is based on VSL as they can be applied directly to value the number of cancer cases[26].

A value is assigned to the proportion of additional cases that are fatal. A review of key sources provides different valuations for a statistical life that can be applied in the European or UK specific context, which are summarised in Table 4.18. The estimates sourced from literature reviews are used and uplifted to 2021 prices to produce a lower and an upper-bound estimate:

- Low estimates for value of a fatal cancer, taken from the HSE (2016): £1.5 million (2021 prices); and
- high estimate for value of a fatal cancer, taken from ECHA (2016): £4.9 million (2021 prices).

Table 4.18: Values for preventing a fatal cancer

Source	Original Value	Year of original value	Value (£, in 2021 prices)	Observations
ECHA (2016) Willingness-to-pay values for various health	€3.5m - €5m	2012	£3.4m-£4.9m	ECHA used a binary discrete choice approach to

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[23] The difference between male and female fatality rates is 1% (42 and 43% respectively).

[24] Consideration was made of other sources, which presented figures both higher and lower than 43%. It was concluded that the 43% presented by the UN would be used due to its reliability and average position between high and low figures.

[25] VSL is the aggregation of individuals' willingness to pay for fatal risk reduction and therefore the economic value to society to reduce the statistical incidence of premature death in the population by one.

[26] QALY/DALYs on the other hand are initially non-monetary estimates (but can then be valued) and would require much more detailed data/assumption on when the worker might get cancer and how many years they would live with the cancer before premature death.

endpoints associated with chemicals exposure				find a WTP to prevent premature death, elicited in the context of cancer
UK Health and Safety Executive (HSE 2016) - Costs to Britain of Work-Related Cancer	£1.27 million	2013	£1.5 million	Average cost of fatal cancer (all cancer types) per case of work-related cancer

Notes:

1. Euro values were converted from € to £ using the average exchange rate in 2012 from EUROSTAT before being uplifted to 2021 prices using UK treasury GDP deflator (2013 – 2020) and the Office for National Statistics (ONS) consumer price index (CPI) (2020 – 2021).

Non-fatal cancer cases

For non-fatal cancer cases, the burden (cost) of the illness can be measured by estimating 'tangible' costs such as medical costs and productivity lost during the convalescence and adding combining this with WTP to avoid the illness, which can estimate the additional 'intangible' costs such as pain, grief, and suffering. The relevant values identified are reported in Table 4.19 (note: there were estimates from US studies which were previously reported in the previous AfA, but not used and therefore not reported here). The estimates sourced from literature reviews are used and uplifted to 2021 prices to produce a lower and an upper-bound estimate:

- Low estimates for value of a non-fatal cancer, taken from the HSE (2016): £63,000 (2021 prices); and
- high estimate for value of a fatal cancer, taken from ECHA (2016): £402,000 (2021 prices).

Table 4.19: Values of preventing a non-fatal cancer in the economic literature

Source	Original Value	Year of original value	Value (£, in 2021 prices)	Observations
ECHA (2016) Willingness-to-pay values for various health	€410,000	2012	£402,000	This values Cancer morbidity (generic). This

endpoints associated with chemicals exposure				value expresses the WTP to avoid any disutility caused by the cancer morbidity in addition to premature death
UK Health and Safety Executive (HSE 2016) - Costs to Britain of Work-Related Cancer	£53,100	2013	£63,000	The average cost per case of a work-related non-fatal cancer (all types)

1. Figures reported in £2021 prices are rounded to the nearest thousand
2. Euro values were converted from € to £ using the average exchange rate in 2012 from EUROSTAT before being uplifted to 2021 prices using UK treasury GDP deflator (2013 – 2020) and the Office for National Statistics (ONS) consumer price index (CPI) (2020 – 2021).

Estimating benefits of a refused authorisation

Based on the monetised values for fatal and non-fatal cancer cases, the process of estimating the benefits (avoided costs) of reduced worker exposure to trichloroethylene is shown in Figure 4.11.

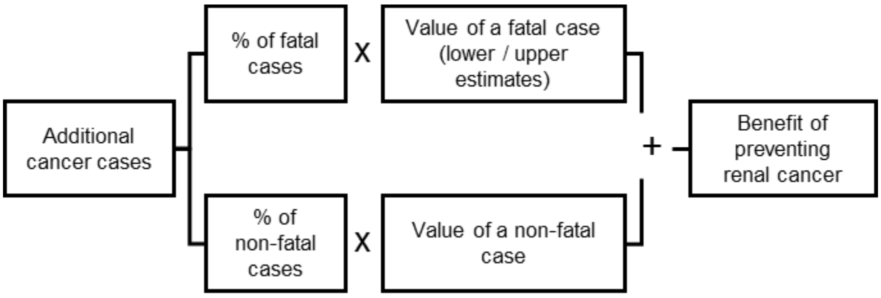

Figure 4.11: Step-wise method for estimating the benefits of avoiding cancer

4.5.2 Trichloroethylene exposure (inhalation) to ENTEK workers

As described in the Exposure Scenario (ES), ENTEK's workers are potentially exposed to low levels of trichloroethylene during the production of battery separators, which would either continue in the applied for use scenario or cease in the non-use scenario. To quantify and estimate the value of the associated health impacts, dose-response relationships developed in April 2014 by the RAC of ECHA (2014) are used as per the original AfA. The assessment is based on there being no thresholds for cancer effects of trichloroethylene for renal (kidney) cancer, based on exposure of 8 hours per working day over a working life of 40 years.

What is the risk to ENTEK workers developing cancer?

In order to estimate the excess cancer risk for workers at the ENTEK site in Newcastle (UK) as a result of exposure to trichloroethylene, the workers are firstly separated into production workers (working on the factory floor and all maintenance staff) and non-production workers (non-factory floor). Average exposure for each group is derived using measured data as well as modelled estimates of short-term exposure (15 minutes) at drying operations.[27]. The number of ENTEK workers within each group (production and non-production) and each gender, as well as their average exposure to trichloroethylene is reported in Table 4.20.

Table 4.20: Excess risk and average exposure at ENTEK site to trichloroethylene per worker

Type of worker	Excess risk	Number of workers	Average exposure	Basis for exposure
Production workers	1.15E-04	106	14.39 mg/m^3	Average exposure from all exposure scenario activities (not weighted by time spent on each activity).
Non-production workers	1.26E-07	28	1.5 mg/m^3	Badged monitoring in training room (non-factory floor).

Notes: Of the 106 production workers, 10 are based part of the week in the office and part of the week on the factory floor. For conservative purposes, it is assumed that those 10 workers have the same exposure levels as those based solely on the factory floor.

The production workers at ENTEK have a 12-hour shift (rather than the assumed 8 hours per day exposure used in the BAuA studies), which includes 1 hour and 20 minutes of

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[27] Model used in ECETOC TRA v.3, Process category (PROC) 2 is used for drying operations in the model.

breaks in which it is compulsory for the worker to leave the factory floor. The average number of hours worked during a week is 42 hours, ~38 hours excluding breaks, i.e. which is similar to the total hours used in the BAuA studies (when excluding break times). Non-production workers have a usual working day of 8 hours (40 hours per week). It has been assumed that the exposure-risk relationships presented in the previous section, which was estimated for a presumed exposure of 8 hours per day, holds for both production and non-production workers. The rationale is that their weekly exposure to trichloroethylene is of similar duration, even though their daily exposure is not.

The additional risk of developing renal cancer for production and non-production workers is obtained by using worker exposure data and the dose response relationships (see Box 4.1). The calculation steps are presented in Figure 4.12. The final result - "Additional cancer cases" - corresponds to the total number of additional cancer diagnoses across all ENTEK's workers from a working life-time exposure of 40 years.

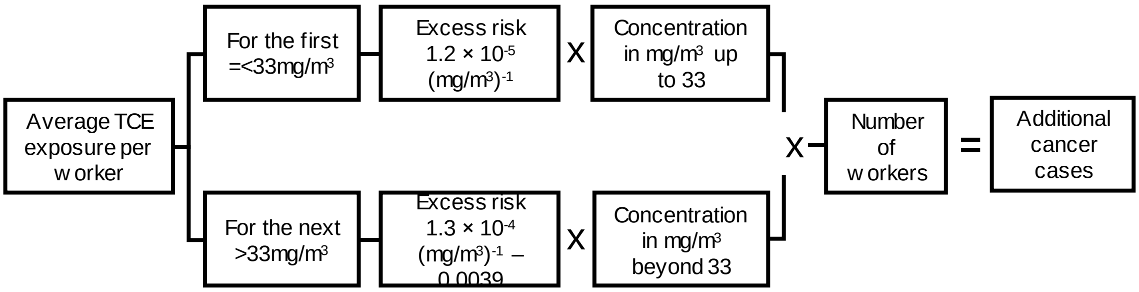

Figure 4.12: Illustration of the step-wise method for estimating the additional renal cancer cases from inhalation exposure

The resulting additional risks for ENTEK workers are reported in Table 4.21. Given ENTEK's level of exposure to trichloroethylene and small workforce, the continued use of trichloroethylene from a working life-time exposure of 40 years is expected to result in less than one (1) additional cancer diagnosis.

Table 4.21: Additional renal cancer cases

Average exposure to trichloroethylene	**Additional cancer diagnoses**	
	Production worker	**Non-production worker**
Best estimates (shown in Table 4.20)	0.02978543	0.00050400

Table 4.22 summarises the health impacts on ENTEK workers under different assumptions for exposure levels, exposure durations and fatality rate for the cancer cases. The 'best' estimate for the health impacts on ENTEK workers is ~£6k-£21k, whilst the worst-case upper bound is at £199k. The 'Low' and 'High' estimates reflect different valuation factors used, HSE (2016) and ECHA (2016) respectively See Table 4.22).

Table 4.22: Summary of the estimated total value of worker health impacts of trichloroethylene exposure (Use 1)

Sensitivity analysis	Description	Low estimate (nearest £)	High estimate (nearest £)
'Best' estimate	This is based on using values for variables that best reflect the actual situation. The excess risk is pro-rated (12/40) to reflect the 12-year review period	£ 6,133	£ 21,059
Sensitivity 1	This assumes 40 years of exposure	£20,444	£70,197
Sensitivity 2	This assumes non-production workers at the ENTEK site are exposed to the same level as production workers.	£27,342	£93,882
Sensitivity 3	This assumes non-production workers at the ENTEK site are exposed to the same level as production workers and any possible cancers are all fatal.	£60,771	£198,518

Notes: Estimates are given in 2021 prices. The 'Low' valuation factor, £1.5m for fatal and £63,000 for non-fatal cancer, is from [HSE], and the 'High' valuation, £4.9m fatal and £402,000 for non-fatal cancer, is from [ECHA].

4.5.3 Trichloroethylene exposure (inhalation) to workers in the same industrial estate(s)

When assessing trichloroethylene as a non-threshold substance, any potential risk to (non-ENTEK) workers in the same industrial estate(s) from exposure to fugitive and vented trichloroethylene emissions must be assessed.

Air modelling of stack and fugitive emissions was carried out in 2014 for the previous AfA. Updated modelling was carried out in early 2021, specifically for this AfA. ENTEK employed a contractor who carried out a Dispersion Modelling Assessment using data provided by ENTEK on emissions and working procedures.

The model uses the worst weather conditions over the period of 2015 to 2019, that is, conditions that would result in the largest emissions around the site during this period. The year 2016 was the worst year for weather conditions and exhibited the highest exposure levels. Therefore, in other years, under 'normal' weather conditions, trichloroethylene emissions would be confined much closer to the site. As shown in Figure 4.13 even when using this conservative approach, the levels of trichloroethylene around the site are very low, with a range of 0.48 – 12.24 µg/m^3 modelled for 2016 (Redmore, 2021).

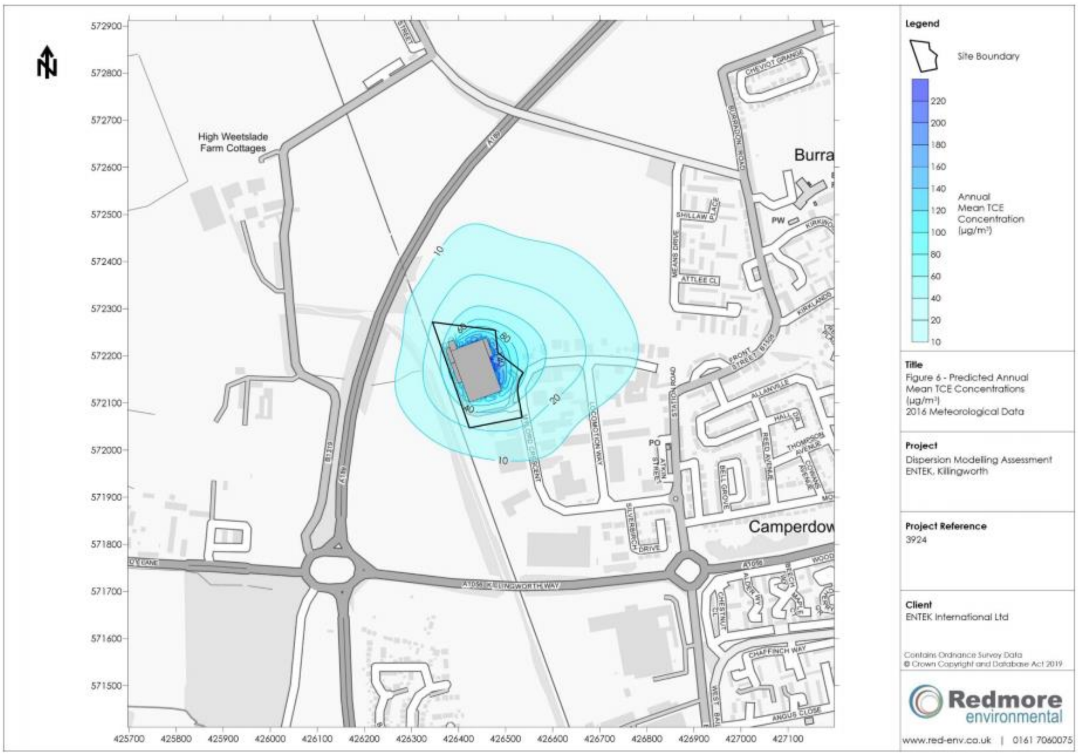

Figure 4.13: Air modelling results - Concentrations of TRE around the ENTEK site (2019)

Source: Redmore environmental (2021)

For the purposes of constructing a 'worst case' scenario, worker exposure is assumed to occur within the entire Office for National Statistics' (ONS) North Tyneside Super Output Area 008B shown in Figure 4.13. This area encompasses two industrial estates, as well as residential areas, and it is estimated by the ONS that 711 people work in this area.

Adjusting this figure to account for job occupations unlikely to occur on the site[28] as well as for ENTEK employees (96 production, 28 non-production and 10 split office/factory floor employee's exposure is assessed separately in Section 4.5.1), gives an estimate of 430 workers around the site.

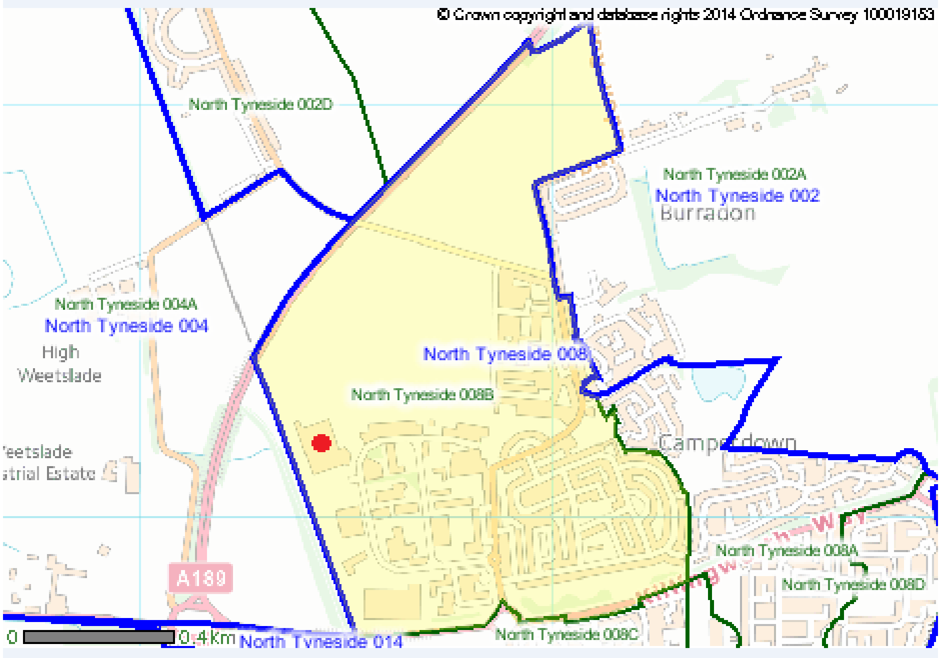

Figure 4.144: ONS Super Output Area North Tyneside 008B

Notes:

1. Adapted from ONS, 2012.
2. The location of the ENTEK site is denoted by the red border.

To avoid potential optimism bias and to estimate a 'worst case' scenario, it is assumed that these 430 workers all work on the same industrial estate and are exposed at 12.24 µg/m^3 (rather than between 0.48 - 12.24 µg/m^3), as shown in Table 4.23. The modelling actually estimates that trichloroethylene exposure is lower for sites further away from the ENTEK site as illustrated in Figure 4.14.

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[28] Health and social workers, education workers and public administration, defence and social security workers were occupations assumed to not take place within the relevant area. These 146 employees were therefore omitted from the analysis.

Table 4.23: Excess risk and average exposure to trichloroethylene – workers in the same industrial estate(s)

	Excess risk	Maximum number of people exposed	Maximum inhalation exposure level
Other industrial workers around the ENTEK site	1.47E-07	430	12.24μg/m^3 (0.0124mg/m^3)

In order to value the risks to workers in the same industrial estates (which would either continue in the applied for use scenario or cease in the non-use scenario), the same worker dose-response relationships developed in April 2014 by the RAC of ECHA (2014) are used (See Box 4.1 in the Section 4.5.1).

Table 4.24 shows that fewer than one additional renal cancer case is estimated to occur as a result of trichloroethylene exposure. This is due to the very low level of exposure and the small number of people potentially exposed.

Table 4.24: Additional renal cancer cases – workers around the site

	Excess risk (inhalation)	Additional cancer diagnoses
Other industrial workers around the ENTEK site	1.47E-07	6.32E-05

Notes:

1. Excess risk is determined based on exposure level and dose response relationships for inhalation exposure (See Box 4.1). See Section 4.5.1 for further details on the method.
2. Additional cancer cases are calculated based on the inhalation excess risk and the number of people exposed. See Section 4.5.1 for further details on the method.

Using the additional cancer cases estimate, the proportion of cancers that are fatal (43% - See Section 4.5.1) and the value of fatal and non-fatal cancers (See Section 4.5.1), Table 4.25 summarises the estimated risk from continued use or the avoided health costs if authorisation is refused. It shows that the total value of risks to workers around the Newcastle site is between £12 - £309, with a best estimate of between £12 and £36.

Table 4.25: Summary of the estimated risk to workers in the same industrial estate(s) to trichloroethylene exposure (nearest £) (based on inhalation only)

Sensitivity analysis	Description	Low benefit estimate	High benefit estimate
Best estimate	This is based on using values for variables that best reflect the actual situation. The excess risk is pro-rated (12/70) to reflect the 12-year review period	£12	£36
Sensitivity 1	This assumes 40 years of exposure	£39	£121
Sensitivity 2	This assumes any possible cancers are all fatal (i.e. no non-fatal cancers)	£95	£309

Notes:

1. Estimates are given in 2021 prices.
2. The 'Low' valuation factor, £1.5m for fatal and £63,000 for non-fatal cancer, is from [HSE], and the 'High' valuation, £4.9m fatal and £402,000 for non-fatal cancer, is from [ECHA].

4.5.4 Trichloroethylene exposure (inhalation and oral) to general population around the Newcastle site

Low levels of fugitive and vented trichloroethylene emissions from the ENTEK site also pose a potential risk (of getting renal cancer) to residents and the general population around the site. As part of the aforementioned dispersion modelling assessment, the concentration at sensitive 'receptors' (i.e. areas which have residential buildings and therefore general public) was modelled shown in Figure 4.15. The predicted annual mean trichloroethylene concentrations for these areas were estimated, based on the worst weather conditions over the period of 2015 to 2019 (2016 typically being the worst year). The results are presented in Table 4.26.

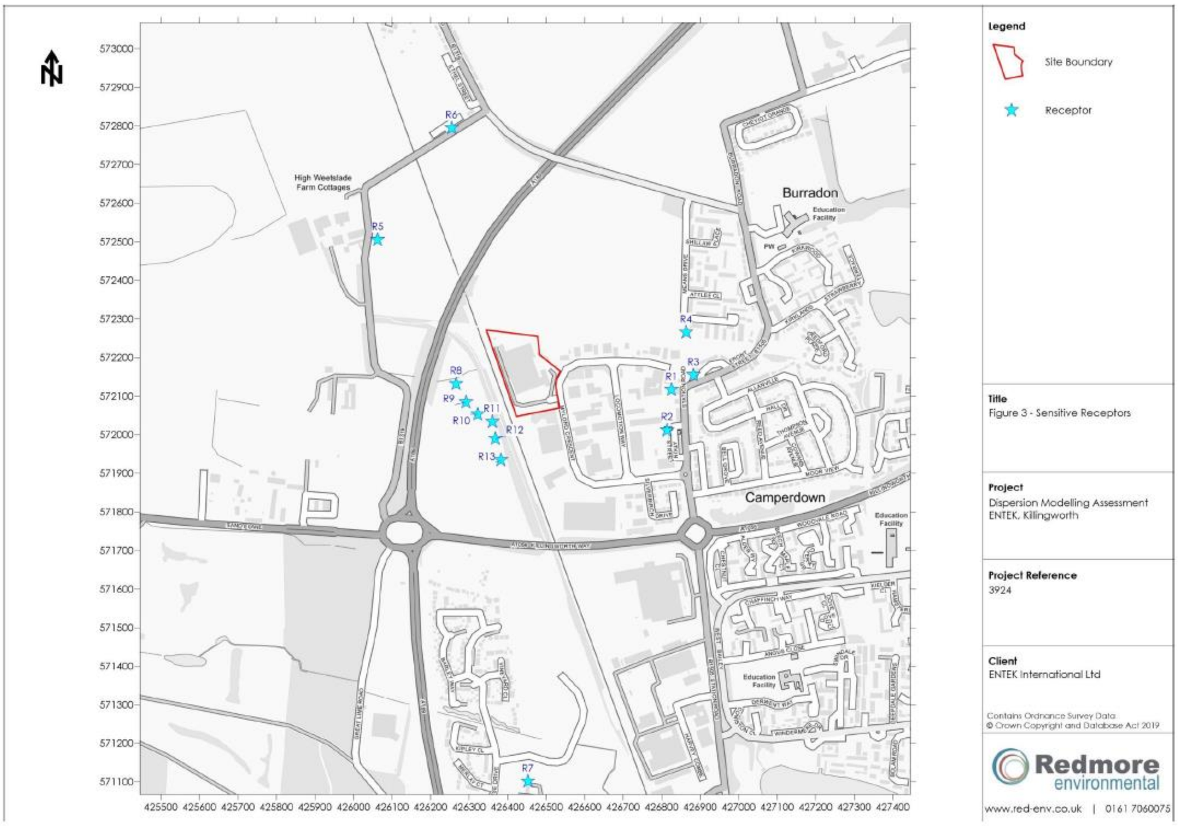

Figure 4.155: Air modelling receptor locations

The predicted annual mean trichloroethylene concentrations for these areas were estimated, based on the worst weather conditions over the period of 2015 to 2019, similarly as what was done for to estimate exposure to workers in areas close to the ENTEK site. The results are presented in Table 4.26.

