CHEMICAL SAFETY REPORT

Part B section 9 and 10

Legal name of applicant(s):	*Rolls-Royce plc*
Submitted by:	*Rolls-Royce plc*
Substance:	*Bis (2-ethylhexyl) phthalate (DEHP)* *EC: 204-211-0 CAS: 117-81-7*
Use title:	*The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.*
Use number:	*1*

Table of Contents

9. EXPOSURE ASSESSMENT (AND RELATED RISK CHARACTERISATION) 1

9.1 Introduction 1
9.1.1. Overview of uses and Exposure Scenarios 2
9.1.2. Introduction to the assessment 3
9.1.2.1. Environment 3
9.1.2.2. Human via environment 4
9.1.2.3. Workers 4
9.1.2.4. Consumers 9

9.2. Exposure scenario 1 for workers: The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades 9
9.2.1. Environmental contributing scenario 1: The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades 10
9.2.1.1. Conditions of use 10
9.2.1.2. Releases 11
9.2.2. Worker contributing scenario 1: Manual shaking, mixing and opening of formulation bottle. Indoors with LEV. 11
9.2.2.1. Conditions of use 11
9.2.2.2. Exposure and risks for workers 12
9.2.3. Worker contributing scenario 2: Transfer and sampling of formulation bottle. Indoors with LEV. 12
9.2.3.1. Conditions of use 12
9.2.3.2. Exposure and risks for workers 12
9.2.4. Worker contributing scenario 3: Pouring fluid for application and use of wipes, Indoors with LEV. 13
9.2.4.1. Conditions of use 13
9.2.4.2. Exposure and risks for workers 13
9.2.5. Worker contributing scenario 4: Diffusion Bonding and superplastic formation. 13
9.2.5.1. Conditions of use 13
9.2.5.2. Exposure and risks for workers 14

9.3. Combined exposure for all WCS 14

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE 15

10.1. Human health (related to combined, shift-long exposure) 15
10.1.1. Workers 15
10.1.2. Consumers 16

10.2. Environment (combined for all emission sources) 17
10.2.1. All uses (regional scale) 17
10.2.1.1. Total releases 17
10.2.1.2. Regional exposure 18

Tables

Table 74 a. Overview of exposure scenarios 2
Table 74 b. Overview of Contributing Scenarios 2
Table 75. Local releases during the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades. 3
Table 76. DEHP air concentrations measured during mixing and rebottling (ES1-WCS1 and ES1-WCS2) 4
Table 77. DEHP air concentrations measured during application apparatus cleaning (ES1-WCS3) 4
Table 78. DEHP air concentrations measured during application (ES1-WCS3) 5
Table 79. DEHP air concentrations measured during laboratory assessment (ES1-WCS2) 5
Table 80. DEHP levels in wipe samples measured during mixing and rebottling (ES1-WCS1 and ES1-WCS2) 5
Table 81. DEHP levels in wipe samples measured during cleaning (ES1-WCS3) 5
Table 82. DEHP levels in wipe samples measured during application (ES1-WCS3) 6
Table 83. DEHP levels in wipe samples measured during application (ES1-WCS1, ES1-WCS2) 6
Table 84. Summary of calculated exposure levels of DEHP for ES1 7
Table 85. Type of risk characterisation required for workers 8
Table 86. Environmental RMMs 11
Table 87. PNECs and Relevant EQSs or EALs 15
Table 88. DNELs for workers and the general population 15
Table 89. The Margin of Safety Calculation for indirect exposure of humans via the environment 18

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.1 Introduction

Bis (2-ethylhexyl) phthalate (DEHP) is produced outside of the EU and the applicant directly imports the stop-off formulation which contains 5% w/w DEHP. The only use for which the applicant is applying for authorisation is for "the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades" which is the total Service Life of DEHP for this application, (IU1).

General remarks

Human health – worker and consumer

DEHP has a harmonised classification under Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) of Repr. 1B (H360FD) – may damage fertility and may damage the unborn child. The exposure scenario developed for this application for authorisation minimises the potential risk from this intrinsic property of DEHP by demonstrating adequate control in the use of DEHP through Risk Management Measures (RMM).

The most likely route of workers exposure to DEHP is through inhalation and/or dermal contact. In industrial settings, ingestion is not an anticipated route of exposure. DEHP is not labelled for skin and eye irritation or skin sensitization.

Exposure to the general population is not relevant since the DEHP used in the early stages of the aero engine fan blade production as a diffusion bonding stop-off formulation is later destroyed by heat in the final stages of production of the finished blade. The aero engine fan blades are manufactured from three sheets of titanium representing the two outer skins and the internal corrugated structure. A diffusion bonding stop-off formulation containing 5% w/w DEHP is applied to define the internal structure and then the three pieces are bonded in a high temperature pressure vessel (temperatures over 700° C for several hours). The blade is twisted and the cavity inflated at very high temperature using an inert gas in a shaped die to yield its final aerofoil shape. Any residual DEHP in the fan blade is destroyed (by heat) in the bake-out stage. No significant releases to the environment are expected from the use of the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades. In addition, all waste contaminated with DEHP is disposed of by incineration off-site by a licensed hazardous waste contractor. Therefore, the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades will not contribute to DEHP exposure to the general population.

The following DNELs were derived for DEHP (Section 5.11.2):

Route of exposure	Workers
Inhalation (mg/m3)	0.88
Dermal (mg/kg bw/d)	1.882
Oral (mg/kg bw/d)	Not relevant
Parenteral (mg/kg bw/d)	Not relevant

For the worker occupational exposure assessment, repeated detailed workplace air-monitoring and dermal/surface wipe testing for DEHP was conducted at the Company's diffusion bonding facility during 2012 by an Accredited Laboratory (Bureau Veritas UK Ltd).

