

Information gathering in addition to the draft recommendation of priority substances for inclusion in Annex 14 of UK REACH 2025

Supporting document for the reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥ 0.1% w/w 4-heptylphenol, branched and linear

■ EC: -

CAS: -

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1 Introduction

HSE is seeking GB specific information on the reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥ 0.1% w/w 4-heptylphenol, branched and linear], to assist with future prioritisation work for recommendations to the Authorisation List (Annex 14) of UK REACH. This document outlines the information currently available to HSE, and interested parties are invited to provide information to refine this assessment. In particular, GB specific data on uses and associated tonnages is sought to verify the information and conclusions presented.

Background and context for seeking this information is provided in the document entitled "Technical rationale for the development of the recommendation 2025".

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¹ "Technical rationale for the development of the recommendation 2025", available from here: https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx

2 Background information for prioritisation in GB

2.1 Substance Identity

Identity of the substance in the UK REACH Candidate List:

Name: Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear² (RP-HP) [with ≥ 0.1% w/w 4-heptylphenol, branched and linear]

EC Number: -

CAS Number: -

The abbreviation RP-HP refers to the product of a chemical reaction between 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and the alkylphenol 4-heptylphenol, branched and linear (4-HPbl)². RP-HP is a so-called UVCB substance (substance of Unknown or Variable composition, Complex reaction products or Biological materials).

A non-exhaustive list of relevant identifiers falling within scope of this entry include:

Substance Name	EC Number	CAS Number
Formaldehyde, reaction products with phenol heptyl derivs. and 1,3,4-thiadiazolidine-2,5-dithione	939-460-0	1471311-26-8
Formaldehyde, reaction products with branched and linear heptylphenol, carbon disulfide and hydrazine	300-298-5	93925-00-9

² 4-heptylphenol, branched and linear include substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol. This covers any of the individual isomers or a combination thereof. 4-HPbl is registered under UK REACH as phenol, heptyl derivs., with EC No.: 276-743-1 and CAS No.: 72624-02-3. Further information on substance identity is provided in HSE's Technical Report on RP-HP, Section 2.2 (HSE, 2025).

HSE has prepared a Technical Report on RP-HP that provides further information on the substance identity, hazards and use profile of this material (<u>HSE, 2025</u>).

2.2 Intrinsic properties

Substances that can be defined as 4-heptylphenol, branched and linear (4-HPbl)² are identified as Substances of Very High Concern (SVHCs) according to Article 57(f) of UK REACH as they are considered to have endocrine disrupting (ED) properties for which there is scientific evidence of probable serious effects to the environment (ECHA, 2016a). HSE's Technical Report on RP-HP (HSE, 2025) notes this conclusion was based on the read-across of ED effects from other alkylphenols³, together with screening information on ready biodegradation. The latter showing 4-HPbl not to be rapidly degradable for the purposes of environmental hazard classification (ECHA, 2016b). At the time of the SVHC identification of 4-HPbl under EU REACH (2016), the UK did not consider there to be valid environmental ED data available for 4-HPbl itself⁴.

RP-HP, with ≥ 0.1% w/w 4-heptylphenol, branched and linear, is identified as meeting the criteria of Article 57(f) for the reasons above and was included in the UK REACH Candidate List on 1st January 2021 in accordance with Article 59(1A) of UK REACH.

2.3 Volume used in the scope of authorisation

No UK REACH registrations have been submitted for substances identified as having EC numbers: 939-460-0 or 300-298-5 or CAS numbers: 1471311-26-8 or 93925-00-9.

The available information from Downstream User Import Notifications (DUINs)⁵ suggests that RP-HP may be imported into GB, with 45 DUINs submitted for substances identified as having EC numbers 939-460-0 or 300-298-5 or CAS RNs 1471311-26-8 or 93925-00-9.

HSE does not have information on the levels of 4-HPbl present in any RP-HP that might be supplied to GB. However, as noted in Section 3.1 below, there are no longer any active registrations under EU REACH for substances identified with the above EC and CAS numbers. Also, as noted in Section 3.2, whilst the substance is listed on Annex 14 of EU

³ These other alkylphenols included: p-(1,1-dimethylpropyl)phenol, EC: 201-280-9, CAS: 80-46-6, and 4-tert-octylphenol, EC: 205-426-2, CAS: 140-66-9.