Table 4.26: Predicted annual mean trichloroethylene concentrations

Sensitive Receptor	**Predicted annual mean trichloroethylene concentration (µg/m^3)**				
	2015	**2016**	**2017**	**2018**	**2019**
Residential – Station Road	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Residential – Station Road	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d

Sensitive Receptor	**Predicted annual mean trichloroethylene concentration (µg/m³)**				
	2015	**2016**	**2017**	**2018**	**2019**
Residential – Front Street	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Residential - Means Drive	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Residential – Great Lime Road	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Residential – Aged Miners' Homes	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Residential – Killingworth Drive	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Proposed Residential - Salters Lane (16/01889/FUL)	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Proposed Residential - Salters Lane (16/01889/FUL)	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Proposed Residential - Salters Lane (16/01889/FUL)	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Proposed Residential - Salters Lane (16/01889/FUL)	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Proposed Residential - Salters Lane (16/01889/FUL)	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d
Proposed Residential - Salters Lane (16/01889/FUL)	Blank 63d	Blank 63d	Blank 63d	Blank 63d	Blank 63d

Source: Redmore environmental (2021). Notes: Values presented do not represent a time-series of concentration data, rather worst-case concentrations in each year.

Any potential human health risks to the general population and residents from inhalation exposure can be assessed by utilising these concentration estimates in conjunction with population figures for the ONS's North Tyneside Super Output Area 008B area (see Figure 4.14). The ONS estimated the population of this area to be 1,737 in 2019 (ONS, 2020), which is a small population increase of 34 on the census data from 2011 - which was used in previous AfA work. The data from the most recent census - carried out in early 2021 – has not yet been published.

In order to estimate the current population of the surrounding area, additional research into planning applications for residential housing within close proximity of the site was carried out. Since 2011, a housing development named 'Cygnet Park' has been built directly to the West of the ENTEK plant. Based on the number of houses that are to be built here by the year 2024 (198 houses), and assuming the houses will contain on average 2.4 people (average of household size in the UK (ONS, 2017)), result in an estimated population of 475 people living in Cygnet Park. With no other housing developments either constructed or in planning - according to North Tyneside's Planning department website - it is assumed that there are approximately 2,178 living within the area i.e. the 2019 ONS estimate of 1,737 residents plus the 475 people living at Cygnet Park.

A very conservative exposure scenario has been estimated using the highest predicted inhalation exposure for 2015 - 2019 of 12.24 ($\mu g/m^3$) (see Table 4.26) and assuming that the entire resident population is exposed at this level (i.e. assuming no decrease or change in concentration as distance from ENTEK site increases). Table 4.27 shows that fewer than one additional renal cancer case is estimated to occur due to the low excess risk. This is due to the low level of exposure and the small number of people potentially exposed.

Table 4.27: Additional renal cancer cases – general population around the site

Exposure route	Excess risk	People exposed	Worst-case exposure	Additional cancer diagnoses
Inhalation	7.83E-07	2,178	Blank 63e	0.003503591
Oral	8.25E-07			

Notes:

1. Modelled oral exposure concentrations have been taken directly from the exposure scenario within the CSR.
2. Additional cancer cases are calculated based on the combined (inhalation and oral) excess risk and the number of people exposed (2,178). See Section 4.5.1 Approach for deriving and valuing excess cancer risks.
3. 4.5.1.1 What types of health impacts are relevant from trichloroethylene exposure? For further details on the method.
4. Oral is included due to the additional availability of data present for the general population around the site. The equivalent data was not available for ENTEK workers, or those working near the site

The assessment is based on there being no thresholds for cancer effects of trichloroethylene for renal (kidney) cancer using continuous population exposure over 70 years and the ECHA dose response relationships for the general population (see Box 4.1). This is an overestimate, since it is unlikely that all of the general population exposed (at very low concentrations) will continue to reside for 70 years the same area. Table 4.30 presents a summary of the monetised estimated risk from continued use or the avoided health costs if authorisation is refused. It shows that the total value of risks to the general population around the Newcastle site are between £ 405 -£ 17,168, with a best estimate of between £ 405 and £1,392.

Table 4.28: Summary of the estimated risk to the general population around the site to trichloroethylene exposure (nearest £) (based on inhalation only, in order to make an equal comparison across affected groups)

Sensitivity analysis	Description	Low benefit estimate	High benefit estimate
Best estimate	This is based on using values for variables that best reflect the actual situation. The excess risk is pro-rated (12/70) to reflect the 12-year review period	£405	£1,392
Sensitivity 1	This assumes 40 years of exposure	£2,365	£8,119
Sensitivity 2	This assumes any possible cancers are all fatal (i.e. no non-fatal cancers)	£5,255	£17,168

Notes:

1. Estimates are given in 2021 prices.
2. The 'Low' valuation factor, £1.5m for fatal and £63,000 for non-fatal cancer, is from [HSE], and the 'High' valuation, £4.9m fatal and £402,000 for non-fatal cancer, is from [ECHA].

4.6 Impact on the environment

As part of the screening of impacts (see Section 6.1), no significant environmental impacts were identified. The risks to 'man via the environment' from releases to air are already assessed in the Exposure CSR. The remainder of trichloroethylene into the environment is from permitted releases to wastewater. Currently only a small volume is released to wastewater (0.944 kg/year) which is treated at the local sewage treatment works before its release into the aquatic environment. Releases to wastewater are compliant with ENTEK's environmental permit (see Section 4.4.1).

Under the non-use scenario, imports of battery separators would increase the amount of greenhouse gases due to additional transportation distances (either from the US or China where other battery separator manufacture site are located). This increase is likely at least to offset the environmental costs of a small volume of trichloroethylene released to wastewater (0.944 kg/year). Therefore overall, there is not expected to be significant net environmental impact.

5 SELECTION OF THE "NON-USE" SCENARIO

5.1 Efforts made to identify alternatives

This section presents the efforts taken towards finding potential alternatives to trichloroethylene, and is broken down in the following sub-sections:

- 5.1.1 Research and development - presents a summary of the R&D with methylene chloride, the potential candidate identified in the 2014 Application for Authorisation, and a review of the status of the alternative solvents identified in the previous application.
- 5.1.1.1 Alternative solvents - presents a selection of identified new potential alternative solvents and a summary of the technical feasibility R&D.
- 5.1.1.2 Summary of R&D with solvent alternatives - reviews and summarises the status of and R&D with alternative solvents.
- 5.1.1.3 Alternative technologies - presents a selection of identified new potential alternative technologies a summary and the technical feasibility R&D.
- 5.1.1.4 Conclusions on alternative technologies - reviews the outcome of the R&D with the alternative technologies.

5.1.1 Research and development

The 2014 analysis of alternatives for the previous application concluded that there were no alternatives that are suitable and available to the applicant for the replacement of the Annex XIV substance function. Since then, ENTEK has identified a number of possible solvent alternatives that have been tested at laboratory scale.

As well as research on possible solvent alternatives, investigation of the possibilities for manufacture of separators [redacted] (Blank 64), as well as 'separator-free' batteries is on-going. However, there are many specific technical difficulties to be overcome for these products to be technically feasible and commercially viable (this is set out in detail in confidential parts of this document).

Review of alternatives identified in the original Application for Authorisation

Table 5.1 below presents a summary of the solvents that were researched for their potential to replace trichloroethylene in the ENTEK process in the 2014 application. The status of the technical and economic feasibility of the alternatives, and their availability are considered to be the same since the 2014 application, while the risk in some cases has increased and has been updated where relevant. Each substance was evaluated against the criteria of technical feasibility, economic feasibility, risk and availability. It was noted that:

- The assessment of economic feasibility can be complex and is not simply a case of comparison of the cost of the possible alternative with the Annex XIV substance.
- In some cases where the possible alternative has already been shown as not technically feasible or will lead to equal or greater risk than the Annex XIV substance, there is little point in the assessment of economic feasibility, because that becomes irrelevant.

Table 5.1 Summary of findings of the analysis of alternatives for the substances identified in 2014 (with status of risks updated)

Substance	Technical feasibility	Economic feasibility	Similar or additional risk?	Availability
n-hexane	Possible on basis of lab trials. Presents difficulties due to high volatility and very high flammability. Is more difficult to use for a continuous process.	No - The large, expected capital cost to switch and loss in profits compared to the costs of building additional production lines in other factories, means this alternative is not economically feasible.	Highly flammable. Neurotoxin and reproductive toxin. Likely to come under further regulatory pressure in future. Presents control difficulties due to high volatility.	Yes
Dichloro-methane (methylene chloride)	Possible on basis of lab trials. Not technically feasible without considerable further research and commercial testing for customer acceptability of the product.	No - The large, expected capital cost to switch and loss in profits compared to the costs of building additional production lines in other factories, means this alternative is not economically feasible.	Suspect Carcinogen (Carc. 2) and under review as a presumed Carcinogen (Carc. 1B) under EU REACH. Still under assessment as Endocrine Disrupting substance. Currently being assessed under CoRAP against the following initial grounds for concern: Carcinogenic Suspected Mutagenic Suspected Reprotoxic Potential endocrine disruptor Suspected Sensitiser	Yes
Tetrachloroethylene	Possible on basis of lab trials.	No - The large, expected capital cost to switch and loss in profits	Suspect Carcinogen (Carc. 2).	Yes

Substance	Technical feasibility	Economic feasibility	Similar or additional risk?	Availability
(perchloroethylene)	Not technically feasible without considerable further research and commercial testing for customer acceptability of the product.	compared to the costs of building additional production lines in other factories, means this alternative is also not economically feasible.		
Vertrel® SDG	Possible on basis of lab trials. Recovery could be problematic. Not technically feasible without considerable further research and commercial testing for customer acceptability of the product.	No - The large, expected capital cost to switch and loss in profits compared to the costs of building additional production lines in other factories, means this alternative is also not economically feasible.	No. However, little data available.	Yes
1,2- trans-dichloroethylene	Possible on basis of lab trials. Recovery could be problematic. Not technically feasible without considerable further research and commercial testing for customer acceptability of the product.	No - The large, expected capital cost to switch and loss in profits compared to the costs of building additional production lines in other factories, means this alternative is also not economically feasible.	No. However, little data available.	Yes
n-propyl bromide (1-bromopropane)	Possible on basis of lab trials. Not technically feasible without considerable further research and commercial testing for customer acceptability of the product.	No - The large, expected capital cost to switch and loss in profits compared to the costs of building additional production lines in other factories, means this alternative is also not economically feasible.	SVHC (reproductive toxin). Flammable. On the EU REACH Candidate List (Annex XIV) requiring Authorisation – sunset date expired.	Yes
D-Limonene	Possible on basis of lab trials. Likely to be problems with solvent recovery and recycling.	No - The large, expected capital cost to switch and loss in profits compared to the costs of	Flammable. Dangerous to the environment. Skin sensitiser.	Yes

Substance	Technical feasibility	Economic feasibility	Similar or additional risk?	Availability
		building additional production lines in other factories, means this alternative is also not economically feasible.		
Acetone	No – does not perform function to remove process oil effectively.	No - The large, expected capital cost to switch and loss in profits compared to the costs of building additional production lines in other factories, means this alternative is also not economically feasible.	No	Yes

Methylene Chloride was selected as a candidate alternative solvent in 2014. The technical performance of a methylene chloride was tested in a portable extractor in a US plant. The portable extractor can be considered equivalent to a pilot plant built by ENTEK for testing alternatives, where the oil extraction takes place in an extractor, the purpose of which is to produce separators using alternative solvents and to review the manufacturing performance and constraints.

The investigation found that methylene chloride is incompatible with the steel used in the production lines. In addition, the extraction rate was found to be different to trichloroethylene. These differences alone would require ENTEK to change the materials used and design of its production line extensions, which is likely to lead to acceptability issues with customers. Despite these challenges, ENTEK attempted to test a separator made with methylene chloride within a lead acid battery and to test its performance. ENTEK does not have the knowledge or capacity to build and test lead acid batteries. In addition, as already indicated, due to contractual obligations with some of its customers ENTEK itself cannot build batteries commercially. A third-party company was commissioned to build a pilot battery and test it with separators produced using methylene chloride as the oil extraction solvent. ENTEK's customers were approached to test the product according to standard tests, but they were unwilling to conduct performance tests with a battery that was not built by themselves (to ensure it meets the specifications). The battery manufacturers were also unwilling to build a sample battery using separators made with methylene chloride.

From a hazard point of view, methylene chloride is now subject to Restrictions under EU REACH, and its classification as a carcinogen Carc. 2 is under review as a presumed Carcinogen, Carc. 1B. It is also still being reviewed as a mutagen, reproductive toxin, potential endocrine disruptor and as a sensitising agent. For these reasons (manufacturing issues, impossibility to test a new product and increased regulatory restrictions) further experimentation for the use of methylene chloride as a replacement solvent for trichloroethylene was stopped.

As stated in the 2014 application AoA document, other solvent substances that showed some promise in 'bench-scale' trials were also under some regulatory scrutiny in the EU and elsewhere. Although only one substance is currently an SVHC (n-propyl bromide) and is therefore subject to the need for authorisation, this could still change in the future especially for n-hexane, which is a neurotoxin and a reproductive toxin. Tetrachloroethylene is still classified as a suspected carcinogen (Category 2). It is therefore unlikely to be a long-term sustainable business strategy to invest in substances with these risk profiles that would present similar challenges for emission/release control as trichloroethylene. The implementation of a solvent alternative must therefore take account of possible regulatory changes that would have a severe impact on the use of the substance in the future. It is clear that for substances that showed the possibility for being alternatives to trichloroethylene in the ENTEK process, (namely n-hexane, tetrachloroethylene and methylene chloride) that the regulatory and risk profile for these substances now and in the future would rule them out as sensible options. This is true also for n-hexane since it is a particular focus due to its known use for the process of making PE separators, the financial implications of converting the facility or relocating the facility were set out in the 2014 application and was concluded that it would not be economically viable for ENTEK to convert or rebuild or relocate its UK plant to use n-hexane. The implications for ATEX[29] and explosive atmospheres was described in the 2014 AfA AoA document.

5.1.1.1 New alternative solvents

The challenge in finding a replacement for trichloroethylene can also be visualised by comparing Kamlet-Taft plots. Kamlet-Taft parameters are used to identify a solvent's polarity, i.e. their characteristics and behaviour in solution (Tariqul Islam et al. 2020). In such plots, solvents are identified by π^* (a measure of their polarity and polarizability) and β (a measure of their basicity or hydrogen-bond accepting ability) values. Figure 5.1 shows a Kamlet-Taft plot for common **aprotic** solvents, the area occupied by trichloroethylene has been circled on the chart. Trichloroethylene has extremely low basicity and an intermediate polarity value.

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[29] Legal requirements for controlling explosive atmospheres and the suitability of equipment and protective systems used in them. See https://www.hse.gov.uk/fireandexplosion/atex.htm#whatatex

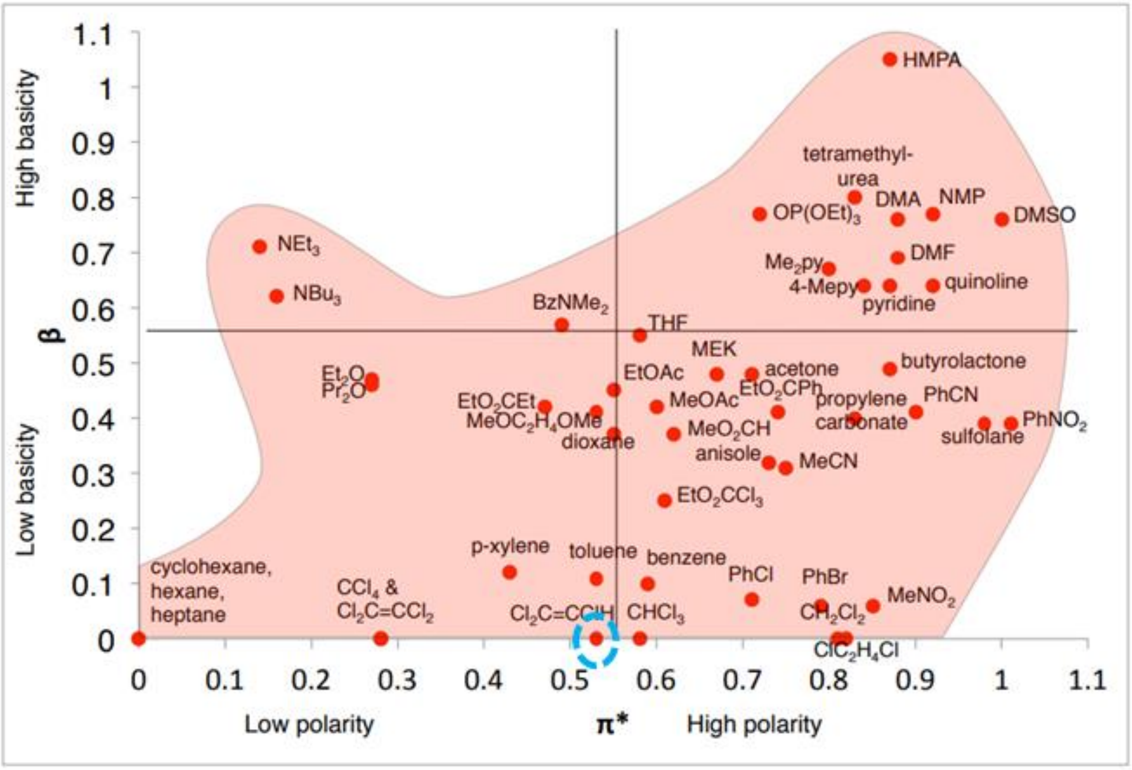

Figure 5.1: Kamlet-Taft plot of common aprotic solvents

In Figure 5.2, a Kamlet-Taft plot is shown for common **protic** solvents (i.e., containing OH or NH_2 groups with labile protons), where trichloroethylene resides in the area of the blue circle. It should be noted that only trifluoroacetic acid resides in the same region as trichloroethylene. The corrosive properties of trifluoroacetic acid would immediately eliminate it as a potential solvent replacement in the ENTEK separator manufacturing process.

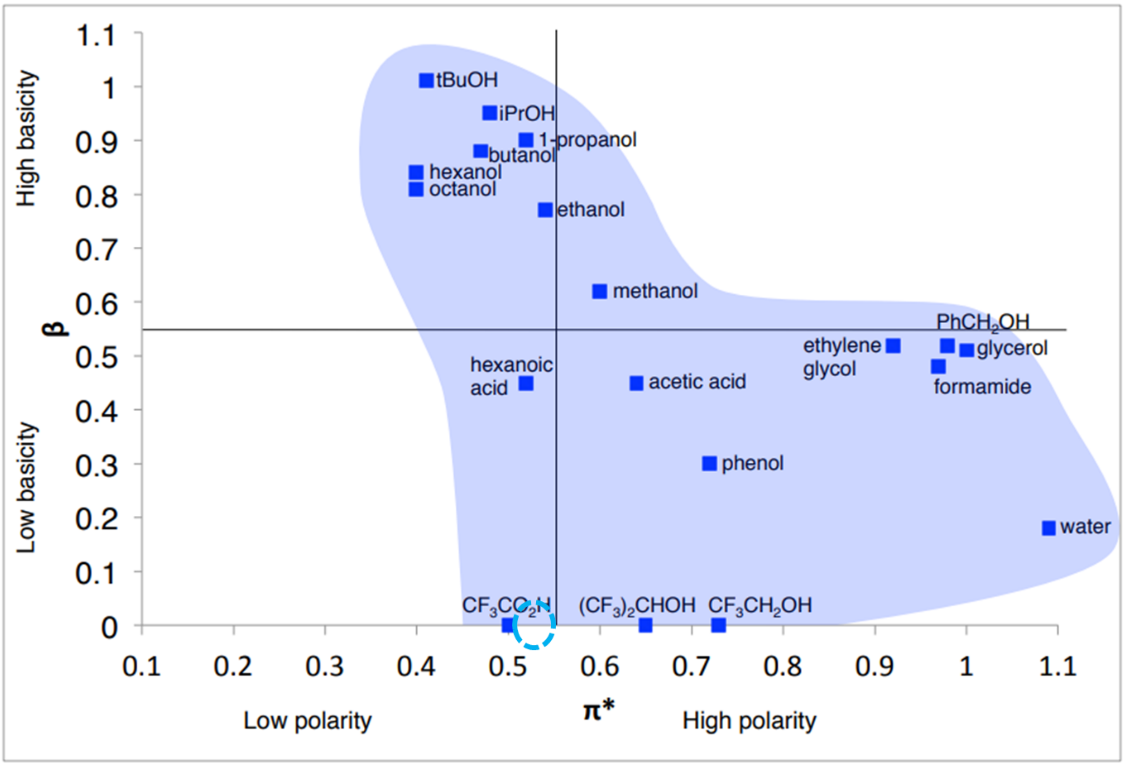

Figure 5.2: Kamlet-Taft plot of common protic solvents

There is currently much academic research on "green" solvents that attempt to address environmental, health, and safety concerns in the pharmaceutical and chemical manufacturing industries. Figure 5.3 and Figure 5.4 show Kamlet-Taft parameters for a variety of 'green' aprotic and protic solvents, respectively. None of the solvents map onto the basicity-polarity region of trichloroethylene.