Environment

In other industries, releases of DEHP into the environment are to be expected during production mainly via wastewater and mainly via exhaust gases for processing when this involves heating (formulation, calendering, extrusion, injection moulding). However, Rolls-Royce's processes involve ambient temperature application of

the DEHP formulation and heating is only applied once the blade is sealed.

No significant releases to the environment are expected from the use of the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades. Analysis of the emission and waste streams at the Company's diffusion bonding facility has been conducted during 2012 and 2013 by an Accredited Laboratory (Environmental Scientifics Group, ESG). The complete service life of DEHP is within Company's diffusion bonding facility as the DEHP is destroyed (by heat) in the final stages of the manufacture of the aero engine fan blades.

All waste potentially containing DEHP is sent for incineration off-site by a licensed hazardous waste contractor.

The UK Environment Agency's H1 Environmental Risk Assessment Framework was used to assess the significance of releases of chemicals to water and air, and this assessment in detailed in Section 10.2.

9.1.1. Overview of uses and Exposure Scenarios

Tonnage information:

Assessed tonnage: <1 tonnes/year based on:

<1 tonnes/year manufactured / imported

<1 tonnes/year used

Tonnage supplied per market sector:

There is no change to the tonnage or concentration of DEHP in the Stopyt 62A formulation since the original Authorisation application was submitted.

The following table lists all the exposure scenarios (ES) assessed in this CSR. There are no changes to conditions from the original Authorisation application.

Table 74 a. Overview of exposure scenarios

Identifiers*)	Market Sector	Titles of exposure scenarios	Tonnage (tonnes per year)
ES 1: IW-1	IW	The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades	<1
***) Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)**			

Table 74 b. Overview of Contributing Scenarios

Contributing scenario	ERC / PROC	Name of the contributing scenario	Size of the exposed population
ES 1: The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades			
ECS 1	ERC 5	The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.	N/A – DEHP is consumed by the process (not released)
WCS 1	PROC 5	Manual shaking, mixing and opening of formulation bottle. Indoors with LEV	30
WCS 2	PROC 8b	Transfer and sampling of formulation bottle	30

		contents. Indoors with LEV	
WCS 3	PROC 10	Pouring formulation fluid for application and use of wipes, Indoors with LEV	30
WCS 4	PROC 1	Diffusion Bonding and superplastic forming.	N/A – closed process

9.1.2. Introduction to the assessment

9.1.2.1. Environment

The quantities of DEHP involved are very small; up to 1 tonne of DEHP (5% w/w DEHP in a diffusion bonding stop-off formulation) are used each year at the site, spread evenly across each day and shift. Quantities of DEHP released to the atmosphere and to watercourses are insignificant as DEHP was not detected using a low LOD. All DEHP waste from the process is disposed of as hazardous waste by a registered waste contractor. Once the blades have been manufactured, there is no residual DEHP within the blade and thus there is no potential for DEHP health impacts during use.

Scope and type of assessment:

Stack emissions monitoring and waste effluent monitoring of DEHP in 2013 was carried out by Environmental Scientific Group Limited.

Table 75. Local releases during the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.

Identifier	Local DEHP concentration in effluent water during emission episode (mg/L)	Local DEHP concentration in air (total) mg/m3
ES1*	<0.001 0.001 <0.001	<0.0013** <0.0013** <0.0013**

Notes:

* ES1 includes all of the contributing scenarios (ES1-WCS1, ES1-WCS2, ES-WCS3 and ES1-WCS4).

** Measurements were below the limit of detection. The DEHP emission rate was measured at <0.0003 g/hour.

The Osprey Turbo-scrubber stack emission gases were sampled (2 hours duration) on 3 separate occasions at the site using XAD2 sorbant tubes and the DEHP content was determined by GC-MS. All of the sample results were below the limit of detection, <0.0013 mg/m3 DEHP, which was also the same for a field blank sample (<0.0013 mg/m3 DEHP). The UK Environment Agency's H1 Environmental Risk Assessment Framework (EA2011a) was used to assess the significance of releases of chemicals to air, and this assessment is detailed in Section 10.2.

The final combined site effluent stream (prior to discharge into sewer) was also sampled on 3 separate occasions and the DEHP content determined. The DEHP content of the site effluent was determined to be ≤0.001 mg/L (or <1 ug/L). The UK Environment Agency's H1 Environmental Risk Assessment Framework (EA2011b) was used to assess the significance of releases of chemicals to water, and this assessment is detailed in Section 10.2.

No further environmental exposure assessments of DEHP were carried out during the preparation of the DEHP consortium's CSR for Exposure Scenario situations of the in-door processing of DEHP formulations. The justification was that it was common knowledge that processing of DEHP without heating did not lead to significant releases. For example Cadogan D., pers. comm. confirms that releases to water, air and soil are not expected as (1) water is not used during the process, (2) no heating is involved, and (3) these are all indoor processes.

9.1.2.2. Human via environment

No quantifiable releases of DEHP to the environment were measured from the Company's manufacturing facility and therefore its processing operations involving the DEHP formulation make no contribution to this potential route of human exposure.

9.1.2.3. Workers

Scope and type of assessment:

The inhalation worker exposure measurements for the activities associated with this use of DEHP in the diffusion bonding stop-off formulation have been assessed by collection of measured values from repeated detailed workplace air-monitoring and wipe testing for DEHP, conducted by Bureau Veritas UK Ltd at the diffusion bonding facility site during 2012 for ES1-WCS1, ES1-WCS2 and ES1-WCS3.

ES1-WCS4 is a closed process and thus there were no appropriate measurements to be made.