⁴ Comments submitted by the UK (as the Member State Competent Authority for REACH) in the response to comments document from ECHA's Member State Committee (November 2016); https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e180d72891,

⁵ GB-based companies who imported substances from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a DUIN submitted to HSE.

REACH, no applications for authorisation have been published on the European Chemicals Agency (ECHA) website. This implies that there may be no ongoing use of the substance in the EU, or that it is being used at low tonnages with the level of the relevant constituents below 0.1 % w/w.

Overall, given the uncertainty⁶ regarding the DUIN database and the information regarding use in the EU, HSE does not have accurate information on the tonnages actually placed on the GB market in scope of authorisation. However, it is expected to be low, if at all.

2.4 Wide-dispersiveness of uses

RP-HP has reportedly been used as a corrosion inhibitor in lubricants and greases for machinery and vehicles (ECHA, 2017a; ECHA, 2019b). This includes use in products such as gear oils which are supplied for consumer use. Therefore, use at industrial sites and by professionals and consumers is possible. HSE's Technical Report for RP-HP (HSE, 2025) notes that web searches carried out by Austrian regulators identified "numerous" products containing RP-HP in concentrations up to 2.5% (ECHA, 2017b). At that time, the EU registrants of RP-HP stated that it was not technically or economically feasible to purify RP-HP to the point where 4-HPbI levels were below 0.1% w/w.

It is possible that RP-HP will be imported into GB as part of finished articles (e.g., vehicles or machinery), although the imported articles would be out of scope of authorisation.

Further information on use is provided in HSE's Technical Report for RP-HP (HSE, 2025).

2.5 Further considerations for priority setting

Based on information available (<u>HSE, 2025</u>), it is estimated that between approximately 70 and 1,050 kg per year of RP-HP could be emitted into the GB environment. The fraction of 4-HPbI in RP-HP-containing products is unknown. However, the emissions of 4-HPbI would constitute a small proportion of the above figure. Assuming the level of 4-HPbI could vary between 1 and 10% (range chosen in the Technical Report to provide an illustrative assessment only) the annual level of 4-HPbI release within GB from use of RP-HP might

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⁶ DUINs could be submitted for substances imported from the EU-27 into GB at any point within the two years prior to EU exit. They represent an approximate snapshot of substances on the GB market in the period before EU exit. As DUIN submission was a simple process and free of charge, companies may have under or over-reported substances (potentially erring on the side of caution to be compliant). Consequently, the DUIN data needs to be treated with caution. Many former DUs will not (currently) have full information on the identity of the substances they import from the EU. This is because most substances are placed on the market as mixtures and the full composition of those mixtures is not always given on a Safety Data Sheet (SDS) or a SDS may not be required. In addition, substances could be imported by multiple importers in lower volumes (i.e. below 1 tonne/year/importer); in these cases, the substances did not need to be included in a DUIN submission as there would be no registration duty under UK REACH for each importer.

be in the range <1-105 kg. This does not account for quantities that might be imported in articles, although it is noted that this would not be addressed by addition to the authorisation list.

It is also noted that where a substance is listed on Annex 14 due to the presence of a minor constituent or an impurity, the actual substance of concern may be present at concentrations well below those that would ordinarily trigger the authorisation requirement. For example, if RP-HP [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear] was present in a mixture or another substance at 0.1% w/w, this would be within scope of authorisation. However, in this case, the actual concentration of 4-HPbl would be well below 0.1% w/w which would not otherwise trigger authorisation.

A further consideration is that 4-HPbl potentially has other uses and could be present as a constituent or impurity in other 4-alkylphenols. The potential tonnage associated with other uses/substances has not been determined.

3 Other factors and considerations

In addition to the above, HSE notes the 'Defra rationale for prioritising substances in the UK REACH work programme; 2025-2026'⁷, which states:

"The Appropriate Authorities will consider the criteria set out in the UK REACH Regulations, alongside a range of relevant factors including those identified in the 'New approach to ensure regulators and regulation support growth' UK Government Action Plan. In taking forward this strategic approach, the Appropriate Authorities will consider drawing from the regulatory decisions that the EU has made in this area (where appropriate)."

Recognising this, information is provided below to support the Appropriate Authorities consideration of regulatory consistency with decisions made by the EU.

3.1 EU prioritisation activity

RP-HP was included in the EU Candidate List for authorisation on 15th January 2018, following ECHA's decision ED/01/2018 (<u>ECHA</u>, 2018).