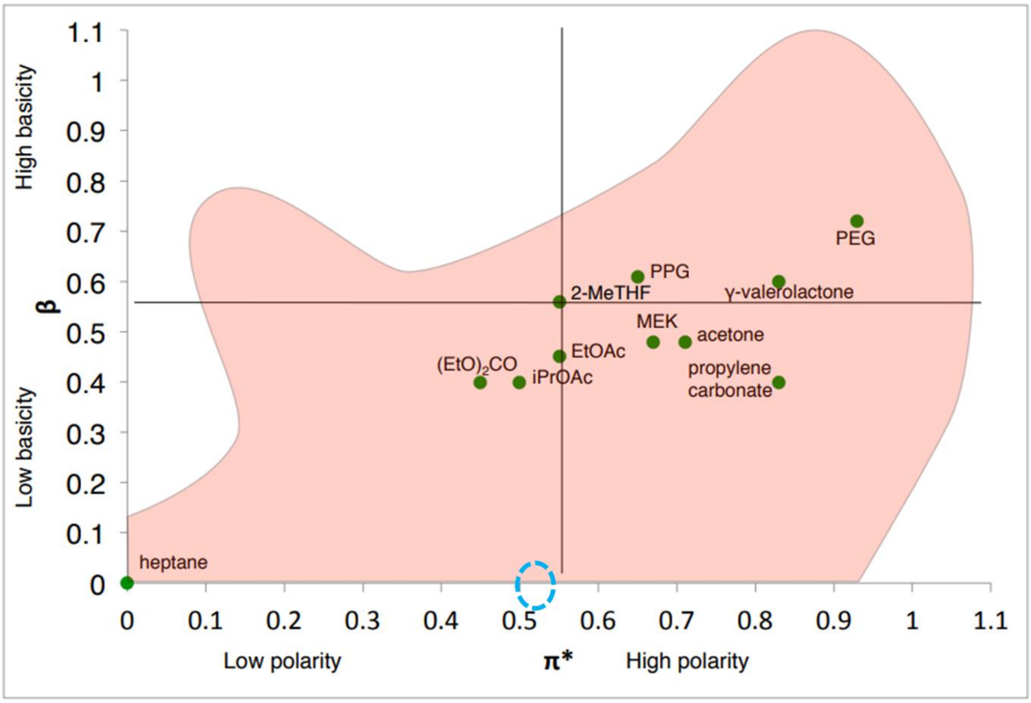

Figure 5.3: Kamlet-Taft plot for 'green' aprotic solvents

[source: Jessop et al. (2012) Solvatochromic parameters for solvents of interest in green chemistry Green Chem. 14, 1245 **DOI:** 10.1039/C2GC16670D]

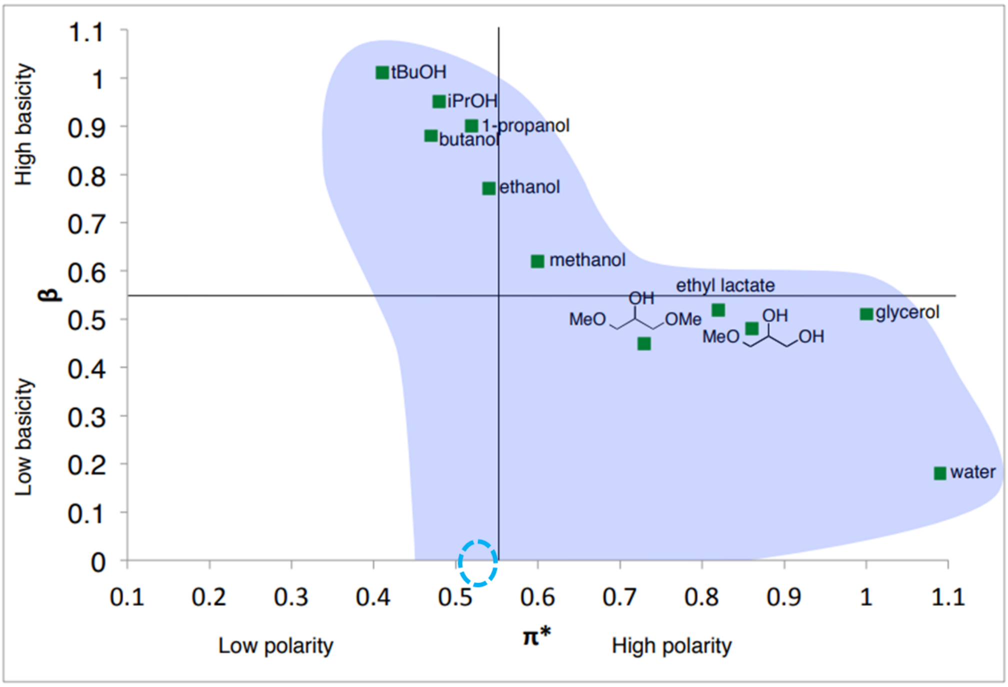

Figure 5.4: Kamlet-Taft plot for 'green' protic solvents

[source: Jessop et al. (2012) Solvatochromic parameters for solvents of interest in green chemistry Green Chem. 14, 1245 **DOI:** 10.1039/C2GC16670D]

As newer solvents and solvent mixtures have become commercially available since the last REACH application (e.g., Cyrene™), ENTEK has continued to evaluate them.

ENTEK has investigated ten additional solvents as part of its research and development efforts to find an alternative to trichloroethylene. These are listed below:

1. Augeo® Clean Plus
2. Augeo® Clean Multi
3. Cyrene™
4. Ethyl butyrate
5. Isopar™ G
6. Propyl propionate
7. Tergo™ Metal Cleaning Fluid (MCF)
8. Solstice® PF-HFP
9. Dowclene™ 1601 – identified as a solvent of interest, but ENTEK has not been able to get a sample at the time of writing the report.
10. SolVantage® MP300

Physico-chemical properties

The physiochemical properties of additional alternative solvents have been investigated and listed in Table 5.2. Data on the properties allows screening of the candidates for technical performance and potential issues. Section 4.3.1, Function of trichloroethylene, assesses the importance of some of the parameters and further analysis is given below.

The values in the table are taken from the ECHA disseminated dossiers of the substances where available or applicable, or from other publicly available sources, as indicated, or from SDS sheets when the substance is a formulation or other sources were not available or suitable.

Boiling point is used to determine behaviour of the solvent. The high boiling point of SolVantage® MP300 (>221ºC, compared to 87ºC of trichloroethylene) may negatively impact the separation from process oil, this is also applicable to Cyrene™ (227ºC) and Augeo® Clean Plus (230.5ºC).

The relatively high density of trichloroethylene means that the extractor can be water capped. Only Augeo® Clean Plus, Cyrene™ and Tergo™ MCF have a density greater than 1.

Vapour pressure is important for effective evaporation and trichloroethylene's vapour pressure makes it easy to distil and recycle. Trichloroethylene has a very high vapour pressure (9.9 kPa). Ethyl butyrate (1.7 kPa) and propyl propionate (1.8 kPa) have high vapour pressures, while Solstice® PF-HFP is a gas. The other identified alternatives have a relatively low vapour pressure and will require process changes.

Viscosity will be used to determine how the substance is handled, there is no cut-off value.

Low surface tension prevents pore collapse when the solvent is removed from the sheet. Surface tension measurements are not always available. For the substances with measurements, only Cyrene™ has the potential to be problematic.

Heat of vaporisation measures the amount of heat required to change 1 kg of a substance from a liquid state into a gas, which in turn is related to boiling point, and therefore is a good measure for the energy demands on the plant to generate solvent laden vapour. There are insufficient values to make a comparison.

The solvent alternative ideally needs to be non-flammable or at a minimum have a flashpoint that is significantly above room temperature. A flash point near ambient temperature poses a risk to workers. Ethyl butyrate has a flash point near ambient temperature. The ECHA disseminated dossier reports a flash point of 58°C for propyl propionate. The entry also states "the flashpoint of n-pentyl propionate is 58°C". It is assumed that this value has been erroneously attributed to propyl propionate and the table below presents the value of 18°C as reported in the SigmaAldrich 2021 safety data sheet. This was not known at the time of candidate selection.

Water solubility is important in the recovery process, where the solvent and water form an immiscible layer. Dowclene™ 1601 has a very high-water solubility (6.3 g/100cc, compared to 0.11 g/100cc for trichloroethylene) which is likely to negatively impact the potential for oil recovery, this is also a likely scenario for Augeo® Clean Plus (3.46 g/100cc).

Table 5.2 Key physicochemical properties of possible alternatives in comparison to trichloroethylene

Solvent name	**Chemical EC name**	**CAS /EC number**	**Boiling point (°C)**	**Relative Density (g/ml)**	**Vapour Pressure at 25°C (mm Hg)**	**Viscosity at 25°C (mm^2/s)**	**Surface Tension at 25°C (dynes/cm)**	**Heat of vaporisation (cal/g)**	**Flash Point closed cup (°C)**	**Solubility in water (25°C) (g/100cc)**	**Reference**
Trichloroethylene	Trichloroethylene	79-01-6 / 201-167-4	87	1.45	9.9 kPa	0.58	26.4	56.4	Not flammable	0.11	ECHA[30] PubChem[31]
Augeo® Clean Plus	1,3-Dioxolane-4-methanol, 2-methyl-2-(2-ethylpropyl)-	5660-53-7 / 692-614-6	230.5	1.003	30 Pa at 20°C	18	No data available	No data available	113	3.46	ECHA[32] Solvay 2016
Augeo® Clean Multi	Isopropylideneglycerol	100-79-8 / 202-888-7	192.3	1.06	34 Pa at 20°C	12	33.5	No data available	90	Completely soluble	ECHA[33] Solvay 2017
Cyrene™	Dihydrolevoglucosenone	53716-82-8 / 807-130-4	227	1.25	28 Pa	13.8	72.5 at 22°C	No data available	108	Completely soluble	ECHA[34] Circa Group data sheet (no date)
Ethyl butyrate	-	105-54-4 / 203-306-4	121	0.879	1.7 kPa at 20°C	0.71 at 20°C	24.5 at 20°C	86.4	28	0.21 at 30°C	ECHA[35] PubChem[36]
Isopar™ G	Hydrocarbons, C10-C12, isoalkanes, <2% aromatics	NA / 923-037-2	160-174	0.75	200 at 20°C	1.2	22.9	No data available	44	0.027-2000 mg/l	ECHA[37] ExxonMobil 2021 ExxonMobil (no date) NIST[38]

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[30] https://echa.europa.eu/registration-dossier/-/registered-dossier/14485/4/9 accessed June 2021

[31] https://pubchem.ncbi.nlm.nih.gov/compound/Trichloroethylene accessed June 2021

[32] https://echa.europa.eu/registration-dossier/-/registered-dossier/9997/4/4 accessed June 2021

[33] https://echa.europa.eu/registration-dossier/-/registered-dossier/12258 accessed June 2021

[34] https://echa.europa.eu/registration-dossier/-/registered-dossier/16252 accessed June 2021

[35] https://echa.europa.eu/registration-dossier/-/registered-dossier/17594

[36] https://pubchem.ncbi.nlm.nih.gov/compound/Ethyl-butyrate accessed June 2021

[37] https://echa.europa.eu/registration-dossier/-/registered-dossier/13772 accessed June 2021

[38] https://webbook.nist.gov/cgi/cbook.cgi?ID=C106365&Units=SI&Mask=4#Thermo-Phase accessed June 2021

Solvent name	**Chemical EC name**	**CAS /EC number**	**Boiling point (°C)**	**Relative Density (g/ml)**	**Vapour Pressure at 25°C (mm Hg)**	**Viscosity at 25°C (mm^2/s)**	**Surface Tension at 25°C (dynes/cm)**	**Heat of vaporisation (cal/g)**	**Flash Point closed cup (°C)**	**Solubility in water (25°C) (g/100cc)**	**Reference**
Propyl propionate	-	106-36-5 / 203-389-7	122-124	0.88	1.8 kPa	0.7	26.5	89.5	19	0.53	ECHA[39] Sigma-Aldrich 2021 PubChem[40]
Tergo™ MCF	Trans-dichloroethylene Heptafluorocyclopentane Methoxytridecafluoroheptene	156-60-5 / 205-860-2 430-710-1 / 15290-77-4 NA / 1708962-18-8	47	1.29	No data available	0.42 cP	21	No data available	Does not flash	slight	MicroCare 2021
Solstice® PF-HFP	Trans-1-Chloro-3,3,3-trifluoropropene	102687-65-0 / 700-486-0	19	Liquefied gas	1065 hPa at 20°C	Liquefied gas	Liquefied gas	Liquefied gas	Liquefied gas	0.19 at 20°C	ECHA[41] Honeywell 2015
Dowclene™ 1601	3-Butoxypropan-2-ol Butoxy-1-propanol	5131-66-8 / 225-878-4 15821-83-7 / 605-138-0	170 - 175	0.88	0.83	3.85 at 20°C	26.1	66.9	63	6.3	SAFECHEM 2017 DOW (no date)
SolVantage® MP300	Distillates, hydrotreated light	64742-47-8 / 265-149-8	>221	0.799	0.03 at 20°C	<5	No data available	No data available	29-70 (96 in SDS)	insoluble	ECHA[42] Brulin 2020

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[39] https://echa.europa.eu/registration-dossier/-/registered-dossier/21994 accessed June 2021

[40] https://pubchem.ncbi.nlm.nih.gov/compound/Propyl-propionate accessed June 2021

[41] https://echa.europa.eu/registration-dossier/-/registered-dossier/10762 accessed June 2021

[42] https://echa.europa.eu/registration-dossier/-/registered-dossier/15375 accessed June 2021

Classification and labelling

The classifications for each alternative solvent are presented in Table 5.3 and are taken from the CLP inventory[43]. The EU CLP Regulation as amended, is retained in GB law and all existing EU harmonised classification and labelling in force on 31 December 2020, are retained in Great Britain as GB mandatory classification and labelling (GB MCL)[44]. The classifications are used in a further initial screening of the identified alternatives and are also considered in Section 5.1.1.5.

The properties, hazard and risk potential of the shortlisted solvents are reviewed in more detail in Section 5.3.

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[43] https://echa.europa.eu/information-on-chemicals/cl-inventory-database

[44] https://www.hse.gov.uk/chemical-classification/legal/clp-regulation.htm

Table 5.3 Classification and labelling (C&L)* or other known or potential risks of possible alternatives in comparison to trichloroethylene

Solvent	Chemical name	CAS / EC number	Classification and labelling	C&L	Comment
Trichloroethylene	Trichloroethylene	79-01-6 / 201-167-4	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H336 Muta. 2, H341 Carc. 1B, H350 Aquatic Chronic 3, H412	GB MCL	
Augeo® Clean Plus ketal	1,3-Dioxolane-4-methanol, 2-methyl-2-(2-ethylpropyl)-	5660-53-7 / 692-614-6	Eye Dam. 1, H318	Notified - Joint Entry	The main active ingredient has been registered under EU REACH (at 10-100 tpa). No information on chronic toxicity.
Augeo® Clean Multi ketal	Isopropylideneglycerol	100-79-8 / 202-888-7	Eye Irrit. 2A, H319	Notified - Joint Entry	ECHA has requested further studies with the substance and the data are not yet available.
Cyrene™	Dihydrolevoglucosenone	53716-82-8 / 807-130-4	Eye Irrit. 2, H319	Notified - Joint Entry	The main active ingredient has been registered under EU REACH (at 100-1000 tpa).
Ethyl butyrate	-	105-54-4 / 203-306-4	Flam. Liq. 3, H226 Eye Irrit. 2, H319	Notified - Joint Entry	
Isopar ™ G	Hydrocarbons, C10-C12, isoalkanes, <2% aromatics	NA / 923-037-2	Flam. Liq. 3, H226 Asp. Tox. 1, H304	Notified - Joint Entry	
Propyl propionate	-	106-36-5 / 203-389-7	Flam. Liq. 3, H226 Acute Tox. 4, H332	GB MCL	The main active ingredient has been registered under EU REACH (at 10-100 tpa). No information on chronic toxicity.
Tergo™ MCF	trans-dichloroethylene	156-60-5 / 205-860-2	Flam. Liq. 2, H225 Acute Tox. 4, H332 Aquatic Chronic 3, H412	GB MCL	Methoxytridecafluoroheptene (CAS 1708962-18-8) is likely to be equivalent to methoxytridecafluoroheptene isomers, EC 946-374-7
	Heptafluorocyclopentane	430-710-1 / 15290-77-4	Aquatic Chronic 3, H412	GB MCL	
	Methoxytridecafluoroheptene	no EC / 1708962-18-8	Aquatic Chronic 4, H413	from MSDS	

Solvent	Chemical name	CAS / EC number	Classification and labelling	C&L	Comment
Solstice® PF-HFP	trans-1-Chloro-3,3,3-trifluoropropene	102687-65-0 / 700-486-0	Press. Gas (Liq) Aquatic Chronic 3, H412	Notified - Joint Entry	May explode if heated.
Dowclene™ 1601	1-Butoxy-2-propanol Propanol, 2-butoxy-	5131-66-8 / 225-878-4 15821-83-7 / 605-138-0	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Not classified	GB MCL Notified	
SolVantage® MP300	distillates, hydrotreated light	64742-47-8 / 265-149-8	Asp. Tox. 1, H304	GB MCL	

* Manufacturers, importers or downstream users have to (self)classify and label hazardous substances. For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers) and for other substances on a case-by-case basis, classification and labelling is harmonised throughout the EU to ensure an adequate risk management. This is done through harmonised classification and labelling (CLH). The UK has adopted the existing EU harmonised classification and labelling and are referred to as GB mandatory classification and labelling (GB MCL). For substances without GB MCL the classification referred to as Joint Entries is the classification according to CLP presented in the EU REACH registration dossier of the substance, and which is supported by the registrants of the Joint Submission. Where the latter is also not available, the table reports classifications presented in the MSDS

The classification and labelling overview presented in Table 5.3 indicates that none of the alternatives has the potential to cause cancer or genetic defects. In addition, none are listed as SVHCs under EU REACH. The main risks identified relate to a lack of long-term toxicity data to make a definitive evidence-based assessment of their hazard. In the case of Augeo® Clean Multi ketal the European Chemicals Agency has requested additional genotoxicity data that are not available at the time of writing the report.

5.1.1.2 Technical feasibility experiments

Initial technical feasibility experiments have been carried out that involved collecting an oil-filled, polyethylene/silica precursor sheet from an ENTEK production line. An oil-filled sheet is a precursor to both STD and LR separators. The oil-filled sheet was then cut into ~ 160 mm x ~160 mm pieces that were individually placed in the alternative solvents for various time periods to evaluate extraction rates and efficiency. The solvent-laden sheets were then dried at elevated temperature and the resultant separator properties were evaluated. The major characterisation data that were collected from these laboratory experiments included:

- Solubility of ENTEK process oil in each alternative solvent: this parameter measures the compatibility of the alternative solvent with the process oil.
- Rate of process oil extraction for each alternative solvent: this parameter is key for production timings.
- Shrinkage of solvent-laden separator upon drying: shrinkage is relative to porosity, which is necessary for a correct functioning of the separator and forms part of the customer specifications, it is also a measure for equipment compatibility, specifically the calender rolls.
- Impact of trace solvent in the separator on lead-acid electrochemistry: this parameter assesses the potential leaching impact of the solvents on the performance of a battery.
- Separator electrical (ionic) resistance: key parameter of performance and part of customer specifications, see Section 4.3.3.1 and Annex 1.
- Separator mechanical properties: as above.

The tests are designed to address technical performance and mimic the different stages of the production process. More details on the purpose and impact of each endpoint are presented under each assessment. It should be noted that laboratory extraction and drying experiments give only a partial answer in regard to the feasibility of an alternative solvent. ***Full scale production trials are required before any definitive decision can be made regarding an alternative solvent.*** This is necessary to ensure that expected throughputs can be met on existing equipment and that the final separator properties and roll characteristics meet specification. Furthermore, closed loop recovery of any alternative solvent must be demonstrated via (1) distillation and (2) vapour adsorption-desorption in carbon beds. Such large-scale trials would also be required by battery manufacturers attempting to qualify any new separator or change to the separator manufacturing process with their OEM (original equipment manufacturer) customers.

It is difficult to perform such trials at the ENTEK UK plant because the carbon bed, oil recirculation, and water recovery systems for the four production lines are coupled together forming a highly integrated process system. A large investment would be required to isolate a production line, implement a stand-alone distillation and carbon bed system, and carry out a full-scale production trial with an alternative solvent.

Further details on costs associated with replacement solvents and technologies are presented in Section 5.3.

The following sections present the laboratory (‘bench-scale’) trials conducted to determine the potential suitability of the new alternative solvents. The trials compare the performance of trichloroethylene to the alternative solvents rather than setting cut-off criteria in each test, unless otherwise stated.

Solubility of process oil and rate of extraction for each alternative solvent

The process oil must be soluble in the solvent in order for extraction to take place. ENTEK tested solubility through a visual assessment by mixing three parts by volume of solvent and one part by volume of oil in tubes. Figure 5.5 shows that oil is insoluble in Cyrene™, partially soluble in Augeo® Clean Multi and fully miscible in Augeo® Clean Plus. Augeo® Clean Multi and Augeo® Clean Plus required heat (50ºC) and ultrasonication to achieve solvency.

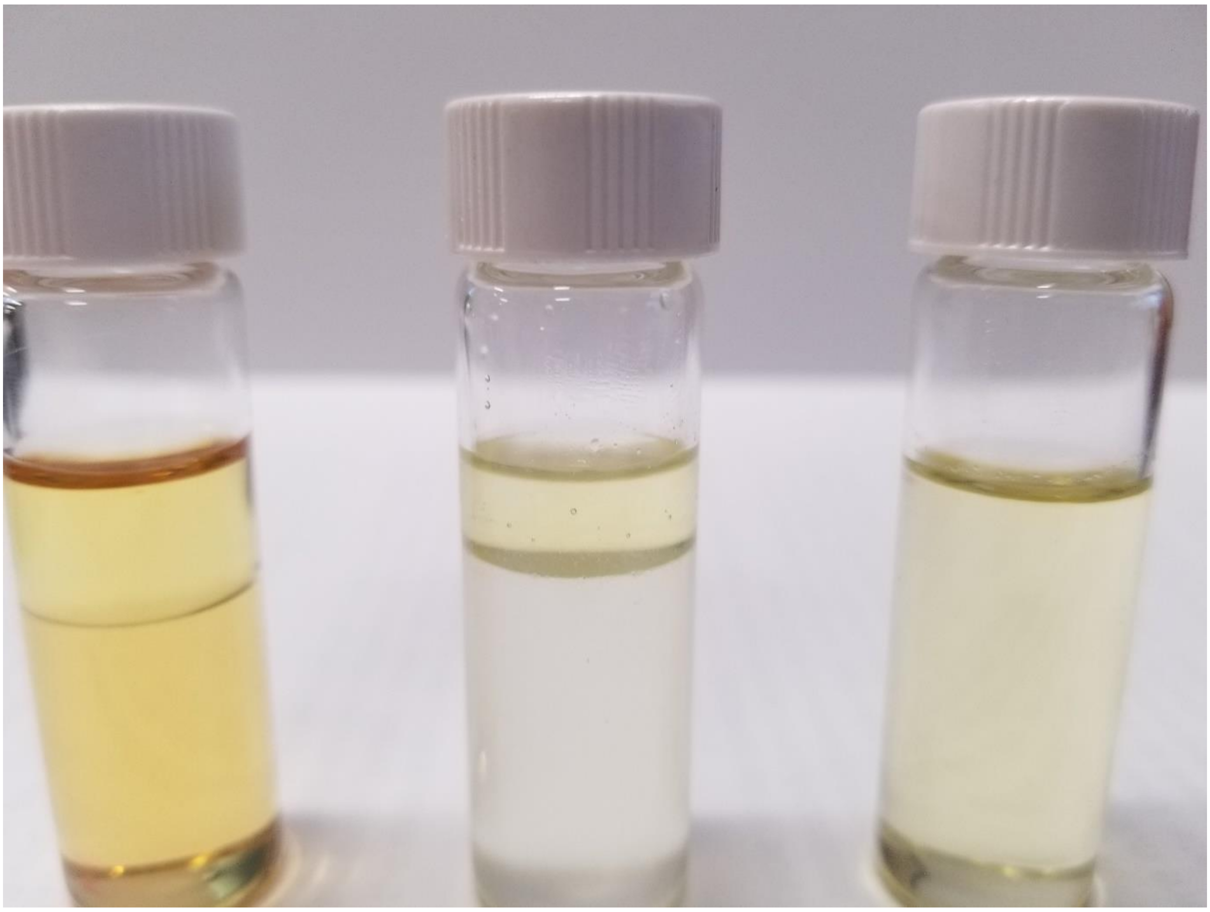

Figure 5.5: Oil solubility check in (left to right) Cyrene™, Augeo® Clean Multi, and Augeo® Clean Plus

ENTEK performed laboratory experiments to evaluate the extraction rate using the alternative solvents. These experiments were performed on oil-filled precursor sheets used in both STD and LR separators and obtained from a separator production line. The extraction was performed at room temperature with an excess amount of solvent under agitation in a large beaker. Samples were removed at 10 second intervals, for a period up to 60 seconds, dried, and then weighed to determine the amount of oil that had been extracted. The experiment was repeated three different times for each solvent.