Air-monitoring samples (ES1-WCS1, WCS2 and WCS3)

Air-monitoring samples were collected by drawing a measured volume of air at around 200cm^3/min though quartz tenax tubes, this sampling stage is similar to MDHS 32, although rather than use solvent desorption as in MDHS 32, thermal desorption GC/MS was used to identify and quantify the DEHP collected to a much lower detection limit (equivalent to ~0.01 mg DEHP/m^3). The sorbent tubes were placed within the operator's breathing zone (target flow rate 200 cm^3 per minute) for a target time of 15 minutes. The overall recovery of DEHP from controlled spiked tubes was 70% efficient.

All of the measured concentrations of airborne DEHP during the mixing and rebottling process were below the limits of detection (the individual limits of detection for each sample will vary depending on factors such as the actual flow rate of the pumped air and the length of time of sampling).

Table 76. DEHP air concentrations measured during mixing and rebottling (ES1-WCS1 and ES1-WCS2)

Date of sampling	Sample type	Airborne level of DEHP (mg/m^3)
20 July 2012	Operator 1	<0.005
20 July 2012	Static background	<0.004
17 October 2012	Operator 2	<0.007
17 October 2012	Static background	<0.007
24 October 2012	Operator 3	<0.006
24 October 2012	Static background	<0.005

All of the measured concentrations of airborne DEHP during the cleaning process were below the limits of detection.

Table 77. DEHP air concentrations measured during application apparatus cleaning (ES1-WCS3)

Date of sampling	Sample type	Airborne level of DEHP (mg/m^3)
11 June 2012	Operator 1	<0.003
11 June 2012	Static background	<0.004
17 October 2012	Operator 2	<0.004
17 October 2012	Static background	<0.004
24 October 2012	Operator 3	<0.003
24 October 2012	Static background	<0.004

All of the measured concentrations of airborne DEHP during the application process were below the limits of detection.

Table 78. DEHP air concentrations measured during application (ES1-WCS3)

Date of sampling	Sample type	Airborne level of DEHP (mg/m^3)
11 June 2012	Operator 1	<0.004
11 June 2012	Static background	<0.003
17 October 2012	Operator 2	<0.003
17 October 2012	Static background	<0.003
24 October 2012	Operator 3	<0.004
24 October 2012	Static background	<0.003

All of the measured concentrations of airborne DEHP during the laboratory assessment process were at or below the limits of detection.

Table 79. DEHP air concentrations measured during laboratory assessment (ES1-WCS2)

Date of sampling	Sample type	Airborne level of DEHP (mg/m^3)
11 June 2012	Operator 1	<0.010
11 June 2012	Static background	<0.015

Surface and wipe-test samples (ES1-WCS1, WCS2 and WCS3)

Dermal wipe samples were taken in order to assess whether the absorption of DEHP via skin contact was a contributing factor to overall exposure; additional samples from potentially contaminated surfaces, such as door handles, were also taken to assess possible exposure to other staff on the site. Dermal wipe samples were taken using methods based on those described by Fenske et al (1999). The entire hand was wiped systematically using three wipes. The first was used to sample the palm beginning by wiping the palm horizontally across the wrist and continuing horizontal wipes up the entire palm, then repeating the entire procedure with vertical wipes from the wrist to the base of the fingers. The second wipe was used to wipe the back of the hand in the same manner while the third wipe was used to wipe the fingers. The overall extraction efficiency of DEHP from wipe samples was 80%.

All of the amounts of DEHP from wipe samples taken during the mixing and rebottling process were below 1 µg (microgram)

Table 80. DEHP levels in wipe samples measured during mixing and rebottling (ES1-WCS1 and ES1-WCS2)

Date of sampling	Sample type	Total amount of DEHP on wipe (µg)
24 October 2012	Operator 1	<1
24 October 2012	Door handle	<1
25 October 2012	Operator 2	<1
25 October 2012	Door handle	<1

All of the amounts of DEHP from wipe samples taken during the cleaning process were below 1 µg (microgram).

Table 81. DEHP levels in wipe samples measured during cleaning (ES1-WCS3)

Date of sampling	Sample type	Total amount of DEHP on wipe (µg)
24 October 2012	Operator 1	<1
24 October 2012	Outside of pump trap	<1
24 October 2012	Computer mouse on control unit	<1
25 October 2012	Operator 2	<1
25 October 2012	Outside of pump trap	<1
25 October 2012	Computer mouse on control unit	<1

All of the amounts of DEHP from wipe samples taken during the application process were below 1 µg (microgram).

Table 82. DEHP levels in wipe samples measured during application (ES1-WCS3)

Date of sampling	Sample type	Total amount of DEHP on wipe (µg)
24 October 2012	Operator 1	<1
24 October 2012	Control room door handle	<1
25 October 2012	Operator 2	<1
25 October 2012	Operator 3	<1
25 October 2012	Control room door handle	<1

All of the amounts of DEHP from wipe samples taken during the laboratory assessment and waste disposal process were below 1 µg (microgram) i.e. at or below the level of detection.

Table 83. DEHP levels in wipe samples measured during application (ES1-WCS1, ES1-WCS2)

Date of sampling	Sample type	Total amount of DEHP on wipe (µg)
24 October 2012	Storage container door handle	<1
24 October 2012	QC microscope	<1
24 October 2012	Waste disposal storage cabinet door handle	<1
24 October 2012	Waste disposal plant room door handle	<1
24 October 2012	Waste disposal bottle carrier handle	<1
25 October 2012	Storage container door handle	<1
25 October 2012	QC microscope	<1
25 October 2012	Waste disposal storage cabinet door handle	<1
25 October 2012	Waste disposal plant room door handle	<1
25 October 2012	Waste disposal bottle carrier handle	<1
25 October 2012	Operator 1 (waste disposal)	<1
25 October 2012	Waste disposal – edge of waste bin	<1