RP-HP was prioritised by ECHA and included in its 9th recommendation (<u>ECHA, 2019a</u>). The following points were noted in the Annex 14 background document (<u>ECHA, 2019b</u>) at that time:

- The EU REACH registration data indicated that RP-HP was manufactured in and/or imported into the EU in quantities of ≥ 10 to < 100 tonnes per year, with all tonnage appearing to be in scope of authorisation.
- Uses in scope of authorisation included uses at industrial sites e.g. formulation of lubricant additives, lubricants and greases, use in lubricants and greases in vehicles and machinery. Use by professional workers and consumers (e.g. in lubricants and greases in vehicles and machinery) were also included.

Defra rationale for prioritising substances in the UK REACH work programme; 2025-2026, available at: https://www.gov.uk/government/publications/uk-reach-rationale-for-prioritising-substances-in-the-uk-reach-work-programme-2025-to-2026

⁸ 'New approach to ensure regulators and regulation support growth, available at 'https://www.gov.uk/government/publications/a-new-approach-to-ensure-regulators-and-regulationsupport-growth

RP-HP with ≥ 0.1% w/w 4-heptylphenol, branched and linear was added to <u>Annex 14 of</u> <u>EU REACH</u> on the 8th April 2022 (<u>Commission Regulation (EU) 2022/586</u>).

It is noted that, at the time of drafting this document, the data available on the ECHA website⁹ indicate that there are no longer any active registrations under EU REACH for the substances identified as having EC numbers 939-460-0 or 300-298-5 or CAS numbers: 1471311-26-8 or 93925-00-9.

3.2 EU authorisations

RP-HP with ≥ 0.1% w/w 4-heptylphenol, branched and linear was added to Annex 14 of EU REACH with a sunset date of 1st May 2025 and latest application date of 1st November 2023.

No applications for authorisation have been published on the ECHA website to date.

3.3 Consideration of regulatory decisions in the EU

HSE is not aware of any applications for authorisation having been submitted to ECHA for this substance. It is also noted that the EU registration data at the time of drafting indicate that there are no active registrations under EU REACH for the substances identified as having EC numbers 939-460-0 or 300-298-5 or CAS numbers: 1471311-26-8 or 93925-00-9. It may be that there is no ongoing use of the substance in the EU, or only use at low tonnages with the level of the relevant constituents below 0.1 % w/w. It is not possible for HSE to confirm.

3.4 Conclusions based on current information held by HSE

HSE does not have any data to suggest that the use profile for RP-HP in GB is different to that in the EU. As noted in Section 3.3, the available data suggest that substitution has already taken place or the level of 4-HPbl reduced to below 0.1% w/w. As such, we would not expect to receive any applications for authorisation if it was added to Annex 14 of UK REACH.

Also, adding RP-HP to Annex 14 of UK REACH may not be the most effective way to manage a concern that is driven by the presence of a constituent (i.e., 4-HPbl). This is particularly because that constituent may also be present in other substances for which use would not be impacted by action targeted at RP-HP alone.

However, including RP-HP [with ≥ 0.1% w/w 4-HPbl] on Annex 14 of UK REACH would provide consistency in decision making and could lead to clarity for those who trade with

⁹ ECHA CHEM; ECHA's public chemicals database (https://chem.echa.europa.eu/).

the EU e.g., by not having to operate dual systems. This could reduce the administrative workload of companies in the chemicals sector or those using chemicals and therefore have positive socio-economic benefits.

HSE is seeking further information on RP-HP and, in particular, GB-specific data on the uses and associated tonnages to help refine this assessment.

4 References

Commission Regulation (EU) 2022/586 of 8 April 2022 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Available at: https://eur-lex.europa.eu/legal-

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ECHA, 2019b. Background document for reaction products of 1,3,4- thiadiazolidine-2,5-dit hione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]. Document developed in the context of ECHA's ninth recommendation for the inclusion of substances in Annex XIV – October 2019. Available at: https://echa.europa.eu/documents/10162/fa57323d-6e4d-a482-1fb8-18fe0aa07bd6

HSE (2025). Agency Technical Report on Reaction Products of 1,3,4-thiadiazolidine-2,5-di thione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP). July 2025. Available at: https://www.hse.gov.uk/reach/assets/docs/technical-report-rp-hp.pdf

5 Declarations

Within this document we have provided links to documents and information found on ECHA's website: https://echa.europa.eu/

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Further information

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