Figure 5.6 shows the results of the extraction experiment. The dashed line represents a residual oil value of 15% wt, which is the target value for ENTEK separator production. Augeo® Clean Plus and Multi had to be ultrasonicated and heated to achieve solubility. Compared to trichloroethylene, samples extracted with the new solvent candidates have higher residual oil contents for a given extraction time. These data indicate that each of the new solvent candidates are less efficient at oil extraction than trichloroethylene. While they still might be viable in a production process, ***ENTEK would be forced to slow down***

its production lines, increase the length of its extractors, or heat the alternative solvent to an elevated temperature in its extractors. Such changes would have a large impact on separator cost and plant capacity (See section 5.3).

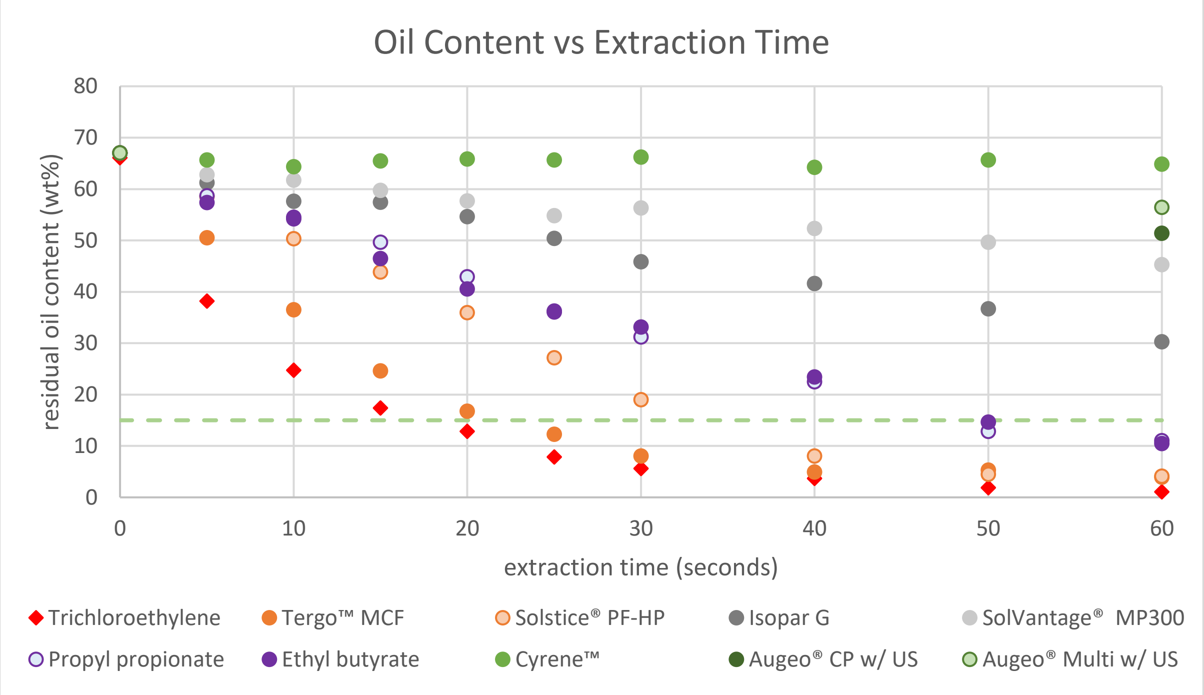

Figure 5.6: Residual oil content (% weight) vs. extraction time (seconds) for various solvents, average of three trials.

Based upon the extraction rate data, diffusion coefficients were calculated from the slope of the lines shown in Figure 5.7 for each alternative solvent. The dashed line indicates the 15% target oil concentration.

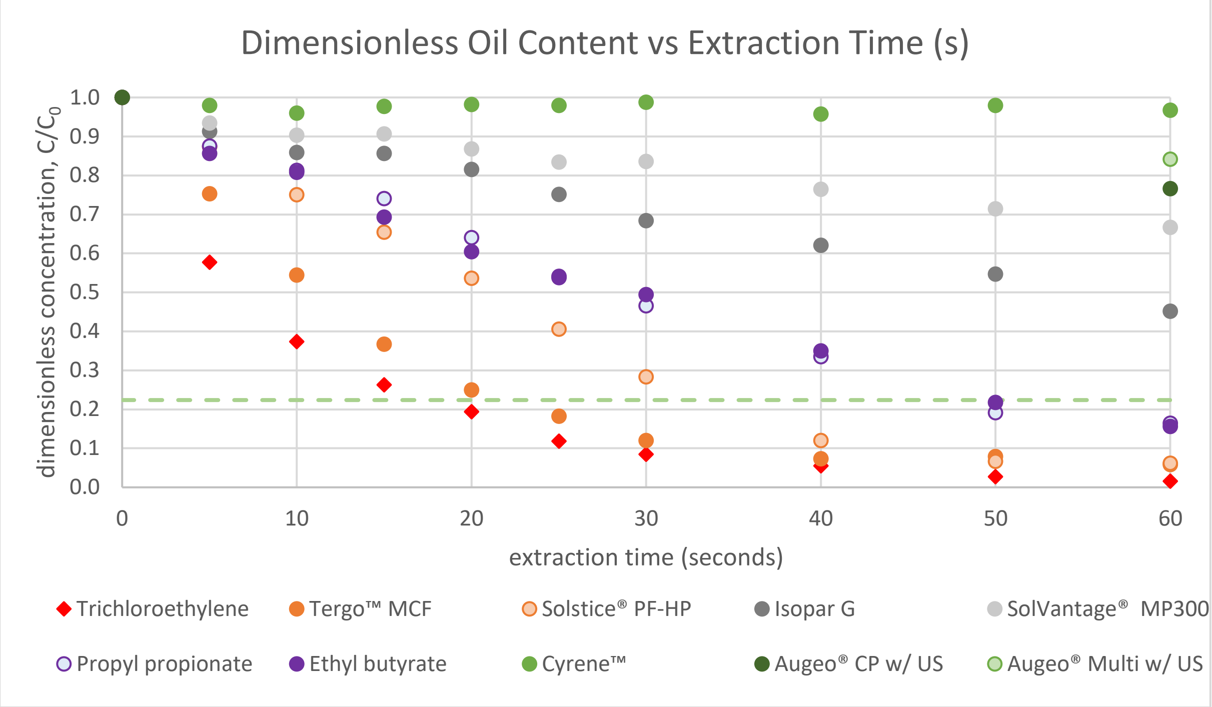

Figure 5.7: Oil concentration (dimensionless) vs time for various extraction solvents.

A relative diffusion coefficient ratio was then calculated from the slope for each solvent divided by the trichloroethylene slope. Table 5.4 presents the extraction data and relative diffusion coefficients for all candidate alternative solvents.

Table 5.4 Rates of oil extraction compared to trichloroethylene

Solvent	**Slope of ln(C/C_0) vs. time**	**Relative Diffusion Coefficient Ratio vs. trichloroethylene**
Trichloroethylene	-0.0673	1.00
Solstice® PF-HP	-0.0528	1.27
Tergo™ MCF	-0.05	1.35
Propyl propionate	-0.0318	2.12
Ethyl butyrate	-0.0307	2.19
Isopar™ G	-0.0126	5.34
SolVantage® MP300	-0.0063	10.68
Augeo® CP	-0.0044	15.30
Augeo® Multi	-0.0029	23.21
Cyrene™	-0.0003	224.33

Conclusions on solubility and rate of process oil extraction

The data show that all new solvent candidates provide slower oil extraction compared to trichloroethylene. Much longer extraction times were observed with non-halogen containing solvents such as ethyl butyrate, n-propyl propionate, and Isopar™ G.

Cyrene™ and Augeo® Multi are eliminated as a potential alternative solvent based upon their lack of/partial solubility of naphthenic process oil and slow extraction rates.

Shrinkage of solvent-laden separator upon drying and resulting porosity

Once the oil has been extracted to its target level of 15%, the solvent-laden sheet then passes into the dryer. In the ENTEK drying process, steam is used to evaporate the solvent from the sheet for the standard (STD) separator and hot air is used in the case of the LR separator. In the laboratory experiments, the solvent-laden sheets were simply dried unrestrained in an air-circulating oven at ~ 120ºC to determine the amount of shrinkage in all three dimensions. As the solvent is evaporated from the porous sheet, there exists a capillary force exerting on the pore walls. The capillary force depends upon surface tension of the solvent, the contact angle, and the pore radius as shown in the following equation:

$$P_c = (\gamma_{LV} \cos \Theta) / r$$

where Pc equals capillary pressure, γLV is surface tension at the liquid-vapor interface, Θ is the contact angle, and r equals pore radius.

These capillary forces lead to the collapse or compaction of the pores, resulting in dimensional shrinkage and smaller pore size distribution in the finish separator compared to the oil-filled precursor.

Table 5.5 shows the measured separator shrinkage and associated volume change after drying from each of the listed solvents.

Table 5.5 Shrinkage of polyethylene sheet on drying compared to trichloroethylene

Solvent	**MD Shrinkage (%)**	**CMD Shrinkage (%)**	**Thickness Shrinkage (%)**	**Relative Volume after Shrinkage**
Trichloroethylene	11.0	5.7	5.0	0.80
Isopar™ G	8.3	7.7	8.7	0.77
SolVantage® MP300	9.4	9.6	15.4	0.69
Augeo® Clean Plus (heated ultrasonic extraction & water rinse)	15.4	10.8	7.1	0.70
Propyl propionate	8.8	6.8	4.9	0.81
Tergo™ MCF	6.1	5.1	6.9	0.83

Separator shrinkage is important because it affects the final separator properties such as porosity, pore size distribution, and also enables ENTEK to determine if the same calender rolls (that impart the rib pattern to the oil-filled sheet) can be utilized to achieve the same final separator profile.

Conclusions on shrinkage and porosity

From the data, it is clear that only two of these alternative solvents result in less or equivalent separator shrinkage compared to when the drying is done from trichloroethylene: propyl propionate and Tergo™ MCF. The reduced separator shrinkage obtained using these alternative solvents tested would result in higher porosity compared to the remainder of the tested alternatives, while this may be beneficial to separator electrical (ionic) resistance, it means that the final separator profile (rib spacing, shoulder width, thickness) may be out of specification using the existing calender rolls. ENTEK has over 55 different calender/profile rolls at its UK plant that would need to be re-machined or replaced if any of the alternative solvents, other than possibly propyl propionate or Tergo™ MCF, were used.

Impact of trace solvent in the separator on lead-acid electrochemistry: Electrochemical Compatibility

Trace amounts of residual solvent may leach out in the final separator and have the potential to affect the purity of the sulfuric acid in a battery, thereby negatively impacting the performance and life of a lead-acid battery. As such, ENTEK evaluated the electrochemical compatibility (ECC) of a sample trichloroethylene PE separator (leached) and compared to a blank of sulfuric acid, i.e. with no 'leachate'. These were then compared to leachates from separator samples that were extracted and dried from the alternative solvents to a residual oil content of ~ 15%.

In this test, a 7-gram sample from each separator type was leached in sulfuric acid (sp. gr. = 1.21) for 7 days at 60°C. A cyclic voltammogram was performed on pure sulfuric acid (sp. gr. = 1.21, referred to as acid blank) and then on the same acid with 10 ml of leachate. The 3-electrode apparatus for performing the cyclic voltammograms is shown in Figure 5.8. The cathodic and anodic scans for a trichloroethylene-extracted separator are shown in Figures 5.9 and 5.10, respectively.

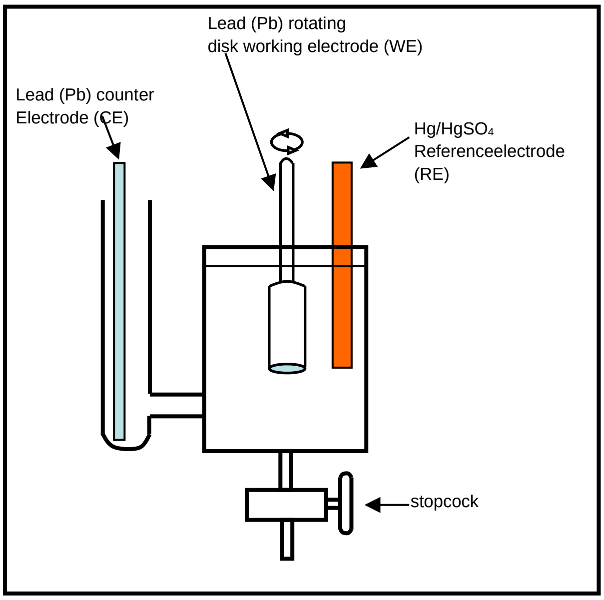

Figure 5.8: Schematic diagram of the electrochemical cell used for ECC testing

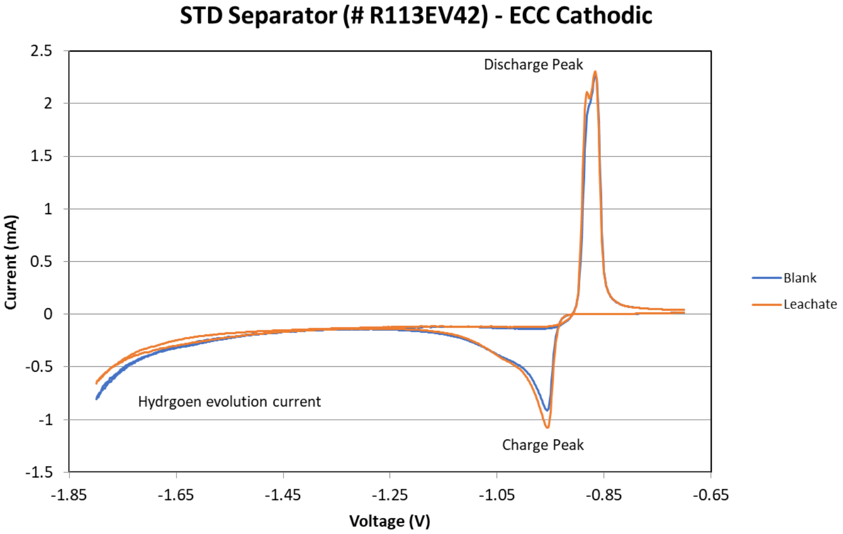

Figure 5.9: Cathodic scan for trichloroethylene-extracted separator shows only a small increase in hydrogen overpotential with little change in the charge or discharge peaks.

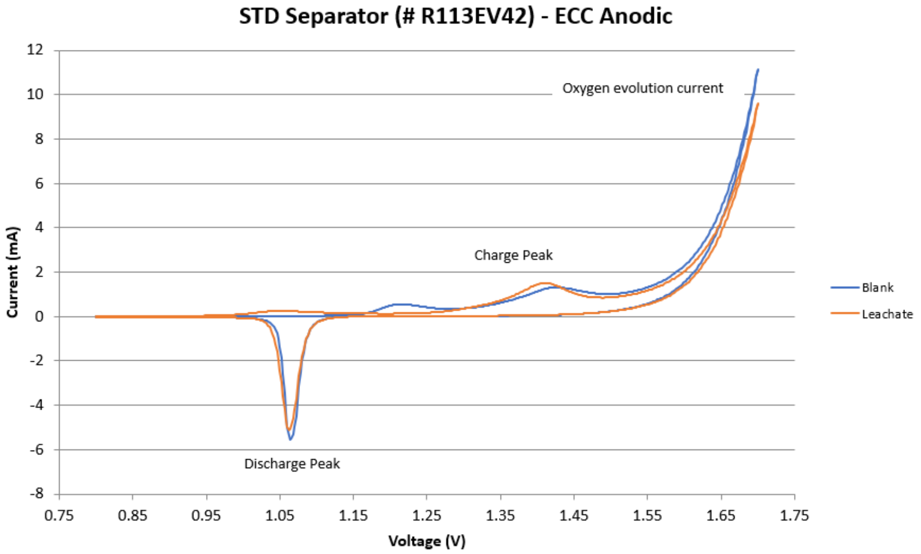

Figure 5.10: Anodic scan for trichloroethylene-extracted separator shows no change in oxygen evolution, or in the charge and discharge peaks.

ENTEK performed ECC tests on separators extracted from each of the new alternative solvent candidates. Leachates from all of the separators had a minimal impact upon the behaviour of the positive (anodic scan) lead electrode, while some leachates from separators extracted with the alternative solvents (e.g., Augeo® Clean Plus) had a larger increase in the hydrogen over-potential (>50 mV at 1 mA) as compared to the trichloroethylene-extracted separator.

Table 5.6 summarises the ECC test data and shows that leachates from separators extracted with each of the listed solvents gave acceptable results [“0” = same as control; “+” = positive compared to control].

Table 5.6 ECC test data summary

Solvent	Cathodic scan	Anodic scan
Trichloroethylene standard	0	0
Augeo® Clean Plus	+	0
Propyl propionate	+	0
Isopar™ G	0	0
SolVantage® MP300	0	0
Tergo™ MCF	0	0

Conclusions on Electrochemical Compatibility

Isopar™ G and SolVantage® MP300 had a similar performance to trichloroethylene. The slight increase in hydrogen overpotential with Augeo® Clean Plus and propyl propionate could actually lead to some beneficial results in a lead-acid battery (e.g., reduced water loss). Overall, three of the alternative solvent candidates appear viable based upon ECC testing: Isopar™ G, SolVantage® MP300 and Tergo™ MCF. Note that the beneficial results for Augeo® Clean Plus and propyl propionate are associated with chemistry that could reduce water-loss in separators when used in batteries. Battery manufacturers generally want to reduce water-loss and there are various approaches to this. However, although this could be a beneficial feature of these possible alternatives, it is outweighed by the considerable disadvantage of the extraction rate provided by these substances (as shown in Table 5.4).

Separator Properties: mechanical strength and electrical (ionic) resistance

The two most important battery separator properties are electrical (ionic) resistance and mechanical strength, in particular puncture strength. Battery separators, extracted to ~15% residual oil with the alternative solvents, were tested in accordance with Battery Council International (BCI) test procedure #03B3 to measure electrical resistance. In this test, the separators were first boiled in water for 10 minutes and then soaked in sulfuric acid (sp.gr = 1.28) for 20 minutes prior to measuring their electrical (ionic) resistance in a Palico Low Resistance Measuring System unit. Electrical resistivity (mohm-cm) was obtained for each separator type by multiplying the electrical resistance (mohm) by the area of the separator (cm²) through which current flows and dividing by the backweb thickness (cm) to eliminate the effect of backweb thickness variation.

As shown in Figure 5.11 and Table 5.7 the electrical resistivity of the separators extracted from alternative solvents are comparable to the trichloroethylene control, except for the case of SolVantage® MP300. During extraction experiments it was noticed that the SolVantage® samples stuck to the drying pans as if the solvent acted as a plasticizer for UHMWPE allowing it to melt and flow during drying, closing off porosity.

Table 5.7 Electrical resistance and resistivity of samples extracted to target 15% residual backweb oil

Solvent	Resistance (mΩ·cm²)	Resistivity (mΩ·cm)	Thickness (mm)
Trichloroethylene	86	2906	0.296
Augeo® Clean Plus	62.8	3469	0.181
Isopar™G	62.9	3558	0.177
SolVantage® MP300	306.1	16989	0.18
Propyl propionate	61.1	3302	0.185
Tergo™ MCF	53.4	2703	0.198

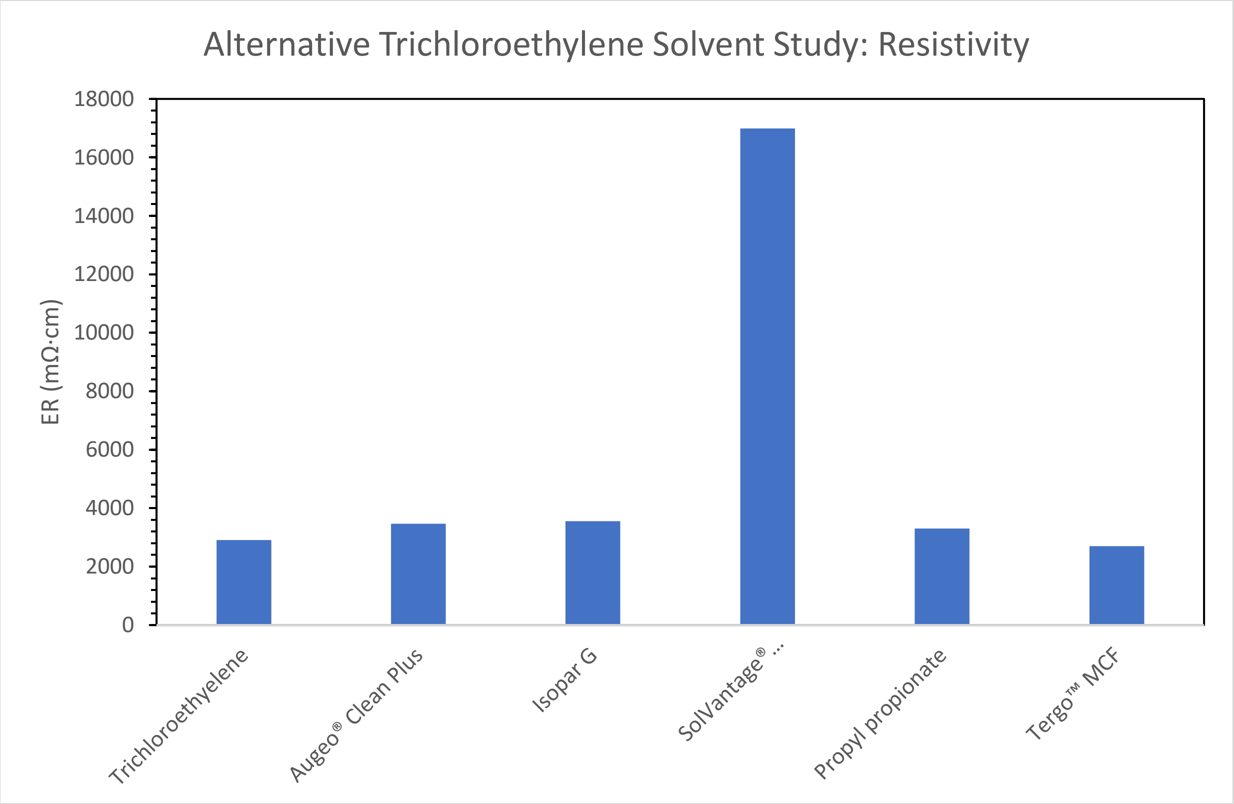

Figure 5.11: Electrical resistivity (mohm-cm) of battery separators extracted with various solvents to ~15% residual oil content.

The puncture strength of the separators was measured in accordance with BCI test procedure # 03B11 using a 1.9 mm diameter flathead pin. The absolute puncture strength was then divided by the backweb thickness to provide a comparison of the separators produced from different extraction solvents.

The normalised puncture strength data (Figure 5.12) show all samples to be within an acceptable range. Although the 17% lower value for the Tergo™ MCF separators is potentially of concern, the result is likely explained by the lower shrinkage and higher porosity that resulted after drying.