Table 84. Summary of calculated exposure levels of DEHP for ES1

Identifier	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3) Short term*	*Inhalatory exposure (mg/kg/day)*	*Dermal exposure (mg/kg/day)*	*Combined exposure (mg/kg/day)*
				Acute Measured	*Calculated**	*Calculated***	*Calculated*
ES1-WCS1	Manual shaking, mixing and opening of formulation bottle. Indoors with LEV	5	Low volatility liquid carried out in a vented booth or extracted enclosure. Avoid carrying out operation for more than 4 hours continuously. Wear chemically resistant gloves (tested to EN374), coverall and eye protection in combination with basic employee training	<0.01	<0.0015	<0.0008579	<0.0024
ES1-WCS2	Transfer and sampling of formulation bottle. Indoors with LEV	8b	Low volatility liquid carried out in a vented booth or extracted enclosure. Avoid carrying out operation for more than 4 hours continuously. Wear chemically resistant gloves (tested to EN374), coverall and eye protection in combination with basic employee training				
ES1-WCS3	Pouring fluid for application and use of wipes, Indoors with LEV	10	Low volatility liquid carried out in an extracted enclosure. Avoid carrying out operation for more than 4 hours continuously. Wear chemically resistant gloves (tested to EN374), coverall and eye protection in combination with basic employee training				
ES1-WCS4	Diffusion Bonding and superplastic formation	1	Closed system, indoors, no likelihood of exposure. Wear chemically resistant gloves (tested to EN374), coverall and eye protection in combination with basic employee training	NA	NA	NA	NA

Notes:
NA- Not Applicable as Closed System
*- Uptake calculation for inhalation:
The occupational (8-hour day) internal exposure by inhalation absorption can be calculated:

$$U = \frac{C\ x\ V}{BW}$$

The default calculation assumes an 8-hour day/5-day week which would equate to 40 hours per week. The shift pattern operated by the Rolls-Royce operatives is based upon a 12-hour shift, working a total of 7 shifts in a 2-week period (equivalent to an average of 42 hours per week). In addition, the actual exposure time is only a fraction of each hour worked (typically 15 minutes) up to a maximum of 50 minutes in an hour. Therefore of the average 42 hours per week worked, there is a maximum exposure time of 50/60 * 42 = 35 hours which is less than the default value of 40 hours, therefore no further correction has been made to ensure that a conservative approach is maintained.

Values used for the calculation of inhalation and dermal exposures to DEHP are as follows:
U is the uptake (mg/kg/day)
C is the concentration, for inhalation exposure (mg/m^3), corrected for extraction efficiency (70% for inhalation measurements)
V is the inhalation rate (10 m^3/day)
BW is the body weight of a worker (70 kg)

Based upon a concentration of 0.01 mg/m^3 the internal exposure (mg/kg bw/day) based on an 8-hour shift is calculated to be 0.0015 mg/kg bw/day. The default calculation assumes an 8-hour day/5-day week which would equate to 40 hours per week. The shift pattern operated by the Rolls-Royce operatives is based upon a 12-hour shift, working a total of 7 shifts in a 2-week period (equivalent to an average of 42 hours per week). In addition, the actual exposure time is only a fraction of each hour worked (typically 15 minutes) up to a maximum of 50 minutes in an hour. Therefore of the average 42 hours per week worked, there is a maximum exposure time of 50/60 * 42 = 35 hours which is less than the default value of 40 hours, therefore no further correction has been made to ensure that a conservative approach is maintained.

The total exposure of a worker over an 8-hour shift is calculated to be 0.0015 mg/kg bw/day. Based upon the inhalation DNEL of 0.88 mg/kg bw/day the RCR is calculated to be <0.01.

**- Uptake calculation via the dermal route
The occupational (8-hour day) internal exposure by inhalation absorption can be calculated:

U = C/BW

Although all of these results were below 1 µg, an overestimate of 1 µg is used for the calculation purposes.
The number of dermal exposures per shift can be calculated on the basis that up to 8 fan blades can be produced per shift and the operator can have up to 6 dermal exposure incidents per blade production. These assumptions are combined to 48 possible dermal exposure incidents per shift. Exposure to DEHP per dermal exposure is assumed to be the detection limit (1 µg).
A worker is exposed on 48 occassions per shift, therefore the worst case scenario is an exposure of 48 µg DEHP across a shift duration. While this is a likely overestimate of the true exposure, it was recommended by RAC for calculation purposes going forward.
Using the uptake calculation described for the airborne samples with the following values:
C = 48 µg per day
BW = 70 kg (Bodyweight)
and also correcting for efficiency (80%), gives a calculated internal exposure from the dermal route of 0.8579 µg/kg/bw/day
The total exposure of a worker over an 8-hour shift is calculated to be 0.0008579 mg/kg bw/day. Based upon the dermal DNEL of 1.88 mg/kg bw/day the RCR is calculated to be <0.00045.

Table 85. Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion DNEL / dose – response relationship (see section 5.11.2)
Inhalation	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level): 0.88 mg/m³
	Local Long Term	Quantitative	No hazard identified
Dermal	Systemic Long Term	Quantitative	DNEL (Derived No Effect Level): 1.882 mg/kg bw/day
	Local Long Term	Quantitative	No hazard identified

Comments on assessment approach related to toxicological hazard:

The assessment approach uses measured data from Rolls Royce's site. RAC have provided feedback on Rolls Royce's initial assessment and specified that an exposure value of 48 µg per day should be used for the dermal risk assessment, based on the use of up to 6 wipes during the production of a blade, and the production of up to 8 fan blades per shift, as detailed within Chapter 2 of this CSR. As such, a worst case assumption could be that a worker is exposed 48 times per shift to a maximum of 1 µg DEHP (itself a worst case figure, given that all measured data suggests the actual exposure is below this level). In line with the RAC assessment, the 48 µg per day exposure value has been taken forward as a basis for the assessment.