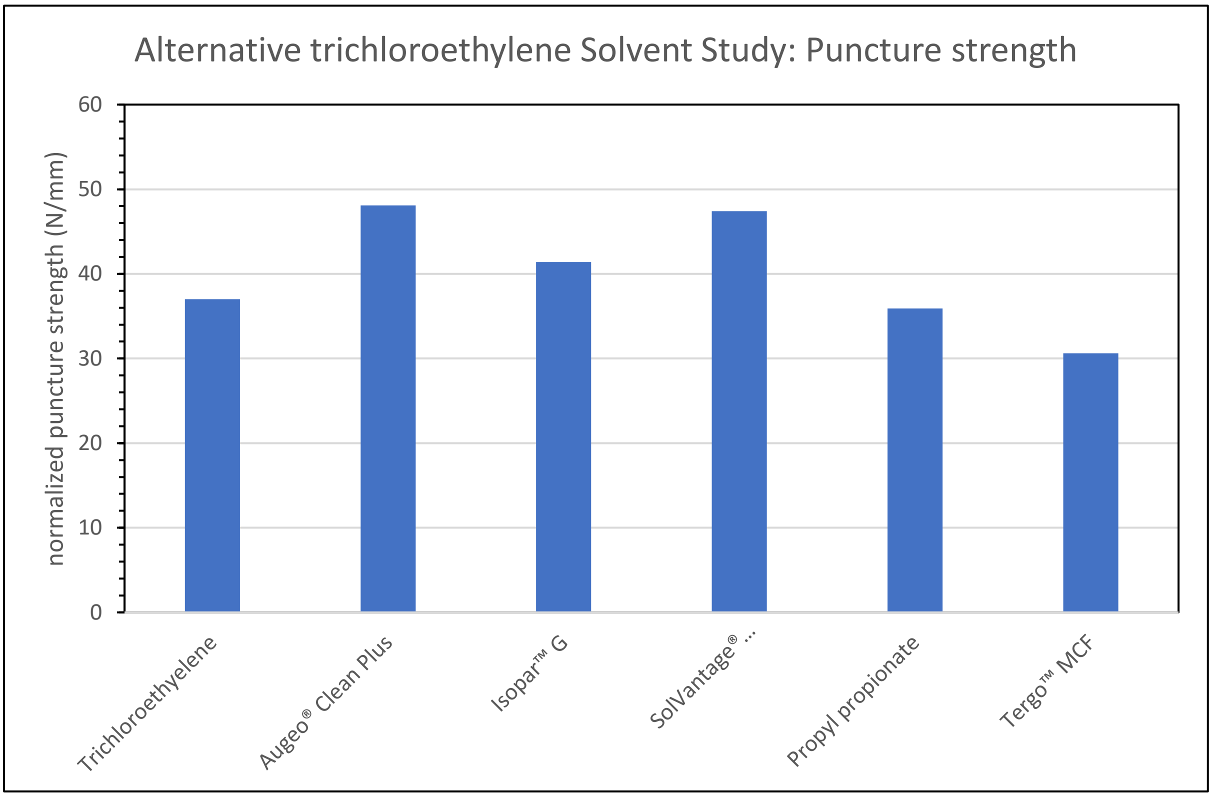

Figure 5.12: Normalised separator puncture strength.

Figure 5.12 shows the separator puncture strength normalised by backweb thickness. The graph shows some increase in puncture strength for high-shrinkage samples, namely Augeo® Clean Plus and SolVantage® (see analysis of shrinkage previously assessed). This is an indication of pore collapse.

Conclusions on separator properties

Based on electrical resistivity (see Figure 5.11), the solvent SolVantage® does not allow the battery separator to function. On the basis of normalised puncture strength, the high shrinkage samples Augeo® Clean Plus and SolVantage® appear to have collapsed pores.

The other solvents tested for electrical resistance and puncture strength are roughly comparable to trichloroethylene.

5.1.1.3 Conclusion on solvent alternatives

This section presents firstly a conclusion of the R&D results and then a more general conclusion on the identification of alternative solvents taking into account, properties, availability and risks.

Summary of R&D with solvent alternatives

A summary of the tests conducted on the alternative solvents identified in this application and their performance compared to trichloroethylene is presented in Table 5.8.

Table 5.8 Testing on alternative solvents - summary of outcomes

	Testing outcomes (compared to performance of trichloroethylene)					
Substance	**Oil solubility**	**Oil extraction rate**	**Shrinkage of separator**	**Electrochemical compatibility**	**Electrical resistivity**	**Puncture strength**
Augeo® Clean Plus	Fully	Much slower	Increased	Slightly better	Similar	Pore collapse
Augeo® Clean Multi	Partial	Much slower				
Cyrene™	Not soluble	Much slower				
Ethyl butyrate		Much slower				
Isopar™ G		Much slower	Increased	Similar	Similar	Similar
Propyl propionate		Much slower	Acceptable	Slightly better	Similar	Similar
Tergo™ MCF		Similar	Slightly reduced	Similar	Similar	Similar
Solstice® PF-HFP		Slower				
SolVantage ® MP300		Much slower	Increased	Resistance issue	Too high	Pore collapse

Solstice® PF-HFP is a gas and is incompatible with the extraction and recovery processes, therefore further testing was not carried out beyond the extraction rate, even though its performance was comparable to trichloroethylene.

Ethyl butyrate has a low Flash Point (26ºC) which makes it incompatible with solvent extraction and recovery processes due to the risk posed. No further testing was carried out beyond the extraction rate. Propyl propionate also has a low Flash Point (19ºC), which has been erroneously reported as 58ºC in several databases. This was not obvious at the time of conducting the studies.

Dowclene™ 1601 has been successfully used for the replacement of trichloroethylene in vapour degreasing (Rolls-Royce, 2012, Notice to Suppliers[45]). However, ENTEK was not able to obtain a sample for the purpose of conducting bench-scale trials and therefore no feasibility studies were carried out on this alternative. A theoretical assessment of the technical feasibility is possible, but ultimately the suitability of a candidate solvent must be determined by testing. This alternative was not taken forward to the shortlist on the basis of **lack of availability**.

Of the remaining solvents, it is clear from Table 5.8 that SolVantage® MP300 is not a suitable candidate because it performed worse than trichloroethylene in all studies. Cyrene™ was not soluble in the process oil used in the production of the separators, therefore it is not a compatible solvent on technically viable.

It should be noted that these considerations and the above table are comparisons to trichloroethylene, but do not weigh in the relative importance of each test to the performance of the separator or the impact on productivity.

Overall conclusions on alternative solvents

In order to make a comparison of the alternatives, an overview of the technical feasibility trials, the potential risks and availability of the alternative solvents have been presented in Table 5.9. The availability was assessed based on the EU REACH registration tonnages (last reviewed 04 June 2021) and compared to the current volume needs for

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[45] Notice accessed online at https://suppliers.rolls-royce.com/GSPWeb/ShowProperty?nodePath=/BEA%20Repository/Global%20Supplier%20Portal/NoticesToSuppliers/nts_322//ntsFile in June 2921

trichloroethylene (approximately 46 tpa). A substance registered at a volume of 100 tpa or less is considered unlikely to be able to accommodate an additional demand of 46 tpa.

Table 5.9 Overview of alternative solvents

Substance	Technical Feasibility	Risk	Availability	Conclusion
Augeo® Clean Plus	Possible on basis of lab trials Higher temperature and ultrasonics required for oil removal	Low hazard potential, which can be managed.	No. The substance is registered in Europe with a total tonnage band ≥ 1 to < 10 tonnes per annum.	Rejected on the basis of technical feasibility and availability.
Augeo® Clean Multi	No - only partial solubility with process oil and higher temperature and ultrasonics required for oil removal.	Low hazard potential, which can be managed.	Likely. The substance is registered in Europe with a total tonnage band ≥ 100 to < 1 000 tonnes per annum.	Rejected on the basis of technical feasibility.
Cyrene™	No – does not perform function to remove process oil effectively	Low hazard potential, which can be managed.	Likely. The substance is registered in Europe with a total tonnage band ≥ 100 to < 1 000 tonnes per annum.	Rejected on the basis of technical feasibility.
Ethyl butyrate	Possible on basis of lab trials. However, significantly lower oil extraction rates.	Low flash point near ambient temperature. Hazard will be challenging to manage.	Yes. The substance is registered in Europe with a total tonnage band ≥1 000 to <10 000 tonnes per annum.	Rejected on the basis of technical feasibility and risk.
Isopar™ G	Possible on basis of lab trials However, significantly lower oil extraction rates.	Flammable with a flashpoint ~ 20°C above room temperature. relatively low flashpoint. Hazard may be difficult to manage.	Yes. The substance is registered in Europe with a total tonnage band ≥ 1 000 to < 10 000 tonnes per annum.	Selected as a potential candidate based on technical feasibility and availability. Cautious selection based on extraction rate and flammability.

Substance	Technical Feasibility	Risk	Availability	Conclusion
Propyl propionate	Possible on basis of lab trials. However, significantly lower oil extraction rates.	Low flash point near ambient temperature. Hazard will be challenging to manage.	Unlikely. The substance is registered in Europe with a total tonnage band ≥10 to <100 tonnes per annum.	Rejected on the basis of risk and availability.
Tergo™ MCF	Possible on basis of lab trials. Considerable further research necessary to determine if recovery from carbon beds without affecting composition of the 3-part azeotrope is possible.	Non-Flammable.	Likely. The main ingredient is registered in Europe with a total tonnage band ≥100 to <1 000 tonnes per annum.	Selected as a potential candidate based on technical feasibility, low risk and availability.
Solstice® PF-HFP	Possible on basis of lab trial Liquefied gas with boiling temperature of 19°C is not feasible in our continuous extraction and solvent recovery processes	The substance is a liquified gas and may explode if heated. Hazard will be challenging to manage.	Yes. The substance is registered in Europe with a total tonnage band ≥1 000 to <10 000 tonnes per annum.	Rejected based on the form of the substance and related risk.
Dowclene™ 1601	High water solubility is likely to negatively impact the potential for recovery Unavailable for testing	Low hazard potential, which can be managed.	Yes. The main ingredient is registered in Europe with a total tonnage band ≥10 000 tonnes per annum. However, the material was not available for testing.	Rejected on the basis of lack of availability for trials.

Substance	Technical Feasibility	Risk	Availability	Conclusion
SolVantage® MP300	Much higher boiling temperature will negatively impact separation from process oil Drying separator that was extracted with SolVantage® causes high shrinkage via pore collapse and much higher resistivity to ionic conduction	Low hazard potential, which can be managed.	Yes. The substance is registered in Europe with a total tonnage band ≥100 000 to <1 000 000 tonnes per annum.	Rejected on the basis of technical feasibility.

The Analysis of Alternatives developed in the previous application concluded that there were no alternatives that are suitable and available to the applicant for the replacement of the Annex XIV substance function. Since then, a number of possible solvent alternatives has been identified and tested at laboratory scale by ENTEK. The trials and the properties of the alternative solvents (e.g., water solubility, flashpoint and hazards), indicate that none of them are 'drop-in' replacements for trichloroethylene.

It was found that for Tergo™ MCF and Isopar™ G there was some potential for the replacement of trichloroethylene, and these have been taken forward into the shortlist. However, a considerable amount of further research would be required to determine the technical feasibility of these substances at a commercial scale. In addition, the customer acceptability of the products manufactured using an alternative would also have to be ensured. These themes are explored further in Section 5.3.

5.1.1.4 Alternative technologies

The ENTEK R&D Group has been exploring alternative approaches to trichloroethylene-extracted polyethylene separators.
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2. [redacted]
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4. [redacted]
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Figure 5.13: [redacted].

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Figure 5.17:
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Figure 5.18:

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Figure 5.24: [redacted]

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Figure 5.25: [redacted]xx

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Figure 5.26: [redacted]

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Figure 5.28: [redacted]

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Figure 5.29: [redacted]

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Figure 5.31: [redacted]

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Figure 5.33: [redacted]

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Table 5.10 [redacted]

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5.1.2 Data searches

ENTEK is actively seeking new solvents and/or processes that might be relevant to the production of battery separators. This is done through periodic monitoring of the scientific literature to identify new solvents, processes, new uses of existing chemicals or for new R&D streams. For example, Cyrene™ was identified through an article published in Chemical & Engineering News[46] (American Chemical Society publication).

ENTEK also interacts with various chemical companies and suppliers in Europe and the US for the same purpose. For example, the Augeo® substances were identified through interactions with the chemical company Solvay.

ChemSec Marketplace is a platform for the identification of green chemicals, specifically aimed at removing hazardous chemicals from the market. The site has been screened to identify candidate solvents. Safeco from Eco-Point International BV is being marketed as a replacement for trichloroethylene[47]. While the product is promoted as "green solvent" and free of both trichloroethylene and methylene chloride, a chemical composition is not provided on the website. Chemical composition is of course key to determining if a product can be a possible alternative or not.

5.2 Identification of known alternatives

The alternative solvents identified in the 2014 application have been reconsidered and the alternatives remain not feasible either technically, economically or on the basis of risks, see Table 5.1.

Alternative solvents have been identified and researched since the last application (see Table 5.2) and the main R&D investment ENTEK has made in terms of the removal and/or replacement of trichloroethylene is in (Blank 66) and 'separator-free' battery technologies.

The key separator properties that have been evaluated are:

- electrical (ionic),
- mechanical,
- oxidation resistance,
- porosity,

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[46] https://cen.acs.org/index.html

[47] https://marketplace.chemsec.org/Alternative/Safeco-Cleaner-and-degreaser-based-on-safe-and-easily-degradable-solvents--343

- pore size distribution,
- wettability,
- shrinkage, and
- electrochemical compatibility.

In some cases, the replacement candidates were able to meet the performance standards of trichloroethylene or exceed them, but none was comparable to or performed better than trichloroethylene in all endpoints. Another key parameter is oil extraction rate: as indicated elsewhere, a slower extraction rate would slow down production in order to increase the extraction timings, or the solvent would need to be heated. Both of these options would negatively impact separator costs.

In addition, the separators will be further processed by ENTEK's customers. A number of 'fit for use' parameters have been identified in Table 4.11. The following 'fit for use' parameters have been identified as key for acceptability of a replacement product: winding/unwinding, sealing and enveloping properties. These parameters have not been tested by ENTEK in the bench-scale trials and the candidates' potential to fulfil these criteria is considered in the selection process.

Based on the research presented in previous sections and likelihood of success (determined from experimental data and expert judgement), Tergo™ MCF and Isopar™ G are taken forward into the shortlisted selection of alternative solvents (section 5.3). Blank67 [redacted]

A scenario that considers the implications of ceasing production in the UK and a scenario that considers the implications of moving manufacture of lead-acid battery separators outside of the UK and the EU have been assessed for completeness, and to allow comparison with the identified alternatives.

5.3 Assessment of shortlisted alternatives

5.3.1 Alternative 1: Tergo™ MCF [48]

5.3.1.1 Substance ID, properties (or Description of alternative technique)

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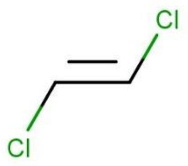
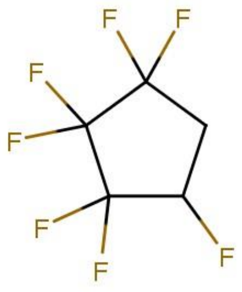
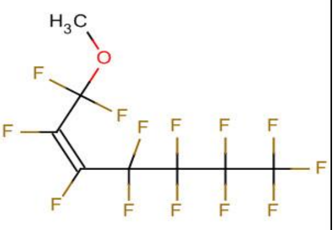
[48] If the Annex XIV substance is replaced by a group of several substance and/or techniques, include the analysis for the group as a whole in one section.

Tergo™ MCF is a three-component azeotrope with trans-dichloroethylene, CAS 156-60-5, EC 205-860-2, being the major constituent and present at 60-95%. Two secondary constituents, heptafluorocyclopentane, CAS 15290-77-4, EC 430-710-1, and methoxytridecafluoroheptene, no EC, CAS 1708962-18-8, are present at 1-5% according to manufacturer's SDS (MicroCare 2021). Methoxytridecafluoroheptene is not present as such in any of the UK HSE or ECHA databases, however its isomers are present as methoxytridecafluoroheptene isomers, EC 946-374-7 and it is considered likely that this is referring to the same substance.

Table 5.11 summarises the substance identifiers of the constituents of Tergo™ MCF.

Table 5.11 Substance identifiers for the Tergo™ MCF constituents

	Constituent present at 60-95%	**Constituent present at 1-5%**	**Constituent present at 1-5%**
EC number:	205-860-2	430-710-1	946-374-7
EC name:	trans-dichloroethylene	1,1,2,2,3,3,4-heptafluorocyclopentane	methoxytridecafluoroheptene isomers
CAS number (EC inventory):	156-60-5	15290-77-4	-
CAS name:	Ethene, 1,2-dichloro-, (1E)-	-	-
IUPAC name:	1,2-Dichloroethene	1,1,2,2,3,3,4-heptafluorocyclopentane	-
CLP Annex I index number:	602-026-00-3	602-104-00-7	NA
EU REACH Annex XIV entry:	NA	NA	NA
Structure			

	Constituent present at 60-95%	**Constituent present at 1-5%**	**Constituent present at 1-5%**
Molecular formula:	C_2H2Cl_2	$C_5H_3F_7$	$C_8H_3F_{13}O$

Source: ECHA[49, 50, 51]

5.3.1.2 Technical feasibility of Alternative 1

Tergo™ MCF is not a technically feasible alternative for ENTEK for their current use of trichloroethylene. If the AfA expires, ENTEK would need to stop use of trichloroethylene at their UK site by 21 April 2023, however, within this timescale it is not technically feasible to substitute from trichloroethylene to Tergo™ MCF. Appendix 2 sets out in detail all the activities that ENTEK would need to carry out to fully substitute away from trichloroethylene to Tergo™ MCF, which total up to at least 12 years. This is considered the minimum time required and is based on the presumption that at no point in the process will Tergo™ MCF fail any of the stages. For example, it is possible that at pilot testing stage Tergo™ MCF will fail to produce a battery separator that will be sufficient to meet customer requirements. This sub-section does however set out further details on progress made by ENTEK with assessing the suitability of Tergo™ MCF to better understand if it could be technically feasible in the future.

The bench-scale trial results are presented throughout Section 5.1.1.1, which show that Tergo™ MCF performed better than any of the other alternative solvents tested.

Tergo™ MCF outperformed the other solvents in oil extraction and its rate is close to that of trichloroethylene. As already indicated, this parameter impacts production timings. The separator shrinkage was slightly less compared to trichloroethylene, which may be an indication of higher porosity. Porosity is part of the product specifications of separators (see Section 4.3.3) and while an increase in porosity in the bench-scale trials does not mean that the alternative is rejected, deviations from the product specifications would be rejected by ENTEK's customers. The shrinkage difference also indicates a change in separator size, which in turn means that the existing calender rolls may be incompatible and would not be able to process the separators (to meet client specifications). There were no issues in electrochemical compatibility of Tergo™ MCF and its electrical resistivity

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[49] https://echa.europa.eu/hr/substance-information/-/substanceinfo/100.005.329 accessed April 2021

[50] https://echa.europa.eu/substance-information/-/substanceinfo/100.102.902 accessed June 2021

[51] https://echa.europa.eu/substance-information/-/substanceinfo/100.251.670 accessed June 2021

was slightly lower than trichloroethylene (2703 vs 2903 mohm-cm), which is favourable. The separator produced with Tergo™ MCF has a lower puncture strength compared to trichloroethylene (which may affect durability). However, this is thought to be due to lower shrinkage and higher porosity rather than an issue with its mechanical property.

There are still some major unknowns regarding equipment and process compatibility that will require substantial investment in R&D:

- Compatibility with stainless steel and galvanised steel used in the existing equipment (potential for corrosion).
- Chemical stability in the conditions used to extract and recover the oil-laden solvent in the STD separator drying process.
- Chemical (particularly the azeotrope) stability during distillation and adsorption to carbon beds followed by desorption with steam.
- Distillation performance – can complete separation for the process oil be achieved in one stage or is a second distillation phase required?
- Compatibility with LR drying process that uses 'cyrogenic' condensation (is the chiller cold enough?).
- As already indicated the sheet shrinkage indicates that there may be some compatibility issues with the existing tooling.

In addition:

- the efficiency of adsorption and steam desorption from activated carbon beds will need to be investigated.
- the flash point of the solvent/oil and mixture needs to be verified.
- the extraction and evaporation rates against the process temperature and sheet thickness need to be investigated.
- The distillation and complete removal of residual solvent from solvent/water mixtures will need to be verified.

It is possible that these investigations will result in process changes to accommodate the production of lead-acid battery separators with Tergo™ MCF, which in turn may require a review of the workplace health and safety practices.

Nevertheless, ENTEK is progressing with the R&D and has signed a non-disclosure agreement with MicroCare LLC, the manufacturer of Tergo™ MCF, to further investigate its use for battery separator manufacturing in the US.

Further details of the planned activities and timescales are presented in Section 6.8.

5.3.1.3 Economic feasibility and economic impacts of Alternative 1

Tergo™ MCF is not an economically feasible alternative for ENTEK for their current use of trichloroethylene. If ENTEK needed to stop use of trichloroethylene at their UK site by 24 April 2023, however, it is not technically feasible to substitute from trichloroethylene to Tergo™ MCF. **Appendix 2** sets out in detail all the activities that ENTEK would need to carry out to fully substitute away from trichloroethylene to Tergo™ MCF, which total up to at least 12 years, as well as the associated cost with each activity.

This is considered the minimum time required and is based on the presumption that at no stage in the process will the Tergo™ MCF fail any of the requirements. For example, it is possible that at pilot testing stage Tergo™ MCF will fail to produce a battery separator that will be sufficient to meet customer requirements.

In order to support the conclusion that Tergo™ MCF is not an economically feasible alternative for ENTEK, this sub-section sets out further details on the estimated costs that ENTEK would incur to substitute from trichloroethylene to Tergo™ MCF i.e. capital costs and testing costs associated with the substitution process, and the forgone profits lost from not being able to produce any battery separators at the UK site using trichloroethylene, as well as the estimated profits to ENTEK from future sales of battery separators at the UK site (after 12 years) using Tergo™ MCF.

Based on work undertaken by ENTEK's Chief Technology Officer and Chief Financial Officer, the activities required, and the associated costs and timings of the substitution activities were calculated and are outlined below in Table 5.12. The table shows that ENTEK would incur costs of £62.6 million from temporary shutdown of UK site and operationalising Tergo MCF as an alternative solvent.

Table 5.12: Costs associated with use of Tergo MCF as an alternative to trichloroethylene

Costs associated with Tergo MCF alternative	**Cost (£ million)**
Project management - Logistics and planning for site closure	**Blank 68**
Redundancy payments (25% of workers made unemployed)	**Blank 68**
R&D - Laboratory Screening Tests	**Blank 68**

Pilot Scale	Blank 68
Model Development	Blank 68
Commercial Scale Up	Blank 68
Battery Testing and Verification	Blank 68
Phased Line Conversions and Industrialization	Blank 68
Contingency 15% - to cover all the unknowns related to the development of the new solvent	Blank 68
TOTAL COSTS	Blank 68

Table 5.12 shows that the largest costs incurred if trichloroethylene is replaced with Tergo MCF are associated with phased line conversions and industrialisation. For a more detailed breakdown of the costs that ENTEK would incur as a result of operationalising Tergo MCF, see **Appendix 2.**

For modelling purposes, it is assumed that ENTEK will continue to produce battery separators at the UK site until they are not allowed to use trichloroethylene. Therefore, the operating profits generated from selling the separators will continue up until 4 April 2023. Furthermore, from 2035, the UK site will be fully operational (using the alternative solvent – Tergo MCF) which means that profits from selling battery separators will again be generated. However, the profits generated will not be the same as under the exemption granted scenario for several reasons:

- The operating profits in 2035 and 2036 are less than the exemption scenario as ENTEK will need to recover its customer base (market share) that will be lost during shutdown and aim to do this by lowering prices of battery separators.
- After 2037 the profits are projected to only be 90% of the profits in AfA scenario as it is believed that 10% of the customer will be permanently lost to competitors.

As a result, the total gross profits over the 20-year assessment period are around (Blank 69)(no discounting) when implementing this alternative, compared (Blank 70) (no discounting) under the exemption granted scenario. In reality, compared to modelling it is unlikely that ENTEK will recovery 90% of their customer base after a 12-year absence even with an aggressive pricing strategy. Therefore, the profits generated using this alternative is considered highly optimistic.

Figure 5.35 shows the breakdown of financial costs and benefits of operationalising Tergo MCF by year. The costs are split over 12 years (2023 – 2034) with the largest cost occurring in 2029. The total capital costs accumulated over the 20-year assessment period is around (Blank 71) (no discounting) as detailed in Table 5.12 and forgone profit from no longer being able to use trichloroethylene of (Blank 72) no discounting).

[redacted]

Figure 5.36: [redacted] (Blank 73)

Table 5.13 shows the total costs, total profits, and net income of this scenario over a 20-year period. With no discounting, the costs of replacing trichloroethylene with Tergo MCF outweigh the generated profits over the time period, resulting in a negative net income of **Blank 74** (no discounting). When applying the opportunity cost of capital of 14% (to present the net present value) the net income for ENTEK if trichloroethylene is replaced with Tergo MCF is Blank 75 over 20 years.

Table 5.13: Total financial costs and benefits to ENTEK of operationalising Tergo MCF

Financial costs and benefits over 20 years	**Cost** **£ million**
Lost profit from not being able to use TCE	**Blank 76**
Total capital costs to cease current production and switch to alternative	**Blank 76**
Profit from using alternative	**Blank 76**
Net profit over 20 years (no discounting)	**Blank 76**
Net profit over 20 years (net present value using 14% discount rate)	**Blank 76**

Table 5.13 clearly demonstrates that this alternative would produce a significant overall financial loss for ENTEK which makes this alternative not economically feasible to ENTEK.

5.3.1.4 Availability of Alternative 1

Tergo™® MCF is currently manufactured and supplied only by MicroCare LLC, a US-based company. The manufacturer indicates that the substance is available globally and approved for use world-wide.[52]

The main ingredient, trans-dichloroethylene, has been registered in Europe under REACH with a total tonnage band ≥100 to <1000 tonnes.

Heptafluorocyclopentane, has been registered in Europe under EU REACH with a total tonnage band ≥1 to <10 tonnes, while methoxytridecafluoroheptene (isomers), is not registered. However, the substances may not require registration if they are impurities of the main substance.

5.3.1.5 Reduction of overall risk due to transition to Alternative 1

The classification and labelling of the product is presented in Table 5.3. The main ingredient is classified as dangerous to the environment and flammable although the whole

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[52] https://www.microcare.com/en-US/Resources/News/Tergo-MCF-is-a-Better-Option-as-nPB-Sunsets-in-Eur accessed April 2021

product is said not to have a flash point (see Table 5.2) and to be non-flammable by the manufacturer. The vapours may become flammable when mixed with air at the following concentrations: Lower explosive limit (LEL) 7 %(volume) and Upper explosive limit (UEL) 15.6 %(volume) (MicroCare 2021) and the substance has a low boiling point (46.2°C). This would need to be taken into consideration during the review of the production processes and performance.

The table below (Table 5.14) presents the key human health and environmental properties of the main constituent, trans-dichloroethylene, and the constituent, 1,1,2,2,3,3,4-heptafluorocyclopentane, where available. There is no information available in the public domain on the properties of the minor constituent methoxytridecafluoroheptene (isomers).

Table 5.14 Properties of the constituents of Tergo™ MCF, where available

Endpoint	**trans-dichloroethylene** [53]	**1,1,2,2,3,3,4-heptafluorocyclopentane**[54]
Human health endpoints		
Acute toxicity	Low acute toxicity observed in oral, dermal and inhalation studies.	Effects observed in the inhalation study (LC50: 14213 ppm), Acute oral toxicity 4 classification proposed
Eye/skin corrosion/irritation	Eye irritation was observed	Some eye irritation observed but insufficient for classification
Skin sensitization	Not assessed due to likely evaporation of the substance before study completion	Not sensitising
Neurotoxicity	CNS depression observed in acute toxicity studies	No data
Chronic Toxicity/Repeated Dose Toxicity	90-day oral and inhalation studies available indicating no test substance-related adverse effects at the highest concentrations tested	28-day oral NOAL 1000 mg/kg. The 90-day inhalation NOAC 2990 mg/m^3
Carcinogenicity	No data	No data

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[53] Source of data: https://echa.europa.eu/registration-dossier/-/registered-dossier/16486 accessed June 2021

[54] https://echa.europa.eu/registration-dossier/-/registered-dossier/30667 accessed June 2021

Endpoint	**trans-dichloroethylene** [53]	**1,1,2,2,3,3,4-heptafluorocyclopentane**[54]
Mutagenicity/Genotoxicity	Negative results were observed in *in vitro* gene mutation study in bacterial cells, an *in vitro* gene mutation study in mammalian cells, an *in vitro* cytogenicity study in mammalian cells, and an *in vivo* micronucleus study.	Negative results were observed in *in vitro* gene mutation study in bacterial cells, an *in vitro* gene mutation study in mammalian cells, and an *in vivo* mammalian somatic cell test.
Reproductive Toxicity	No data	No data
Developmental Toxicity	An inhalation NOEC for maternal toxicity was determined at 2000 ppm and the NOEC for embryo-fetal toxicity was 6000 ppm. Insufficient for classification.	Some embryo-fetal toxicity at 3500 ppm, but insufficient for classification.
Endocrine Activity	Two *in vitro* assays are available on the substance: Aromatase (Human Recombinant) Assay and Steroidogenesis (Human Cell Line - H295R) that indicate no endocrine activity potential.	No data
Respiratory Sensitization	No data	No data
Cardiac sensitization	Beagle dogs were sensitised to the substance when exposed through the air at a concentration of 25-50%	The substance has the potential to cause cardiac arrest in beagle dogs (NOAEL 538 ppm and EC50 2400 ppm)
Ecotoxicity		
Short-term aquatic	EC/LC_{50} values in the range: 36.6-220 mg/l	EC/LC_{50} values in the range: 63.3 mg/l to >47.3 and >100 mg/l
Long-term aquatic	No data	Algal NOEC 24.9 mg/l (growth rate)
Persistence		
Degradation	Slow biodegradative activity concomitant with relatively moderate rate of volatilization	Not biodegradable

Endpoint	**trans-dichloroethylene** [53]	**1,1,2,2,3,3,4-heptafluorocyclopentane**[54]
Bioaccumulation	The endpoint is waived based on low potential for bioaccumulation (log K_{ow} <3)	No data. However, the substance has a log K_{ow} 2.4, therefore it has a low potential for bioaccumulation.

The data taken from the ECHA disseminated dossier[55] of the main ingredient trans-dichloroethylene, on the whole indicate that it has a lower hazard potential compared to trichloroethylene based on the fact it is not mutagenic and has low repeated dose toxicity. There were some observations of CNS depression symptoms in the acute toxicity studies.

Information obtained in the public domain indicates that exposure to trans-dichloroethylene generates small amounts dichloroacetic acid (DCA) in liver tissue[56], a metabolite known to have carcinogenic properties (US EPA 2003) and that is also generated through exposure to trichloroethylene. In an inhalation study (reported in PubChem[57]), rats and mice were exposed to single or repetitive doses of trans-dichloroethylene at 200 ppm, which resulted in histopathological changes, including severe to slight fatty degeneration of the hepatic lobules and Kupffer cells. It is unclear whether this study is the same inhalation repeated dose toxicity in the ECHA disseminated dossier[58], where hepatic fatty degeneration is not reported.

1,1,2,2,3,3,4-Heptafluorocyclopentane appears to be more hazardous than the main ingredient, where some effects in repeated dose and developmental toxicity are observed but are insufficient for classification. Based on the above data, the main concern with this constituent is the observed cardiac arrest in beagles and lack of degradability.

Methoxytridecafluoroheptene (isomers) falls under the category of chemicals defined as Perfluorinated Alkyl substance (PFAS), and with its 13 fluorine atoms it is classed as a long-chain PFAS. This type of substance is highly stable, persistent, with the potential to bioaccumulate. The UK government is investigating the risks that arise from the use of per- and polyfluoroalkyl substances (PFAS) and will consider how best to manage them. This group of substances is also subject to a proposal for restriction in the EU.

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[55] The *Guidance on the preparation of an application for authorisation* (ECHA 2021), indicates that the collection of hazard information for the alternatives should initially be reviewed from registration dossiers and other REACH-related information where available, Box 6, page 66.

[56] https://pubchem.ncbi.nlm.nih.gov/compound/638186#section=Metabolism-Metabolites accessed June 2021

[57] https://pubchem.ncbi.nlm.nih.gov/compound/638186#section=Toxicity-Summary accessed April 2021

[58] https://echa.europa.eu/registration-dossier/-/registered-dossier/16486/7/6/3

There are several uncertainties in the comparison of hazards with trichloroethylene:

- There are no reproductive toxicity data with any of the constituents.
- There are no carcinogenicity data with any of the constituents.
- The are no hazard data with methoxytridecafluoroheptene (isomers), which has the potential to be problematic due to its perfluorinated chain.

The manufacturer indicates that Tergo™ MCF has an ACGIH (American Conference of Governmental Industrial Hygienists) long-term exposure limit (8-hour TWA) of 200 ppm. This is understood to be in reference to the main constituent, trans-dichloroethylene. In comparison, trichloroethylene has a threshold limit value of 10 ppm according to ACGIH. Limits for the other constituents are not available. There is no UK WEL for trans-dichloroethylene or the other constituents to make a comparison with trichloroethylene.

Also, according to the SDS from the manufacturer, the product contains a maximum VOC content of 1178 g/l (Microcare 2021), which is unexpected based on the low boiling point of the substance. There are no cut-off VOC values. It is noted that the value reported in the SDS is higher than any maximum VOC content allowed for paints and varnishes presented in The Volatile Organic Compounds in Paints, Varnishes and Vehicle Refinishing Products Regulations (2012) No. 1715. However, trichloroethylene is also volatile and the manufacturing process is designed to maximise recovery of the solvent and minimise exposure.

It is not known at this stage whether the use of Tergo™ MCF will result in any process changes, which may result in an increased risk of exposure.

In summary, the information available indicates Tergo™ MCF has the potential to exhibit carcinogenic properties, and there are limited data to exclude this completely. The minor constituents of the substance also present some concerning characteristics, particularly the methoxytridecafluoroheptene (isomers) has the potential to be very persistent and bioaccumulative. There are several unknowns, which make it difficult to draw definitive conclusions on the reduction of risk in use from Tergo™ MCF. On the whole, the use of Tergo™ MCF may result in a decrease in human health risks, but an increase in environmental risks.

5.3.1.6 Conclusions on Alternative 1

Tergo™® MCF is potentially attractive in the ENTEK separator manufacturing process because it is non-flammable, but its lower extraction rate compared to trichloroethylene will have a negative capital and operational cost impact.

Additional research and development and engineering analysis are required to evaluate equipment compatibility, chemical stability, distillation, and the efficiency of adsorption and steam desorption from activated carbon beds in the ENTEK manufacturing process. As indicated in Section 5.3.1.2, ENTEK is further reviewing the potential of Tergo™ MCF for the manufacture of lead-acid battery separators with MicroCare LLC in the US.

Another concern is the potential for trans-dichloroethylene to result in the same health concerns associated with other chlorinated solvents (trichloroethylene as well as methylene chloride and perchloroethylene), and an increase in risks for the environment due to the fluorinated compounds present a 1-5%.

Table 5.15 Summary of feasibility for Tergo™® MCF

Shortlisted alternatives assessed in detail	Technically feasible	Economically feasible	Available	Net reduction in risks
Tergo™® MCF	x	x	✓	x

In order for an alternative to be deemed 'suitable', all criteria (technical feasibility, economic feasibility, availability, and reduction to overall risk) need to be met to a level reached by trichloroethylene. Therefore, **Tergo™® MCF is not a feasible alternative for ENTEK for their current use of trichloroethylene.**

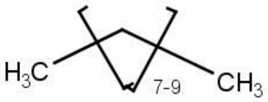
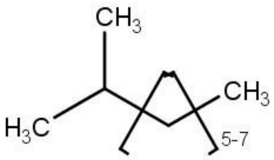
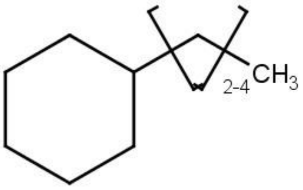
5.3.2 Alternative 2: Isopar™ G

5.3.2.1 Substance ID, properties (or Description of alternative technique)

Isopar™ G is a C10-12 isoparaffin. The substance is registered under EU REACH as hydrocarbons, C10-C12, isoalkanes, <2% aromatics EC 923-037-2 and is a UVCB (unknown or variable composition, complex reaction products or of biological materials).

Table 5.16 summarises the substance identifiers of hydrocarbons, C10-C12, isoalkanes, <2% aromatics.

Table 5.16 Substance identifiers for Isopar™ G, hydrocarbons, C10-C12, isoalkanes, <2% aromatics

EC number:	923-037-2
EC name:	Hydrocarbons, C10-C12, isoalkanes, <2% aromatics
CAS number (EC inventory):	NA
CAS name:	NA
IUPAC name:	Hydrocarbons, C10-C12, isoalkanes, <2% aromatics
CLP Annex I index number:	NA
EU REACH Annex XIV entry:	NA
Structure	The subtance is a UVCB and below is the representative structural feature:   
Molecular formula:	NA UVCB

Source: ECHA[59]

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[59] https://echa.europa.eu/substance-information/-/substanceinfo/100.130.209 accessed April 2021

5.3.2.2 Technical feasibility of Alternative 2

Isopar™ G is not a technically feasible alternative for ENTEK for their current use of trichloroethylene. If the AfA expires, ENTEK would need to stop use of trichloroethylene at their UK site by 24 April 2023, however, it is not technically feasible to substitute from trichloroethylene to Isopar™ G within this timescale. Appendix 2 sets out in detail all the activities that ENTEK would need to carry out to fully substitute away from trichloroethylene to Isopar™ G, which total up to at least 12 years. This is considered the minimum time required and is based on the presumption that at no point in the process will Isopar™ G fail any of the stages. For example, it is possible that at pilot testing stage Isopar™ G will fail to produce a battery separator that will be sufficient to meet customer requirements. This sub-section does however set out further details on progress made by ENTEK with assessing the suitability of Isopar™ G to better understand if it could be technically feasible in the future.

Isopar™ G is a mixture of alkanes with C10-C12 chain lengths. Bench scale trials are presented in Section 5.1.1.2 and whilst they indicate that it is not currently technically feasible, it has the potential to replace trichloroethylene.

One of the main performance issues of concern is the slower extraction rate (5x slower than trichloroethylene), which negatively impacts production timings. Another concern is the introduction of a flammable solvent into the separator manufacturing process.

The separator shrinkage was slightly less compared to trichloroethylene, which negatively affects separator properties. The same considerations made for Tergo™ MCF on this parameter also apply to Isopar™ G (compatibility issues with the calender rolls and meeting product specifications).

There were no issues in electrochemical compatibility of Isopar™ G and its electrical resistivity was slightly higher than trichloroethylene (2703 vs 3558 mohm-cm), which is less favourable. The separator produced with Isopar™ G has a higher puncture strength compared to trichloroethylene, which is considered beneficial.

As with Alternative 1, there are major unknowns regarding the distillation and separation of the ENTEK process oil from Isopar™ G so that each can be re-used in the separator manufacturing process. The relatively low density and vapour pressure of the product means that the extraction and recovery processes are likely to need adjusting. Substantial R&D and engineering investigations will be required to determine whether:

- Chemical stability in the conditions used to extract and recover the oil-laden solvent in the STD separator drying process.
- Distillation performance – can complete separation with no reduction in flash point for the process oil be achieved? Or is a second distillation phase required?
- Compatibility with LR drying process that uses 'cyrogenic' condensation (is the chiller cold enough?)
- As already indicated the sheet shrinkage indicates that there may be some compatibility issues with the existing tooling.

In addition:

- the efficiency of adsorption and steam desorption from activated carbon beds will need to be investigated;
- the flash point of the solvent/oil and solvent/water mixtures needs to be verified;
- the extraction and evaporation rates against the process temperature and sheet thickness need to be investigated.

It is possible that these investigations will result in process changes to accommodate the production of lead-acid battery separators with Isopar™ G, which in turn may require a review of the workplace health and safety practices.

ENTEK is continuing to invest in the research required to determine whether Isopar™ can replace trichloroethylene. Further details on the planned activities and timescales are presented in Section 6.8.

5.3.2.3 Economic feasibility and economic impacts of Alternative 2

Isopar™ G is not an economically feasible alternative for ENTEK for their current use of trichloroethylene. If ENTEK need to stop use of trichloroethylene at their UK site by 24 April 2023, however, it is not be technically feasible to substitute from trichloroethylene to Isopar™ G within this timescale. Appendix 2 sets out in detail all the activities that ENTEK would need to carry out to fully substitute away from trichloroethylene to Isopar™ G, which total up to at least 12 years, as well as the associated cost with each activity. This is considered the minimum time required and is based on the presumption that at no stage in the process will the Isopar™ G fail any of the requirements. For example, it is possible that at pilot testing stage that Isopar™ G will fail to produce a battery separator that will be sufficient to meet customer requirements.

In order to support the conclusion that Isopar™ G is not an economically feasible alternative for ENTEK, this sub-section sets out further details on the estimated costs that

ENTEK would incur to substitute from trichloroethylene to Isopar^{TM} G i.e. capital costs and testing costs associated with the substitution process, and the forgone profits lost from not being able to produce any battery separators at the UK site using trichloroethylene, as well as the estimated profits to ENTEK from future sales of battery separators at the UK site (after 12 years) using Isopar^{TM} G.

Based on work undertaken by ENTEK's Chief Technology Officer and Chief Financial Officer, the activities required, and the associated costs and timings of the substitution activities were calculated and are outlined below in Table 5.17. The table shows that ENTEK would incur costs of £79 million from temporary shutdown of UK site and operationalising Isopar^{TM} G as an alternative solvent.

Table 5.17 Costs associated with use of IsoparTM G as an alternative to trichloroethylene

Costs associated with Isopar^{TM} G alternative	**Costs (£ million)**
Project management - Logistics and planning for site closure	Blank 77
Redundancy payments (25% of workers made unemployed)	Blank 77
R&D - Laboratory Screening Tests	Blank 77
Pilot Scale	Blank 77
Model Development	Blank 77
Commercial Scale Up	Blank 77
Battery Testing and Verification	Blank 77
Phased Line Conversions and Industrialization	Blank 77
Contingency 15% - to cover all the unknowns related to the development of the new solvent	Blank 77
TOTAL COSTS	Blank 77

Table 5.17 shows that the largest costs incurred if trichloroethylene is replaced with Isopar^{TM} G are associated with phased line conversions and industrialisation. For a more detailed breakdown of the costs that ENTEK would incur as a result of operationalising Isopar^{TM} G, see Appendix 2.

For modelling purposes, it is assumed that ENTEK will continue to produce battery separators at the UK site until they are not allowed to use trichloroethylene. Therefore, the operating profits generated from selling the separators produced will continue up until 4 April 2023. Furthermore, from 2035, the UK site will be fully operational (using the alternative solvent – Isopar™ G) which means that profits from selling battery separators will again be generated. However, the profits generated will not be the same as under the exemption granted scenario for several reasons:

- The operating profits in 2035 and 2036 are less than the exemption scenario as ENTEK will need to recover its customer base (market share) that will be lost during shutdown and aim to do this by lowering prices of battery separators.
- After 2037 the profits are projected to only be 90% of the profits in AfA scenario as it is believed that 10% of the customer will be permanently lost to competitors.

As a result, the total gross profits over the 20-year assessment period are around (Blank 78) million (no discounting) when implementing this alternative, compared to (Blank 79) million (no discounting) under the exemption granted scenario. In reality, compared to modelling it is unlikely that ENTEK will recovery 90% of their customer base after a 12-year absence even with an aggressive pricing strategy. Therefore, the profits generated using this alternative is considered highly optimistic.

(Blank 82)

Figure 5.37: **Financial costs and benefits to ENTEK over time of operationalising IsoparTM G** shows the breakdown of financial costs and benefits of operationalising Isopar™ G by year. The costs are split over 12 years (2023–2034) with the largest costs occurring in 2029 and 2033-2034. The total capital costs accumulated over the 20-year assessment period is around Blank 80 million (no discounting) as detailed in Table 5.16 and forgone profit from no longer being able to use trichloroethylene of (Blank 81) million (no discounting).

[redacted]

(Blank 82)

Figure 5.37: **Financial costs and benefits to ENTEK over time of operationalising IsoparTM G**

Table 5.18 shows the total costs, total profits, and net income of this scenario over a 20-year period. With no discounting, the costs of replacing trichloroethylene with Isopar^{TM} G outweigh the generated profits over the time period, resulting in a negative net income (of (Blank 83) no discounting). When applying the opportunity cost of capital of 7% (to present the net present value) the net income for ENTEK if trichloroethylene is replaced with Isopar^{TM} G is (Blank 84) over 20 years.

Table 5.18 Total financial costs and benefits to ENTEK of operationalising IsoparTM G

Financial costs and benefits over 20 years	**£ million**
Lost profit from not being able to use TCE	**Blank 85**
Total capital costs to cease current production and switch to alternative	**Blank 85**
Profit from using alternative	**Blank 85**
Net profit over 20 years (no discounting)	**Blank 85**
Net profit over 20 years (net present value using 14% discount rate)	**Blank 85**

Table 5.18 clearly demonstrates that this alternative would produce a significant overall financial loss for ENTEK which makes this alternative not economically feasible to ENTEK.

5.3.2.4 Availability of Alternative 2

Isopar™ G is manufactured by Exxon-Mobil in the US and there are several distributors in the UK.

Its ingredient hydrocarbons, C10-C12, isoalkanes, <2% aromatics is registered in Europe with a total tonnage band of 1000-10 000 tpa (this information is not available for the UK at the time of writing this report). Therefore, availability is not considered to be an issue based on the available figures.

5.3.2.5 Reduction of overall risk due to transition to Alternative 2

The classification and labelling of hydrocarbons, C10-C12, isoalkanes, <2% aromatics are presented in Table 5.3, where it is classified as an aspiration hazard. The substance is also classified as flammable and has a flashpoint of 45°C. This hazard will require ENTEK to totally change its manufacturing process to ensure the safety of its workforce.

Table 5.19 below presents the key properties of hydrocarbons, C10-C12, isoalkanes, <2% aromatics are presented.