General information on risk management related to toxicological hazard:

The conditions of use detailed within this CSR (sections 9.2.2-9.2.5) specify that all handling of the substance by

workers should occur within a vented booth or extracted enclosure, wearing chemically resistant gloves, and for a maximum of four hours.

9.1.2.4. Consumers

There is no exposure to consumers from the use of DEHP in accordance with this application for Authorisation.

No quantifiable releases of DEHP to the environment were measured from the Company's manufacturing facility and therefore its processing operations involving the DEHP formulation make no contribution to this potential route of human exposure.

9.2. Exposure scenario 1 for workers: The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades

Market sector: IW

Sector of use: SU 17

Article categories: n/a

Environment contributing scenario(s): ECS 1

Worker/Consumer contributing scenario(s): WCS 1, WCS 2, WCS 3, WCS 4

Subsequent service life exposure scenario(s): n/a

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s): n/a

Description of the activities and technical processes covered in the exposure scenario:

This scenario covers all of the industrial activities associated with the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades. Included within this scenario are formulation receipt, formulation mixing and sampling, formulation transfer, brushing of formulation and storage, as well as equipment cleaning, and associated maintenance activities. All these activities take place on an industrial site with mainly contained equipment. The aero engine fan blade manufacturing process is carried out in a restricted-access Class 6-8 Clean Room (ref: ISO 14644-1 cleanroom standards) under strictly controlled cleanroom conditions which protect worker health and also ensure that the highest levels of product quality are achieved. The final stages of the aero engine fan blade production involve the repeated heating of the fan blade, which by this stage contains <0.1% DEHP, to temperatures in excess of 700°C for extended periods. As these temperatures are well in excess of the auto-ignition temperature of DEHP, 380° C, the residual DEHP is destroyed producing water and carbon dioxide as by-products. The blade is twisted and the cavity inflated at very high temperature using an inert gas in a shaped die to yield its final aerofoil shape. If the DEHP is not removed fully at the bake-out stage then the bond will not be 100% and the final product unacceptable.

The quantities of DEHP involved are also very small; considerably less than 1 tonne of DEHP (5 % w/w DEHP in a stop-off formulation) is used each year at the site, spread evenly across each day and shift. There is no measurable release of DEHP to the atmosphere and the level of DEHP in the waste effluent is below the Environmental Quality standard set in Directive CE/2008/105 (1.3 µg/L). All DEHP waste from the process is disposed of as hazardous waste by a registered waste contractor. Once the blades have been manufactured, there is no residual DEHP remaining and thus there is no potential for DEHP health impacts during use.

Manufacture of the DEHP and the preparation of the diffusion bonding stop-off formulation both take place outside of the EU and therefore are not considered in this exposure scenario process. The diffusion bonding stop-off formulation is manufactured in the United States by Wesgo Metals which is a Division of Morgan Technical Ceramics. The diffusion bonding stop-off formulation is imported into the UK by Rolls-Royce Plc and delivered to the site.

In the EU Risk Assessment of DEHP (Volume 80), it concluded that there is reason for concern for workers' health as a consequence of inhalation and dermal exposure during production, processing and industrial end-use of

preparations or materials containing DEHP. A worst-case exposure was assumed for the scenarios on production and industrial use by using monitored data for inhalation exposure and modelled values for dermal exposure. For the scenario of industrial end-use of products containing DEHP, it was assumed that relatively high work temperatures, aerosol generation and considerable skin contact would occur. It also assumed that there was little information available on technical control measures and personal protective equipment used during production and processing to establish their efficiency.

In contrast, a very controlled, specific and low quantity usage is being described in this Exposure Scenario. High quality quantitative exposure data levels of DEHP have been directly measured at the facility during all of the contributing exposure scenarios. These measurements are considered to be relevant, reliable and representative for the operational conditions and risk management measures described in the exposure scenario, and as such, it is these datasets that are used for the exposure estimate.

Rolls-Royce operators wear chemically resistant gloves (tested to EN374), coveralls and eye protection and work within controlled ventilated areas. Rolls-Royce provides operator training when working in these areas as well as specific employee training when working with DEHP. Rolls-Royce site senior management conduct regular Health, Safety & Environmental (HS&E) audits and operator training to ensure compliance with chemicals handling, waste disposal and Personal Protective Equipment (PPE) standards. Rolls-Royce plc applies a hierarchy to risk management measures for hazardous chemicals.

Explanation on the approach taken for the ES:

Repeated detailed workplace air-monitoring and wipe testing, and also environmental stack monitoring and effluent analysis for DEHP was conducted by Bureau Veritas UK Ltd and ESG at the Company's diffusion bonding facility during 2012 and 2013.

9.2.1. Environmental contributing scenario 1: The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades

9.2.1.1. Conditions of use

Product (article) characteristics
▪ Liquid formulation containing DEHP (5% w/w), Yttrium Oxide (<50% w/w), Isopropyl Alcohol (30-40% w/w) and Methyl Isobutyl Ketone (10-50% w/w)
Amount used, frequency and duration of use (or from service life)
▪ < 1 tonne per annum
Technical and organisational conditions and measures
▪ Handle substance within a closed system. ▪ Sample via a closed loop or other system to avoid exposure. ▪ There is no direct release to wastewater– dry processes
Conditions and measures related to sewage treatment plant
▪ There is no release to STP.
Conditions and measures related to treatment of waste (including article waste)
▪ Air emissions: Incinerate, absorb or adsorb vapours stripped from process whenever necessary
Other conditions affecting environmental exposure
▪ All DEHP is consumed in the manufacturing process ▪ All waste potentially containing DEHP is sent for incineration off-site by a licensed hazardous waste contractor.
Additional good practice advice
▪ Dispose of waste cans and containers according to local regulations. ▪ Specific employee training when working with DEHP.

Table 86. Environmental RMMs

Compartment	RMM	Stated Effectiveness
Air	Incinerate, absorb or adsorb vapours stripped from process whenever necessary	Ca.100% - If the DEHP is not removed fully during the bake-out stage then the bond will not be 100% and the final product unacceptable.
Water	Wastewater emission controls are not applicable as there is no direct release to wastewater. – dry processes	n/a
Soil	Soil emission controls are not applicable as there is no direct release to soil.	n/a

9.2.1.2. Releases

Due to the handling processes and on-site measures taken during DEHP use, no significant release of DEHP to the environment is anticipated from the use of the processing of a stop-off formulation containing DEHP during diffusion bonding and manufacture of aero engine fan blades. The complete service life of DEHP is within Company's diffusion bonding facility site as the DEHP is destroyed (by heat) in the final stages of the manufacture of the aero engine fan blades.

All waste potentially containing DEHP is sent for incineration off-site by a licensed hazardous waste contractor.

Conclusion on risk characterisation:

There is no risk to the environment through the use of DEHP in line with the conditions of used outlined 9.2.1.1.

9.2.2. Worker contributing scenario 1: Manual shaking, mixing and opening of formulation bottle. Indoors with LEV.

This contributing scenario covers exposures from opening the formulation bottles after they have been shaken manually and mixed.

9.2.2.1. Conditions of use

	Method
Product (article) characteristics	
▪ Low volatility liquid formulation containing DEHP (5% w/w), Yttrium Oxide (<50% w/w), Isopropyl Alcohol (30-40% w/w) and Methyl Isobutyl Ketone (10-50% w/w)	Measured data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Less than 5L of formulation per shift; equivalent to less than 0.5kg of DEHP per shift ▪ Covers short term exposure (typically 15 minutes per hour across all WCS) in a daily shift exposure of up to 12 hours. There are 7 shifts per 2-week period equating to an average of 42 hours per week.	Measured data
Technical and organisational conditions and measures	
▪ Use vented booth or extracted enclosure.	Measured data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Wear chemically resistant gloves (tested to EN374), coverall and eye protection in combination with basic employee training	Measured data
Other conditions affecting workers exposure	
▪ n/a	

	Method
Additional good practice advice	
▪ Avoid carrying out operation for more than 4 hours continuously. ▪ Specific employee training when working with DEHP.	Measured data

There are no changes to the data that was submitted in the original Authorisation application. All conditions of use remain the same.

9.2.2.2. Exposure and risks for workers

The exposure and risk over the full worker shift is presented in Section 9.1.2.3. A detailed discussion of the methods used to determine exposure is also presented there.

9.2.3. Worker contributing scenario 2: Transfer and sampling of formulation bottle. Indoors with LEV.

This contributing scenario covers decanting/transferring and sampling of the DEHP-containing formulation prior to use in the manufacturing process.

9.2.3.1. Conditions of use

	Method
Product (article) characteristics	
▪ Low volatility liquid formulation containing DEHP (5% w/w), Yttrium Oxide (<50% w/w), Isopropyl Alcohol (30-40% w/w) and Methyl Isobutyl Ketone (10-50% w/w)	Measured data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Less than 5L of formulation per shift; equivalent to less than 0.5kg of DEHP per shift ▪ Covers short term exposure (typically 15 minutes per hour across all WCS) in a daily shift exposure of up to 12 hours. There are 7 shifts per 2-week period equating to an average of 42 hours per week.	Measured data
Technical and organisational conditions and measures	
▪ Use vented booth or extracted enclosure.	Measured data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Wear chemically resistant gloves (tested to EN374), coverall and eye protection in combination with basic employee training	Measured data
Other conditions affecting workers exposure	
▪ n/a	
Additional good practice advice	
▪ Avoid carrying out operation for more than 4 hours continuously. ▪ Specific employee training when working with DEHP.	Measured data

There are no changes to the data that was submitted in the original Authorisation application. All conditions of use remain the same.

9.2.3.2. Exposure and risks for workers

The exposure and risk over the full worker shift is presented in Section 9.1.2.3. A detailed discussion of the methods used to determine exposure is also presented there.

9.2.4. Worker contributing scenario 3: Pouring fluid for application and use of wipes, Indoors with LEV.

This contributing scenario covers the pouring of the DEHP-containing formulation for use in the fan blade manufacturing process. It also covers the use of wipes to remove any spillages.

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
▪ Low volatility liquid formulation containing DEHP (5% w/w), Yttrium Oxide (<50% w/w), Isopropyl Alcohol (30-40% w/w) and Methyl Isobutyl Ketone (10-50% w/w)	Measured data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Less than 5L of formulation per shift; equivalent to less than 0.5kg of DEHP per shift ▪ Covers short term exposure (typically 15 minutes per hour across all WCS) in a daily shift exposure of up to 12 hours. There are 7 shifts per 2-week period equating to an average of 42 hours per week.	Measured data
Technical and organisational conditions and measures	
▪ Use extracted enclosure.	Measured data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Wear chemically resistant gloves (tested to EN374), coverall and eye protection in combination with basic employee training	Measured data
Other conditions affecting workers exposure	
▪ n/a	
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
▪ Avoid carrying out operation for more than 4 hours continuously. ▪ Specific employee training when working with DEHP.	Measured data

There are no changes to the data that was submitted in the original Authorisation application. All conditions of use remain the same.

9.2.4.2. Exposure and risks for workers

The exposure and risk over the full worker shift is presented in Section 9.1.2.3. A detailed discussion of the methods used to determine exposure is also presented there.

9.2.5. Worker contributing scenario 4: Diffusion Bonding and superplastic formation.

This contributing scenario concerns the transfer of the blades, that have had the DEHP-containing formulation applied to them, into a closed system where diffusion bonding and superplastic formation occurs. All the DEHP is consumed (incinerated) as part of the process.