Table 5.19: Key properties of hydrocarbons, C10-C12, isoalkanes, <2% aromatics

Endpoint	**hydrocarbons, C10-C12, isoalkanes, <2% aromatics**[60]
Human health	
Acute toxicity	Low acute toxicity observed in oral, dermal and inhalation studies based on read-across data.
Eye/skin corrosion/irritation	Read-across data indicate some skin irritation potential for some of the constituents of the substance, but insufficient for classification.
Skin sensitization	Not skin sensitising based on read-across data.
Neurotoxicity	Based on read-across data, the acute CNS NOAEC in rats was determined in the range 1500 to 2500 mg/m^3

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[60] https://echa.europa.eu/registration-dossier/-/registered-dossier/15780 accessed June 2021

Chronic Toxicity/Repeated Dose Toxicity	Based on read-across data, the substance is not expected to exhibit toxicity (90-day NOAEL ≥5000 mg/kg, and 90 day NOAEL ≥10400 mg/m^3 both in rats)
Carcinogenicity	Based on read-across data, the substance is unlikely to be a carcinogen.
Mutagenicity/Genotoxicity	Negative results were observed in read-across for the following endpoints: *in vitro* gene mutation in bacterial cells, *in vitro* gene mutation in mammalian cells, *in vitro* cytogenicity in mammalian cells, *in vitro* sister chromatid exchange assay in mammalian cells, *in vivo* micronucleus assay, *in vivo* rodent dominant lethal test.
Reproductive Toxicity	Based on read-across data, the substance is not expected to be reprotoxic.
Developmental Toxicity	Based on read-across data, the substance is not expected to be a developmental toxicant.
Endocrine Activity	No effects on the endocrine system were observed in the read-across reprotoxicity data
Respiratory Sensitization	No data
Cardiac sensitization	No data
Environmental	
Short-term aquatic	EL/LL_{50} >1000 mg/l based on read-across
Long-term aquatic	0.23 mg/l NOELR for invertebrates based on read-across
Degradation	Based on read-across data, the substance is considered to be readily biodegradable
Bioaccumulation	The assessment is based on predictions for its constituents, which indicate it is not bioaccumulative.

The information available in the ECHA disseminated dossier shows that there are no data for the substance itself, and its properties are assessed on the basis of its constituents. The data indicates that there are no foreseen concerns for human health. The substance does exhibit toxicity to invertebrates in long-term studies, although this has not resulted in an environmental classification of the substance and due to its rapid degradation, it will not be a PBT or PMT substance.

According to the manufacturer, Isopar™ G is used in personal care products[61]. The substance is also reported to have consumer uses in the EU, mainly as a lubricant and

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[61] https://www.exxonmobilchemical.com/en/library/library-detail/2889/isopar_fluids_factsheets_en accessed April 2021

degreaser, which indicates that safe use can be achieved without training or the need for specialised equipment[62].

In summary, the information available indicates that the use of Isopar™ G would represent a reduction of hazard in terms of systemic toxicity but increased risk to workforce due to its flammability and flash point.

5.3.2.6 Conclusions on Alternative 2

Table 5.20 summarises the conclusions from the assessment of alternative 2 (Isopar™ G).

Isopar™ G is thought to be available for ENTEK to use, but it is currently not technically and economically feasible for ENTEK. Whilst Isopar™ G has a lower human health and environmental hazard potential compared to trichloroethylene, switching to Isopar™ G would involve large changes to the ENTEK separator manufacturing process because it is flammable and has a flashpoint of only 45ºC. In addition, its significantly lower extraction rate compared to trichloroethylene will have a negative capital and/or operational cost impact.

Table 5.20 Summary of feasibility for IsoparTM G

Shortlisted alternatives assessed in detail	Technically feasible	Economically feasible	Available	Net reduction in risks
Isopar™ G	✗	✗	✓	✓

In order for an alternative to be deemed ‘suitable’, all criteria (technical feasibility, economic feasibility, availability, and reduction to overall risk) need to be met to a level reached by trichloroethylene. Therefore, **Isopar™ G is not a feasible alternative for ENTEK for their current use of trichloroethylene.**

5.3.3 Alternative 3: CONFIDENTIAL Blank 86 [redacted]

[redacted]

[redacted]

[redacted]

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[62] https://echa.europa.eu/substance-information/-/substanceinfo/100.130.209 accessed April 2021

[redacted]

[redacted]

5.3.3.2 Technical feasibility of Alternative 3

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

5.3.3.3 Economic feasibility and economic impacts of Alternative 3

[redacted]

[redacted]

[redacted]

[redacted]

Table 5.21 COSTS ASSOCIATED WITH USE OF TERGO MCF AS AN ALTERNATIVE [redacted]

Costs associated with [redacted]	**Costs (£ million)**
Project management - Logistics and planning for site closure	[redacted]
Redundancy payments (25% of workers made unemployed)	[redacted]
R&D - Laboratory Screening Tests	[redacted]
Pilot Scale	[redacted]
Model Development	[redacted]
Commercial Scale Up	[redacted]
Battery Testing and Verification	[redacted]
Phased Line Conversions and Industrialization	[redacted]
Contingency 15% - [redacted]	
TOTAL COSTS	[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Figure 5.38: [redacted]

[redacted]

[redacted]

Table 5.22 [redacted]

Financial costs and benefits over 20 years	**Cost (£ million)**
Lost profit from not being able to use trichloroethylene	[redacted]
Total capital costs to cease current production and switch to alternative	[redacted]
Profit from using alternative	[redacted]
Net profit over 20 years (no discounting)	[redacted]
Net profit over 20 years (net present value using 14% discount rate)	[redacted]

Table 5.22 [redacted]

5.3.3.4 Availability of Alternative 3

[redacted]

Table 5.23 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

5.3.3.5 Reduction of overall risk due to transition to Alternative 3

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

5.3.3.6 Conclusions on Alternative 3

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Table 5.24 [redacted]

[redacted]

[redacted] (end of Blank 86)

5.3.4 Alternative 4: Cease UK production

5.3.4.1 Technical feasibility of Alternative 4

This alternative (Cease production in the UK) is technically feasible. In order to minimise lost revenue, in this scenario ENTEK would continue to make battery separators using trichloroethylene until the existing AfA expires on 21/04/2023. Complete closure of the UK site is estimated to take 12 months once the existing AfA expires.

In order for ENTEK to cease production of battery separators in the UK, the following steps would be required: planning for site closure, creation and execution of redundancy plan and cancellation of supply contracts. Following this, ENTEK would start the process of disassembling/selling trichloroethylene contaminated equipment (that is viable), including disposal of equipment that cannot be sold/moved. Finally, they would need to finance remediation of land and then arrange an early termination of lease/sale of site (post remediation). All of these steps (and their associated costs) are outlined in Table 5.25.

5.3.4.2 Economic feasibility and economic impacts of Alternative 4

Ceasing production in the UK is not an economically feasible alternative for ENTEK for their current use of trichloroethylene. It is thought that if the AfA is rejected, ENTEK would need to stop use of trichloroethylene in their UK site by 21 April 2023. In order to support the conclusion that ceasing production is not an economically feasible alternative for ENTEK, this sub-section sets out further details on the estimated costs that ENTEK would incur to cease production and the forgone profits lost from not being able to produce any battery separators at the UK site using trichloroethylene.

Based on work undertaken by ENTEK's Chief Technology Officer and Chief Financial Officer the activities required and their associated costs and timings were calculated and are outlined below in Table 5.25. The table shows that ENTEK would incur costs of (Blank 87) from closure of the UK site.

Table 5.25 Costs associated with closure of UK site

Costs associated with closure of UK site	**Costs (£million)**
Project management - Logistics and planning for site closure	**Blank 88**
Redundancy payments (workers made unemployed)	**Blank 88**
Cancellation of any supply contracts	**Blank 88**
Early termination of lease / revenue from sale of site	**Blank 88**

Disassemble existing production equipment in Newcastle site	Blank 88
Remediation of land (for re-use)	Blank 88
Relocate Equipment (assuming it cannot stay on site)	Blank 88
Disposal of Equipment	Blank 88
Contingency 10% - to cover all the unknowns related to the closure	Blank 88
TOTAL COSTS (INCURRED OVER A 12 YEAR PERIOD)	**Blank 88**

Table 5.25 shows that largest cost is associated with disposal of equipment. This is likely due to the levels of trichloroethylene on the site's equipment which will be treated as contamination, thus stopping the resale of equipment without high levels of cleaning/treatment. This is highlighted by the second highest cost, which is disassembling the production equipment. The only financial gain (benefit) is from sale of the site / early termination of the lease; this would occur after remediation of the land.

For modelling purposes, it is assumed that ENTEK will continue to produce battery separators at the UK site until the original AfA expires (21/04/2023). Therefore, the benefits from this alternative scenario are the operating profits generated from selling the separators produced, which continue up to 21 April 2023 and cease thereafter.

Figure 5.39 shows the breakdown of costs and benefits to ENTEK by year. The total capital costs accumulated over the 20-year period is around (Blank 89) million (no discounting). As detailed in Table 5.26 the forgone profit from no longer being able to use trichloroethylene for the 20-year period is (Blank 90) million (no discounting).

[redacted]

Figure 5.39: Costs and benefits of closing UK site by year (NO DISCOUNTING APPLIED)

Table 5.26 details the total costs, benefits and new benefits of closure of the UK site over a 20-year period. The total costs accumulated over the 20-year assessment period is -(Blank 91) million (no discounting). When applying the opportunity cost of capital of 14% (to present the net present value) the net cost to ENTEK is (Blank 92) million over 20 years.

Table 5.26 Total financial costs and benefits to ENTEK of ceasing production of THE UK

Financial costs and benefits over 20 years	**£ million**
Lost profit from not being able to use TCE (no discounting)	**Blank 93**
Total capital costs to cease current production (no discounting)	**Blank 93**
Net profit over 20 years (no discounting)	**Blank 93**
Net profit over 20 years (present value using 14% discount rate)	**Blank 93**

Whilst this is a technically feasible option for ENTEK, Table 5.26 clearly demonstrates that this alternative would only produce significant financial losses for ENTEK with no future income stream within the UK which makes this alternative **not economically feasible to ENTEK**.

5.3.4.3 Availability of Alternative 4

The option of ceasing production at the UK site is available to ENTEK.

5.3.4.4 Reduction of overall risk due to transition to Alternative 4

The risks to workers, general population and the environment (see the Exposure CSR for the assessment) would no longer exist should ENTEK cease production at the Newcastle plant in the UK.

The operational and environmental risks associated with the shut-down, e.g. removal of trichloroethylene, would be temporary and are not considered in this assessment.

5.3.4.5 Conclusions on Alternative 4

Table 5.27 summarises the conclusions from the assessment of alternative 4 (ceasing production of the UK site). Colour-coding has been used to indicate whether the level of feasibility per criteria assessed in Sections 5.3.4.1, 5.3.4.2, 5.3.4.3 and 5.3.4.4. Green relates to the alternative being feasible, yellow relates to a lack of data or understanding and red relates to an alternative that is not feasible.

Ceasing production of the UK site is technically feasible and a readily available option that would have a positive effect in reducing exposure of trichloroethylene in the UK. However, as detailed in Section 5.3.4.2, it would incur significant economic damage to ENTEK (with a net benefit of (Blank 94), with no discounting and discounting based on the opportunity cost of capital of 14%, respectively).

Table 5.27 Summary of feasibility for closure of UK site

Shortlisted alternatives assessed in detail	Technically feasible	Economically feasible	Available	Net reduction in risks
Cease UK production	✓	×	✓	✓

In order for an alternative to be deemed ‘suitable’, all criteria (technical feasibility, economic feasibility, availability, and reduction to overall risk) need to be met to a level reached by trichloroethylene. Therefore, **ceasing production in the UK is not a suitable alternative**.

5.3.5 Alternative 5: Cease UK production and relocation outside UK

5.3.5.1 Technical feasibility of Alternative 5

Ceasing production and relocating outside of the UK is technically feasible alternative for ENTEK for their current use of trichloroethylene. In order to minimise lost revenue, in this scenario ENTEK would continue to make battery separators using trichloroethylene until the AfA expiry date (21/04/23). ENTEK estimate that 6 months after the current AfA expiry date that the UK site will be closed but that it will take 60 months for the new site (outside the UK and EU) to become fully operational. In the previous AfA that ENTEK submitted to ECHA (under REACH), 'Relocate production outside of the EU' was the most likely non-use scenario.

In order for ENTEK to cease production of battery separators in the UK and relocate outside of the UK (and EU), the following two steps would be required: the first step would be the closure of the UK site. This would include planning for site closure, creation, and execution of redundancy plan, disassembling trichloroethylene contaminated equipment and remediation of the site's land (making it safe for re-use). The second step would be to create a new site outside of the UK (and EU). This would include planning, purchase, and construction of the new site location, acquiring regulatory approval for the sites processes (and necessary substances), relocation of equipment from the UK site, recruitment and training of new employees, formation of a new supply chain (including distribution and storage facilities) and the installation of product testing and quality control units. All of these steps (and their associated costs) are outlined in Table 5.28.

For cost purposes, it is assumed that ENTEK would expand the capacity at their new Asian (Indonesia) site, rather than their US site which would be more costly to do so. It is also unlikely that ENTEK would relocate to a new site in the EU, as authorisation for use of trichloroethylene would need to be submitted to ECHA, which would slow down how soon a new site would be operational, as ENTEK would not seek to build a new site in the EU, unless EU authorisation was already granted.

5.3.5.2 Economic feasibility and economic impacts of Alternative 5

Ceasing production in the UK and relocating outside of the UK (and EU) is not an economically feasible alternative for ENTEK for their current use of trichloroethylene. It is thought that if the AfA is rejected, ENTEK would need to stop use of trichloroethylene at their UK site by 21 April 2023. In order to support the conclusion that ceasing production is not an economically feasible alternative for ENTEK, this sub-section sets out further details on the estimated costs that ENTEK would incur to cease production and relocate outside of the UK (and EU) and the forgone profits lost from not being able to produce any battery separators at the UK site using trichloroethylene.

Based on work undertaken by ENTEK's Chief Technology Officer and Chief Financial Officer the activities required and their associated costs and timings were calculated and are outlined below in Table 5.28. The table shows that ENTEK would incur costs of (Blank 95)million from closure of the UK site and costs of (Blank 96)million from opening a new site outside of the UK (and EU). Therefore, the total costs associated with this alternative are (Blank 97)million.

Table 5.28 Costs associated with closure of UK site and creation of new site outside of the UK (And EU).

Costs associated with closure of UK site	**Costs (£million)**
Project management - Logistics and planning for site closure	**Blank 98**
Redundancy payments (workers made unemployed)	**Blank 98**
Disassemble existing production equipment in Newcastle site	**Blank 98**
Remediation of land (for re-use)	**Blank 98**
Costs associated with new site outside of UK (and EU)	
Project management - Logistics and planning for possible new site	**Blank 98**
Regulatory approval	**Blank 98**
Purchase of land for new site	**Blank 98**
Relocate equipment	**Blank 98**
Construction of new site	**Blank 98**
Recruitment and training costs	**Blank 98**
Product testing and quality control	**Blank 98**
Site management procedures	**Blank 98**
Supply chain management – distribution and storage	**Blank 98**
Permits for new site and building? Or is this included in purchase of land for new site above?	**Blank 98**
Water well	**Blank 98**
PPAP and Quality Validations with Customers and OE's	**Blank 98**
Contingency 15% - to cover all the unknowns related to relocation	**Blank 98**

TOTAL (closure and relocation costs)	**Blank 98**

Table 5.28 shows that the largest costs associated with closure of the UK site are from disassembling the equipment. This is likely due to the precautions that need to be taken when dealing with the trichloroethylene contamination and the cleaning/treatment required to enable the equipment to be transported safely. However, the costs associated with creating a new site outside of the UK (and EU) are far larger. Construction of a new site is £84 million alone; this cost can be attributed to the following requirements:

- New solvent storage and delivery system
- New building (with office)
- All new piping (including bulk delivery system piping)
- Mechanical & electrical installations
- Rebuild of some equipment transferred from old site

For modelling purposes, it is assumed that ENTEK will continue to produce battery separators at the UK site until the AfA expiry date on 21 April 2023. Therefore, the operating profits generated from selling the separators produced will continue up until April 2023. Moreover, from 2028 a new site (outside the UK and EU) will become operational, which will sell battery separators and generate profit for ENTEK. However, the profits generated will not be the same as under the AfA granted scenario for several reasons:

- The operating profits in 2028 and 2029 are less than the exemption scenario as ENTEK will need to recover its customer base (market share) that will be lost during shutdown and aim to do this by lowering prices of battery separators.
- After 2030 the profits are projected to only be 95% of the profits in AfA scenario as it is believed that 5% of the customer will be permanently lost to competitors.

As a result, the total gross profits over the 20-year assessment period are around(Blank 99) million (no discounting) when implementing this scenario, compared to (Blank 100)(no discounting) under the AfA granted scenario. In reality, compared to modelling it is unlikely that ENTEK will recovery 95% of their customer base after a 6-year absence even with an aggressive pricing strategy. Therefore, the profits generated using this alternative is considered highly optimistic.

Figure 5.40 shows the breakdown of financial costs and benefits of relocating production outside of the UK by year. The total capital costs accumulated over the 20-year assessment period is around (Blank 101) million (no discounting) as detailed in Table 5.27 and forgone profit from no longer being able to use trichloroethylene of Blank 102 million (no discounting).

[redacted]

Figure 5.40: Costs and benefits over time of setting up a new site outside of the UK and EU

Table 5.29 shows the total costs, total profits, and net income of this scenario over a 20-year period. With no discounting, the costs of relocating production outside of the UK and EU outweigh the generated profits over the time period, resulting in a negative net income of Blank 103 million – no discounting). When applying the opportunity cost of capital of 14% (to present the net present value) the net income for ENTEK from relocating production outside of the UK and EU is Blank 104 million over 20 years.

Table 5.29 total financial costs and benefits to ENTEK from relocating outside of the UK and EU

Financial costs and benefits over 20 years	**Cost** **(£ million)**
Lost profit from not being able to use TCE (no discounting)	**Blank 105**
Total capital costs to cease current production (no discounting)	**Blank 105**
Profit from new production site outside of the UK	**Blank 105**

Net profit over 20 years (no discounting)	Blank 105
Net profit over 20 years (present value using 14% discount rate)	Blank 105

Whilst this is a technically feasible option for ENTEK, Table 5.29 total financial costs and benefits to ENTEK from relocating outside of the UK and EU clearly demonstrates that this alternative (closure of UK and relocation outside the UK and EU) would produce a significant overall financial loss for ENTEK which makes this scenario not economically feasible to ENTEK.

5.3.5.3 Availability of Alternative 5

The option of ceasing production at the UK site and relocating to a new site outside of the UK (and EU) is available to ENTEK.

5.3.5.4 Reduction of overall risk due to transition to Alternative 5

The risks to workers, general population and the environment (see the Exposure CSR for the assessment) would no longer exist should ENTEK cease production at the Newcastle plant and move production outside of the UK and Europe.

The operational and environmental risks associated with the shut-down, e.g. removal of trichloroethylene, would be temporary and are not considered in this assessment.

5.3.5.5 Conclusions on Alternative 5

Table 5.30 summarises the conclusions from the assessment of alternative 5 (ceasing production of the UK site and relocating outside of the UK (and EU)). Colour-coding has been used to indicate whether the level of feasibility per criteria assessed in Sections 5.3.5.1, 5.3.5.2, 5.3.5.3 and 5.3.5.4. Green relates to the alternative being feasible, yellow relates to a lack of data or understanding and red relates to an alternative that is not feasible.

Relocating production outside of the UK (and EU) is technically feasible and a readily available option that would have a positive effect in reducing exposure of trichloroethylene in the UK. However, as detailed in Section 5.3.5.2, it would incur significant economic damage to ENTEK (with a net benefit of – Blank 106 with no discounting and discounting based on the opportunity cost of capital of 14%, respectively).

Table 5.30 Summary of feasibility for relocation of site outside of the UK (and EU).

Shortlisted alternatives assessed in detail	Technically feasible	Economically feasible	Available	Net reduction in risks
Cease UK production and relocate outside of UK and EU	✓	×	✓	✓

In order for an alternative to be deemed 'suitable', all criteria (technical feasibility, economic feasibility, availability, and reduction to overall risk) need to be met to a level reached by trichloroethylene. Therefore, **ceasing production and relocating outside of the UK (and EU) is not a suitable alternative**.

5.4 The most likely non-use scenario

From ENTEK's perspective, the analysis of alternatives clearly demonstrates that there are no 'suitable' alternatives (i.e. one that meets all the criteria). Table 5.31 summarises the AoA results:

Table 5.31 Summary of AoA

Shortlisted alternatives assessed in detail	Technical feasibility	Economic feasibility	Availability	Risk reduction	Overall suitability
1. Tergo™ MCF	×	×	✓	?	×
2. Isopar™ G	×	×	✓	✓	×
	Blank 107				
4. Cease UK production	✓	×	✓	✓	×
5. Relocate outside of UK and EU	✓	×	✓	✓	×

If this authorisation application is refused, ENTEK will be left with only two viable options (Alternative 4: Cease UK production, or Alternative 5: Relocate outside of UK and EU) as alternatives 1-3 will take at least between 9 and 12 years to be operational with no guarantee of success. There are considerable commercial risks in a programme to replace trichloroethylene for ENTEK. For example, the alternatives may fail pilot testing, resulting in ENTEK having to restart the R&D process again with different alternatives.

If this authorisation application is refused, ENTEK will have to close the UK site and decide whether to relocate production to a new site outside of the UK (and EU). However, this is not a clear-cut choice. Not accounting for the opportunity cost of capital (i.e. no discounting of costs and profits) would suggest that ENTEK are better off relocating production outside of the UK as there is a clear market (demand) for their separators. On the other hand, this is a large investment, and accounting for the opportunity cost of capital shows that the payback over a 20-year period is not sufficient compared to just shutting down the plant. Therefore, ENTEK would have to weigh the longer-term benefits of relocation beyond a 20 year period against the short-term costs.

ENTEK have made a strategic decision that ceasing UK production and relocation outside of the UK (alternative 5) is a most likely 'non-use' scenario as there is sufficient demand for their products for the foreseeable future. The assessment in Chapter 6 therefore compares the applied for use scenario (AfA scenario) vs. ceasing UK production and relocation outside of the UK (Alternative 5).

6 IMPACTS OF GRANTING AUTHORISATION

6.1 Human Health and/or Environmental Impacts

This section summarises the human health impacts that were derived in Section 4.5, with a summary of the results presented in Table 6.2 below.

The derived exposure for each population group exposed to trichloroethylene (ENTEK workers, workers within the same industrial estate and the general population) are low as shown second column of Table 6.2 ENTEK production workers are exposed to the greatest levels of trichloroethylene due to their proximity to the substance, at 14.39 mg/m^3, followed by those of whom work and/or live within proximity of the site. The 28 ENTEK workers who are solely office based have the lowest levels of exposure, due to the nature of their job role, which does not require them to come into contact with trichloroethylene.

The excess cancer rate, which was calculated using worker exposure data and the dose-response relationships developed by ECHA (see Box 4.1), is low for all population groups. The analysis revealed that that the total number of cancer cases covering the entire exposed population over a 12-year review period is below one.

The monetised health costs associated with granting an authorisation is presented in column five of Table 6.2 are 'best estimates', whilst estimates from sensitivity testing different parameters are presented in Section 6.6. The costs were calculated using unit values – taken from the economic literature - on the value of avoiding a fatal/non-fatal cancer shown in Table 6.1.

Table 6.1: Valuation factors for monetising avoided cancer cases, in 2021 prices

Cancer outcome	Low estimate	High estimate	Source
Fatal	£3.65 million	£5.17 million	HSE (2016)
Non-fatal	£346,600	£374,900	ECHA (2016)

In total it is estimated that granting an authorisation for trichloroethylene at the ENTEK plant would induce **~0.01 cancer cases** (pro rata 12/40 years) resulting in health costs of ~**£18k – 23k** over a 12-year period.