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	
▪ Low volatility liquid formulation containing DEHP (5% w/w), Yttrium Oxide (<50% w/w), Isopropyl Alcohol (30-40% w/w) and Methyl Isobutyl Ketone (10-50% w/w)	Measured data
Amount used (or contained in articles), frequency and duration of use/exposure	

	Method
▪ Less than 5L of formulation per shift; equivalent to less than 0.5kg of DEHP per shift ▪ Covers short term exposure (typically 15 minutes per hour across all WCS) in a daily shift exposure of up to 12 hours. There are 7 shifts per 2-week period equating to an average of 42 hours per week.	Measured data
Technical and organisational conditions and measures	
▪ Use extracted enclosure.	Measured data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Wear chemically resistant gloves (tested to EN374), coverall and eye protection in combination with basic employee training	Measured data
Other conditions affecting workers exposure	
▪ n/a	

There are no changes to the data that was submitted in the original Authorisation application. All conditions of use remain the same.

9.2.5.2. Exposure and risks for workers

The exposure and risk over the full worker shift is presented in Section 9.1.2.3. A detailed discussion of the methods used to determine exposure is also presented there. Note that WCS4 concerns a closed system so there is not likelihood of exposure.

9.3. Combined exposure for all WCS

The combined exposure duration/frequency across the whole exposure scenario is based on all 4 worker contributing scenarios, they are not accumulative since the same concentration of DEHP is present at each step consecutively. As such, the calculations undertaken only consider a single exposure of DEHP, which would be to a single worker during the process of manufacture of a fan blade, covering all four worker contributing scenarios. There is not additional DEHP to consider in each individual worker contributing scenario detailed within this CSR.

In total there is less than 5L of the formulation handled across the duration of a shift, which is equivalent to less than 0.5 kg of DEHP per shift. The assessment considers short-term exposure, typically a maximum of 15 minutes per hour across all worker contributing scenarios within a daily 12 hour shift. Across a two week period, seven shifts would be worked by a single worker, equating to an average of 42 hours per week.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

The risk characterisation of substance bis-2ethylhexyl phthalate (DEHP) has been conducted based on the PNECs (Predicted No Effect Concentration) and DNELs (Derived No Effect Level) in the following tables.

Table 87. PNECs and Relevant EQSs or EALs

Compartments	*PNEC*	*Units*	*Relevant EQSs or EALs**	*Units*
Sewage treatment works	201 (Section 7.4.2)	mg L^{-1}	Not relevant	
Freshwater	Not relevant (Section 7.1.2.1)	mg L^{-1}	1,3[a]	µg L^{-1}
Freshwater sediment	100 (Section 7.1.2.2)	mg kg_{dwt}^{-1}	Not relevant	
Marine water	Not relevant (Section 7.1.2.1)	mg L^{-1}	Not relevant	
Marine water sediment	10 (Section 7.1.2.2)	mg kg_{dwt}^{-1}	Not relevant	
Soil	13 (Section 7.2.2)	mg kg_{dwt}^{-1}	Not relevant	
Air	Not relevant	mg m^{-3}	0.05 [b]	mg m^{-3}

Notes:

* Environmental Quality Standard (EQS) or Environmental Assessment Level (EAL) that is relevant to assessing the significance of environmental releases

a. This is the EQS for DEHP in surface water as set in Directive 2008/105/EC. A value of 1.3 µg L^{-1} applies as an annual average for DEHP in both inland surface waters and other surface waters.

b. No EAL value for DEHP in ambient air has been set at the European level. In this case, the Environment Agency UK guidance (EA 2011b) indicates that a value of 1/100th of the 8-hour TWA OES (Time Weighted Average Occupational Exposure Standard) can be assumed for a long-term EAL value which equates to 0.05 mg m^{-3} DEHP in air (the UK OES is set by the HSE at 5 mg m^{-3})

The following DNELs were derived for DEHP (Section 5.11.2):

Table 88. DNELs for workers and the general population

Route of exposure	**Workers**	**General population**
Inhalation (mg/m^3)	0.88	Adults: 0.16 Infants/children: 0.12
Dermal (mg/kg bw/d)	1.882	Adults: 0.672 Infants/children: 0.672
Oral (mg/kg bw/d)	Not relevant	Adults: 0.034 Infants/children: 0.034

10.1. Human health (related to combined, shift-long exposure)

10.1.1. Workers

Contributing scenario	**Route of exposure**	**8h TWA exposure values (mg/kg/day)**	**RCR *Long term systemic***	
			Per route of exposure	Combined inhalation

				+dermal
WCS 1, WCS 2 and WCS 3	Inhalation	<0.0015	<0.01	<0.01
	Dermal	<0.0008579	<0.000455	
Maximum exposure for 8 hours	**Inhalation**	<0.0015	<0.01	<0.01 <0.000455
	Dermal	<0.0008579	<0.000455	

RAC have provided feedback on Rolls Royce's initial assessment and specified that an exposure value of 48 µg per day should be used for the dermal risk assessment, based on the use of up to 6 wipes during the production of a blade, and the production of up to 8 fan blades per shift, as detailed within Chapter 2 of this CSR. As such, a worst case assumption could be that a worker is exposed 48 times per shift to a maximum of 1 µg DEHP (itself a worst case figure, given that all measured data suggests the actual exposure is below this level). In line with the RAC assessment, the 48 µg per day exposure value has been taken forward as a basis for the assessment.

*In this table – please present WCSs that may be performed by the same worker/s within one shift

Notes:

The RCR is calculated based upon the DNEL for workers (Section 5.11.2), where:

RCR (inhalation) = measured exposure (mg/m3)/DNEL (0.88 mg/m3) and

RCR (dermal) = measured exposure (mg/kg bw/day)/DNEL (1.882 mg/kg bw/day)

An RCR of less than 1 indicates that the Risk is adequately controlled. In this case, the RCR is greater than 100-fold less than 1.

The MoS is calculated based upon the rat NOAEL of 4.8 mg/kg bw/day, where:

MoS = NOAEL (mg/kg bw/day). /measured exposure (mg/kg bw/day)

The minimum MoS value recommended in the EU Risk Assessment report for DEHP (Volume 80) was 30.

The MoS for this exposure scenario of 3,200 is greater than 100-fold more than the minimum MoS recommended.

There is no applicable calculation of RCR or MOS for ES1-WCS4 as this is a closed system.

10.1.2. Consumers

Not applicable

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

Rolls-Royce believes that the available monitoring data and modelling carried out indicates that there is no impact on human health or the environment from DEHP use at the site. This data along with the controlled process, stringent risk management measures and low quantities of DEHP usage at the site demonstrate Adequate Control of DEHP.

There is no measurable release to the environment since a very high MOS above the relevant environmental quality standards is achieved and therefore the risk is acceptable.

10.2.1.1. Total releases

Aquatic compartment (including sediment and secondary poisoning)

The Environment Agency's H1 Environmental Risk Assessment Framework provides a means of assessing the significance of releases of chemicals to water, as follows (EA 2011a). During 2013, the release concentration (RC) of DEHP in the Rolls-Royce site effluent was measured at <1.0 ug/L (this is the limit of detection and no DEHP was actually detected in the effluent). The site effluent is released to sewer under a trade effluent license and is treated by United Utilities at their local sewage treatment works (STW). For releases of DEHP to sewer, the H1 guidance states that a sewage treatment reduction factor (STRF) of 0.05 can be assumed (i.e. 95% removal of DEHP can be assumed at a STW). The guidance also states an initial dilution (ID) factor of 50 can be assumed for the final STW discharge to surface water as an annual average. Therefore, the predicted DEHP process contribution (PC) in the final STW discharge to surface waters is estimated at <0.001 ug/L (PC = RC* STRF/ID). The PC is estimated to be <0.08% of the EQS for DEHP in surface water and is therefore 'not significant' under the H1 guidance (any release less than 1% of the EQS is considered to be insignificant). For Rolls-Royce releases of DEHP to surface water, the Margin of Safety to the EQS is estimated to be >1,300. Since the MOS is very high then no further assessment of sediment or secondary poisoning is considered to be necessary.

Terrestrial compartment (including secondary poisoning)

The most significant environmental impact to consider in this use scenario is the disposal of hazardous waste arising from use of the formulation containing DEHP. A total of around 30 cubic metres of hazardous waste containing very low levels DEHP is produced per annum from the Site. This waste is transported off-site to a licensed waste treatment facility for incineration by a contractor, giving rise to energy use, CO_2 emissions and small quantities of ash for disposal in hazardous waste landfill. However, due to the relatively low volume of hazardous waste generated by DEHP use, these environmental impacts are judged to be small and do not warrant further quantification.

Atmospheric compartment

The Environment Agency's H1 Environmental Risk Assessment Framework provides a means of assessing the significance of releases of chemicals to air, as follows (EA 2011b). During 2013, the release concentration (RC) of DEHP in the Rolls-Royce stack gases was measured at <0.0013 mg/m^3 (this is the limit of detection and no DEHP was actually detected in the stack). This is 2.6% of the derived EAL for DEHP in air without allowing for any further atmospheric dispersion, indicating a MOS of >38. The effective stack height taking into account nearby buildings is >10 metres. The mass release rate (RR) for DEHP was measured at <0.0003 g/hour from the stack. For releases of stack gases at 10m effective height, the H1 guidance states that a dispersion factor (DF) of 32 can be assumed for a long term average. Therefore, the predicted DEHP process contribution (PC) for release to air is estimated at <2.7 *10^{-6} ug/m^3 (PC in ug/m^3 = RR in g/s* DF in µg/m^3/g/s). The PC is estimated to be <<0.01% of the EAL for DEHP in air and is therefore 'not significant' under the H1 guidance (any release less than 1% of the EAL is considered to be insignificant). For Rolls-Royce releases of DEHP to air, the Margin of Safety to the derived EAL is estimated to be >>1,000,000.

Microbiological activity in sewage treatment systems

The PNEC for DEHP in sewage treatment works (STW) is 201 mg/L. During 2013, the release concentration of DEHP in the Rolls-Royce site effluent to sewer was measured at <1.0 ug/L (this is the limit of detection and no DEHP was actually detected in the effluent). Therefore a MOS of >200,000 for impact on microbial activity at the STW is achieved, indicating a very low risk.

10.2.1.2. Regional exposure

Environment

As detailed in section 10.2.1.1, there is no measurable release to the environment since a very high MOS above the relevant environmental quality standards is achieved and therefore the risk is acceptable.

Human via environment

Table 89. The Margin of Safety Calculation for indirect exposure of humans via the environment

Exposure Route	Air	Waste water
Release concentration based on local measurements of DEHP at site	<0.0013 mg/m^3 <0.0003 g/hour	<0.001 mg/L
Relevant Environmental Assessment Level (EAL) for air or Environmental Quality Standard (EQS) for water	0.05 mg/m^3	0.0013 mg/L
Dilution factor from EA H1 guidance (EA 2011a, 2011b)	32 µg/m^3/g/s	1,000
Predicted process contribution after dilution	2.7 *10^{-6} ug/m^3	0.001 ug/L
Process contribution as % of EAL or EQS	0.000005%	0.08%
Resulting Margin of Safety	18,750,000	1,300

Notes:

The Environment Agency's H1 guidance (EA 2011a, 2011b) has been used for this risk assessment (also see Section 10.2)

In addition to the very high MoS calculated for the air and water, the bioaccumulation potential of this substance is very low, therefore secondary poisoning can be considered negligible.