Table 6.2: Summary of human health impacts

Population exposed	Exposure level (mg/m^3)	Number of exposed people	Excess cancer risk (Inhalation)	Additional cancer diagnosis (40 years)	Monetised cost (Best Estimate) £ (2021)
ENTEK Production Workers	14.39	106	1.15E-04	0.02978543	£16,734 – 21,646
ENTEK Non-production workers	1.5	28	1.26E-07	5.04E-04	
Workers around the ENTEK site	12.24	430	1.47E-07	6.32E-05	£28 - £38
General population around the ENTEK site	12.24	2,178	Inhalation - 7.83E-07 Oral –	0.003503591	£1,106 – 1,431

Total monetised cost	-	-	-	0.033856221 (40 years) 0.010156866 (12 years)	£17,868 – 23,115

Notes: Input factors and assumptions underlying the results are presented in Section 4.5.

There were no significant environmental impacts identified from the release of TCE at the ENTEK plant (as discussed in Section 4.6). The risks to man via the environment from releases to air are assessed in Chapter 10.2 of the Exposure CSR. Only a small volume of trichloroethylene is released to wastewater (0.944 kg/year) which is treated at the local sewage treatment works before its release into the aquatic environment. Any releases to wastewater that occur are compliant with ENTEK's environmental permit (see Section 4.4.1). It was noted in Section 4.6 that under the non-use scenario, imports of battery separators would increase the amount of greenhouse gases due to increased transportation distances (either from the US or China where other battery separator manufacturing sites are located). As a result, any environmental benefits from decrease in trichloroethylene released to wastewater will be more than offset by increasing environmental costs from importation of separators from other countries.

6.2 Economic impacts

As detailed in Section 5.4, the most likely non-use scenario for ENTEK is to cease their UK production from April 2023 (i.e., the last point at which TCE will be allowed in the UK) and relocating its production outside the UK (and likely outside the EU).

In the previous AfA in 2014, closure of the Newcastle plant and relocating outside the UK (and EU) was also the most likely response. Closing the Newcastle plant will impact on the profitability of some of ENTEK's raw materials suppliers who are heavily reliant on demand from ENTEK. Based on the previous SEA in 2014 (see Section 4.2.5 of the 2014 AfA), ENTEK uses several local suppliers in the North-East of England for colourants, antioxidants and stearates and bespoke cardboard boxes. The local supplier for bespoke cardboard boxes used for distributing battery separators to ENTEK's customers, is dependent on orders from ENTEK (who are their main customer) and could shut down if ENTEK stop making battery separators in Newcastle (England). In the 2014 AfA, since the monetised impacts of lost profit to local suppliers were estimated at Blank 108 (PV) or appropriately Blank 109 (PV), for this AfA it was not deemed necessary to quantify and monetise these impacts, since they are small compared to the impacts on ENTEK assessed below and the social costs in Section 6.3.

The analysis of the costs directly incurred by ENTEK (and indirectly affecting UK society as a whole) in the non-use scenario is conducted under the following assumptions:

- ENTEK will incur all capital costs associated with the cessation of production of lead-acid battery separator lines at the UK site. Furthermore, ENTEK will ship the re-usable equipment to the new sites outside the UK, and the land of the UK site will be remediated to allow ENTEK to sell the land (and consequently earn a profit).
- Capital costs incurred outside the UK associated with establishing a new manufacturing site are excluded from the analysis since they are outside the boundary of the analysis (i.e., outside the UK). In line with the same rationale, any profits gained from the new sites are also excluded from the analysis.
- The analysis includes the lost profit made within the UK over 20 years which ENTEK would have lost if it ceased producing battery separators at its Newcastle site. Lost profit is used as it factors both the lost revenue from sales of battery separators as well as the avoided costs of production (and raw materials purchased).
- ENTEK's staff redundancy costs are excluded from the analysis as they represent a transfer payment from ENTEK to its employees. Instead, the social costs of unemployment are considered in Section 6.3.

Based on work undertaken by ENTEK's Chief Technology Officer and Chief Financial Officer the activities required and their associated costs were calculated and are outlined below in Table 6.3. The table shows that ENTEK would incur costs of around Blank 110 from closure of the UK site.

Table 6.3: Costs associated with closure of UK site only

Costs associated with closure of UK site	**Costs (£ million)**
Project management - Logistics and planning for site closure	Blank 111
Disassemble existing production equipment in Newcastle site	Blank 111
Remediation of land (for re-use)	Blank 111
TOTAL closure costs	Blank 111

For modelling purposes, it is assumed that ENTEK will continue to produce battery separators at the UK site until the authorisation request is formally rejected and ENTEK need to stop using TCE (by April 2023). Therefore, the operating profits generated within the UK from selling the separators produced will continue up until April 2023 and then cease thereafter.

Figure 6.1 shows the breakdown of financial costs of ceasing production at the UK site by year. The total capital costs accumulated over the 20-year assessment period is around Blank 112 million (no discounting) as detailed in Table 6.3 over a 12-month period starting in Jan-2023 and forgone profit from no longer being able to use TCE of Blank 113 million (no discounting). As there are no other UK based battery separator manufacturers it is assumed that any displacement of sales/profits will be to sites located outside the UK. This will equate to a net loss to UK society and any future revenue/profits to whichever country the new ENTEK site is located at.

[redacted]

Figure 6.1: Economic costs to ENTEK of ceasing their UK site

Table 6.4 shows the total costs to ENTEK over a 20-year period. With no discounting, the costs of ceasing production at the US site, is Blank 114 (no discounting). When applying the social discount rate of 3.5% (to present the net present value) the net cost to ENTEK is Blank 115 million over 20 years.

Table 6.4: Economic costs to ENTEK within the UK from a refused authorisation

	Costs (£ million)
Lost profit from not being able to use TCE	Blank 116
Total capital costs to cease current production	Blank 116
Net profit over 20 years (no discounting)	Blank 116
Net profit over 20 years (present value using 3.5% discount rate)	Blank 116

6.3 Social impacts

This section explores the social impacts that could be witnessed from the loss of production of ENTEK's battery separators within the UK. The main social impact being assessed within this section is that of the cost of unemployment associated with this loss of manufacturing due to an authorisation for TCE not being granted. At present ENTEK's site in Newcastle employs around 139 people from numerous technical backgrounds, all of whom would be made redundant by April of 2023 if ENTEK was unable to continue to use TCE at the site.

Closure of ENTEK's site will almost certainly have significant knock-on effects to other local and national suppliers due to a loss in ENTEK demand for their product and/or services. This demand is unlikely to be replaced by other battery separator organizations as most are expected to be based outside the UK. This presents difficulties for ENTEK suppliers as it will be increasingly difficult to compete on price with foreign competitors given the additional shipping costs that would be required to transport their products to the new production location, likely Asia, or perhaps the EU.

ENTEK suppliers

Based on previous SEA - ENTEK uses several local suppliers in the North-East of England for colourants, antioxidants and stearates and bespoke cardboard boxes. The local supplier for bespoke cardboard boxes used for distributing battery separators to ENTEK's customers, is dependent on orders from ENTEK (who are their main customer) and could shut down if ENTEK stop making battery separators in Newcastle (England). It is reasonable to assume that although some suppliers will likely have multiple customers i.e. not only ENTEK, many very specialist suppliers, e.g., those providing specialist raw materials to ENTEK, will likely derive a large percentage of their business from ENTEK. Therefore, in the absence of any further information, it is assumed that somewhere between 25 and 100 jobs could be lost in the UK due to the loss of ENTEK business demand.

ENTEK customers

Based on recent announcements regarding a new electric car battery plant in the North East[63] (and possibly other companies to follow) and car production plants locating/staying in the UK, there will be in the future electric car battery manufacturers in the UK. Given that ENTEK is the only UK based PE battery separator and also located in the North East, it is reasonable to assume that ENTEK could be one of their future suppliers. The new

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[63] See: https://www.bbc.co.uk/news/business-57247758 (Assessed 07/07/2021)

electric car battery plant in the North-East is predicted *"to produce 200,000 batteries a year and support thousands of jobs"*. It is difficult to estimate if the loss of ENTEK's supply will affect how much batteries these future UK-based companies can produce. For this SEA, it is estimated that there could be between 0-50 job losses within ENTEK's customer base (See Table 6.5). The low estimate assumes no impact whilst the high estimate assumes some losses but overall minimal as there is time for these suppliers to find a suitable alternative to ENTEK (located outside the UK) whilst these sites are not operational yet.

Total number of jobs lost

A summary of the total number of jobs estimated to be lost due to a refused TCE authorisation can be noted in Table 6.5 below. Most job losses are likely to come from ENTEK itself (139) which equates to around 50 – 84% of the total job losses estimated, i.e. High estimate – 289 total jobs lost, Low estimate – 164 total jobs lost. Low and high estimates are displayed given the uncertainty in calculating the number of jobs that would be lost. It is important to caveat that the ability of battery manufacturers to find sufficient quality alternative separators to ENTEK's, is a key factor driving these estimates.

Table 6.5: Estimated number of jobs lost within the UK

	Estimated number of jobs lost within the UK	
	Low estimate	**High estimate**
ENTEK	139	139
ENTEK suppliers	25	100
ENTEKs customers (battery manufacturers)	0	50
TOTAL	164	289
TOTAL (rounded to nearest 10)	**160**	**290**

Social Cost of unemployment

The guidelines for assessing the social cost of unemployment adopted by the EU chemicals policy expert committee, the *Committee for Socio-Economic Analysis (SEAC),* is used in this report (ECHA, 2016a). This guidance is also deemed applicable and transferable to the case of if a UK REACH authorisation application is refused. The approach seeks to value unemployment impacts based on the following:

- The value of productivity loss during the period of unemployment;
- The cost of job search, 'hiring and firing';

- The impact of being made unemployed on future employment and earnings (a typical opportunity cost also referred to as 'scarring' effect
- The value of leisure time during the period of unemployment

The ECHA (2016a) guidance suggests that a rule-of-thumb approach to value these impacts is to multiply the annual gross wages of employees lost by 2.7. Based on ENTEK's annual financial report on total labour costs, and based on the last 5 years accounts and approximate 135+ staff employed, it is estimated that the average wage of an ENTEK employee at the UK site is around Blank 117 (includes pension contributions but excludes social security payments). It is assumed that this wage level is representative for the wider supply chain. Table 6.6 sets out the estimated social cost of employment within the UK of between £17 million and £30 million, using the 2.7 factor stipulated in the ECHA (2016a) guidance. However, the estimate maybe be an underestimate as it does not include any potential job losses further down the supply chain in end-use sectors that use lead-acid batteries if there is a temporary shortage in supply due to ENTEK no longer producing battery separators in the UK.

Table 6.6 Estimated social cost of unemployment

	Estimated social cost of unemployment (£ millions)	
	Low estimate	**High estimate**
ENTEK	14	14
ENTEK suppliers	3	10
ENTEKs customers (battery manufacturers)	0	5
TOTAL (rounded to nearest 100)	**17**	**30**

6.4 Wider economic impacts

As part of the screening of impacts, no significant macroeconomic impacts were identified. A refused authorisation could impact UK GDP, through production losses and trade balance impacts, as a reduction in UK exports (sales of battery separators to other countries) and an increase in imports (of battery separators) into the UK from the likes of the EU, US and China. However, it is unlikely to lead to any significant macroeconomic impacts due to the size of the UK trade balance and the scale of output lost relative to UK GDP (~£2trillion[64] in 2021) (ONS, 2021).

6.5 Combined assessment of impacts

6.5.1 Comparison of impacts

Table 6.7 summarises the key costs and benefits of a refused authorisation. When comparing the benefits of authorisation Blank 118 to any potential risks Blank 119, it is evident that UK society would be better off were authorisation granted. The sensitivity analysis in Section 6.6 reinforces the conclusions that benefits of continued use weigh any risks.

Table 6.7: High level comparison of key benefits and costs of continued use (PV 2021-40)

Type of impact	Benefits of continued use	Costs of continued use	Net impact
Economic	Continued manufacture of battery separators at Newcastle site resulting in profits to ENTEK of Blank 120million PV Avoided cost to cease UK site Blank 120	No significant impact	A net economic benefit to the UK of at least Blank 121
	Continued profits of local UK based raw material suppliers to ENTEK supplying colorants, antioxidants, stearate, and bespoke cardboard boxes		
Human health	Avoided cost of respiratory impacts from increased transportation emissions of battery separators into the UK	Costs from worker exposure to trichloroethylene, up to £22,000 (best estimate)	A maximum net cost to the UK of up to circa 23k (*undiscounted*)
		Costs from industrial worker exposure to trichloroethylene near	

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[64] https://www.ons.gov.uk/economy/grossdomesticproductgdp#datasets

Type of impact	Benefits of continued use	Costs of continued use	Net impact
	(*not deemed necessary to assess and is therefore is not monetised*)	the site up to £38 (best estimate) Costs to general population from worker exposure to trichloroethylene around the site of up to £1,431 (best estimate)	
Environment	No significant impact	No significant impact	-
Social	An avoided social cost of unemployment calculated at between £17 and £30 million	No significant impact	An avoided net economic cost of up to £30 million.
Macro-economic	No significant impact	No significant impact	-

6.5.2 Distributional impacts

Most of the above impacts will mostly occur within the Northeast of England (i.e. costs and benefits affected similar population). However, this is not necessarily a 'distributional impacts' but it does highlight that the benefits of authorisation would significantly outweigh the costs.

The main impacts of a refused authorisation will fall on the applicant (ENTEK). The applicant will incur economic costs associated with the closure of the UK site (~£8 million PV) in addition to lost profit of around £135 million (PV) over 20 years. The social costs of unemployment from making staff at the ENTEK Newcastle site redundant is estimated at £14 million. These employees will benefit from reduced workplace exposure to trichloroethylene totalling up to £22,000 over a 12 year period. The other beneficiaries of a refused authorisation are workers and households located the near to the Newcastle site from reduced exposure to trichloroethylene in the air, totalling up to £1,500 (best estimate).

Local suppliers of ENTEK within the Northeast of England, who are heavily dependent on ENTEK – e.g. suppliers of colorants, antioxidants, stearate, and bespoke cardboard boxes, are also likely to experience profit loss and reduced staff. The corresponding social costs of unemployment is estimated at £3-10 million, whilst it has not been possible to estimate the profit loss for the suppliers.

The lost profit will not be displaced/replaced within the UK, as ENTEK is the only UK based battery separator manufacturer. Any increased profits will be incurred by battery separator manufacturers located outside the UK (which are outside the scope of this AfA).

6.6 Uncertainty analysis

The main costs and benefits associated with the continued use of trichloroethylene have been quantified and monetised. Non-quantified impacts are therefore not likely to change the outcome of this SEA. Equally, given the large difference between monetised benefits of continued use vs. monetised costs, any uncertainties in the monetary assessment would not change the outcome of the SEA.

Table 4.22 presented the results of a sensitivity analysis on the health costs of continued use. Even if the health impacts were extended from the 12 years ENTEK is seeking authorisation for to 40 years, the health impacts on these workers would only increase from ~£22k to up to ~£72k. If one were to further assume, that non-production workers were exposed to the same level as production workers (which is unrealistic) and also assume that all possible cancers are all fatal, then the total costs of continued use over 40 years increase to ~£200k. This shows that even when combining multiple worse-case assumptions, benefits of continued use (~£160 million PV) are still 800 times higher than the health costs.

In terms of the economic assessment, the main cost component is lost profit to ENTEK from no longer producing battery separators in the UK. Despite expected growth in demand for battery separators over time, the predicted volume of battery separators produced at the Newcastle site (under the AfA scenario in the assessment) remains at 86 million m^2 as that is the maximum output of the Newcastle site. ENTEK do not intend to expand their production in the UK post 2021. This is consistent with existing production levels over the last 5 years which shows the plant is already producing at maximum capacity. Therefore, there is no significant optimism bias in terms of forecasting increased sales over time. Both costs (e.g. production, supplies, wages) and benefits (turnover) are modelled to increase in line with the UK 5 year inflation rate (1.82%) with profitability set as a constant percentage based on the average profit margin achieved over the last 5 years. Even if inflationary changes were removed (to both costs and benefits) total lost profit would be £108 million (PV over the period 2021-40) rather than £127 million (PV over the period 2021-40).

Comparing the worst-case health costs of continued use (~£200k) with the lowest benefits estimate (~£117 million = £108+9) results in benefits of continued use being more than 585 times higher than the health costs. Even if only one year's worth of profits (~£9 million – See Table 4.8) was used only, the benefits of continued use would outweigh the costs by 45 times. Therefore, it is concluded that uncertainties do not affect the outcome of this SEA.

6.7 Information for the length of the review period

It is recommended that an authorisation is granted for ENTEK's use with a 12 year review period. This is based on the following conclusions:

- The emissions of Trichloroethylene have been minimised (as shown in the Exposure Scenario);
- There continues to be no suitable alternatives (nor temporary alternatives) (as shown in the AoA); and
- The benefits of authorisation outweigh the risks by a factor of 8000 (as shown in this SEA).

ENTEK considers a review period of 12 years to be appropriate, based on the ECHA (2013)[65] guidance on setting a review period. The arguments for a 12-year review period are as follows:

- In the previous application, methylene chloride was seen as a possible alternative solvent that would be explored further. However, as set out in Section 5.1.1, despite efforts made by ENTEK, customers were unwilling to even test a separator made with methylene chloride let alone use one. Methylene chloride is thus not an economically viable alternative, whilst its technical feasibility remains unknown.

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[65] (ECHA 2013) – "Setting the review period when RAC and SEAC give opinions on an application for authorisation". Available at: https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf

- The conclusion of the AoA is that there are still no alternatives that are suitable and available to the applicant.

  Blank 122

  - [redacted]

  - ENTEK also continues to explore solvent alternatives. Although it was found that for one or two of the substances (see Section 5) there was some potential for the possible replacement of trichloroethylene, a considerable amount of further research would be required to determine the technical feasibility of these substances at a commercial scale. In addition, the customer acceptability of the products manufactured using an alternative would also have to be ensured. Any alternative solvent would take at least 12 years to implement.

- The non-use scenario (as shown in this SEA) would involve ENTEK shutting down its UK operations and relocating outside the UK (and EU). It would cost ENTEK Blank 123 million (e.g. remediation) to close the production site in the UK and any new site would still use trichloroethylene.

- Battery manufacturers (for lead acid batteries) would still be using battery separators made with TCE from ENTEK for the next 20 years but at a higher cost due to reduced global supply and increased transportation costs.

- The human health risks are small and would continue to be so throughout the review period. Worst-case estimates of human health impacts are ~£200k (in total), but in reality, the impacts would be much lower. If more realistic assumptions on actual exposure are used, the resulting best estimate of health impacts are some ~£23k.

Whilst the UK authority could decide on a shorter authorisation period (i.e. a normal 7 years), ENTEK does not believe this would be beneficial, for the following reasons:

- Risks to workers and the general population are already very low and will continue to be very low. A reduction in risks from 12 years continued use to 7 years continued use would have minimal benefits in monetary terms (best estimate of £10k in total).

- Alternatives that ENTEK are investigating further would still not be commercially feasible in 7 years, hence ENTEK would need to re-apply for authorisation. This would lead unnecessary costs and resource use for ENTEK, and also for HSE who would have to assess the re-application.

- The global market for lead acid batteries is growing over the next 20 years. Advances in lead acid batteries (e.g. stop start technology) mean that lead acid batteries are still likely to be the dominant vehicle battery technology on the market. All vehicle types, including electric vehicles (EVs) with large lithium batteries, have a lead-acid battery. As is detailed in Section 4.2, the global market for electric vehicles (EVs) is increasing, particularly rapidly in Europe. Measures such as the banning of sales of internal combustion engine automotive vehicles by 2035 in the UK will result in EVs being the only options for independent automotive transportation (GOV.UK, 2021). Therefore, the market for lead-acid batteries (also used in EVs as support for the lithium battery pack, safety systems, and other 12V ancillary systems) is likely to continue to grow for the foreseeable future. There is also not foreseen to be any alternative battery products on the market that will dramatically change demand for lead acid batteries to warrant giving a 7 year review period rather than 12 years.

6.8 Substitution effort taken by the applicant if an authorisation is granted

6.8.1 Introduction

The conclusion of this analysis of alternatives is that there are no chemical or technological alternatives that are suitable and available to the applicant for the replacement of the Annex XIV substance function at this time. A number of possible alternatives have been tested at laboratory scale by ENTEK. Although it was found that for some alternatives there was potential for the replacement of trichloroethylene, a considerable amount of further research would be required to determine the technical feasibility and production of the lead acid battery separators with the use of alternative solvents or technologies at a commercial scale. In addition, the customer acceptability of the products manufactured using an alternative would have to be ensured during the process.

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6.8.2 Factors affecting substitution

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6.8.3 List of actions and timetable with milestones

Blank126

[redacted]

[redacted]

Blank 127

6.8.4 Monitoring the implementation of the Substitution Plan

ENTEK International LLC, the parent company of the Newcastle plant, is committed to and continues to invest significantly in the development of next generation separators that do not require the use of trichloroethylene and is particularly interested in the development of Blank 128

6.8.5 Conclusions

The conclusion from the timetable detailed in Appendix 2, Table A2-3 is that a minimum of 12 years would be required to convert to a substitute technology. As previously mentioned, this is a best-case scenario that does not take into account potential for material cost changes, availability and changes in the regulatory landscape.

The test protocol and qualification process will be defined by each battery manufacturer and their OEM customers. So far, they have been unwilling to invest in the required tests.

7 CONCLUSIONS

Section 5.1 set out details of R&D conducted by ENTEK on potential alternatives identified in the 2014 application for authorisation and why they were not deemed to be suitable alternatives. Despite this R&D failing to find a suitable alternative, ENTEK still continues its efforts to find a long-term solution to replacing its use of trichloroethylene, and the remainder of Section 5 sets out why the most promising of any potential 'new' alternatives (replacement solvents and a Blank 129 process) are still not currently feasible (technically and economically) but that ENTEK continues to explore these alternatives further.

In particular, as set out in Section 6.8 ENTEK has set out a 'substitution plan' setting out what they plan to do to try to substitute away from the use of trichloroethylene if authorisation is granted for the requested 12-year review period. The most promising alternative is the confidential manufacture of Blank 130 through Blank 131. There are a number of challenges (e.g. customer acceptability), whereby at best, it will take ENTEK at least 12 years to implement, assuming none of these challenges are insurmountable.

Section 6.5 summarises the key costs and benefits of a refused authorisation. When comparing the benefits of authorisation Blank 132 to any potential risks Blank 133 it is evident that UK society would be better off were authorisation granted. As noted in Section 6.6, the main costs and benefits associated with the continued use of trichloroethylene have been quantified and monetised. Non-quantified impacts are therefore not likely to change the outcome of this SEA. Equally, given the large difference between monetised benefits of continued use vs. monetised costs, any uncertainties in the monetary assessment would not change the outcome of the SEA.

In conclusion, it is recommended that an authorisation is granted for ENTEK's use with a 12-year review period. This is based on the following conclusions:

- The emissions of trichloroethylene have been minimised (as shown in the Exposure Scenario);
- There continues to be no suitable alternatives (nor temporary alternatives) (as shown in the AoA); and

- The benefits of authorisation outweigh the risks by a factor of 8000 (as shown in this SEA).

Further details to justify a 12 year review period are set out in Section 6.7.

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS[66]

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Justification for Confidentiality

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APPENDICES

Public version of the AoA-SEA:

Appendix 1 Product specifications – CONFIDENTIAL

Table A1-2. Detailed product specification of a STANDARD separator

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Table A1-2. Detailed product specification of an LR separator

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Appendix 2 Cost break down for substitution to alternatives – CONFIDENTIAL

Table A2-1: Tergo MCF substitution breakdown costs

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Table A2-2: Isopar G substitution breakdown costs

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