

1 October 2019

Background document for reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear¹]

Document developed in the context of ECHA's ninth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear] is a group entry. Only for the purpose of easier reading, "RP-HP" is used throughout this document when referring to reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear].

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of RP-HP on the Authorisation List or in the registration dossiers² as well as the MSC opinion³ were taken into consideration when finalising the recommendation and are reflected in the present document.

Contents

1. Identity of the substance.....	3
2. Background information for prioritisation.....	3
2.1. Intrinsic properties	3
2.2. Volume used in the scope of authorisation	4
2.3. Wide-dispersiveness of uses.....	4
2.4. Further considerations for priority setting	4
2.5. Conclusion.....	4

¹ The full name of the entry 4-heptylphenol, branched and linear as it is included in the Candidate List is: 4-Heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]

² As of the last day of the public consultation, i.e. 5 December 2018

³ Opinion of the Member State Committee on the draft ninth recommendation of the priority substances to be included in Annex XIV, adopted on 26 June 2019

3. Background information for the proposed Annex XIV entry	4
3.1. Latest application and sunset dates.....	5
3.2. Review period for certain uses.....	5
3.3. Uses or categories of uses exempted from authorisation requirement	5
4. References.....	7
Annex I: Further information on uses	8

1. Identity of the substance

Identity of the substance as provided in the Candidate List⁴:

Name: Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear]
EC Number: -
CAS Number: -

The supporting documentation for the identification of the substances as SVHC contains a non-exhaustive list of substances that are covered by this group entry⁵.

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation⁶. Results of the prioritisation of all substances included in the Candidate List by January 2018 and not yet included or recommended in Annex XIV of the REACH Regulation are available at

https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

The prioritisation results of the substances included in the draft 9th recommendation have been updated as necessary after the public consultation. The updated results are available at

https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft9threc_substances_October2019_en.pdf.

2.1. Intrinsic properties

4-Heptylphenol, branched and linear¹ were identified as Substances of Very High Concern in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because they are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH.

Based on the above, reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear with $\geq 0.1\%$ ⁷ w/w 4-heptylphenol, branched and linear¹ (RP-HP), were likewise identified as substances meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because they are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. Therefore, RP-HP were included in the Candidate List for authorisation on 15 January 2018, following ECHA's decision ED/01/2018.

⁴ For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

⁵ Non-exhaustive list of numerical identifiers: <https://echa.europa.eu/documents/10162/b33d78f4-946c-1d4d-e923-1ade7869c464>

⁶ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

⁷ Ref. to REACH, Article 56(6)a

2.2. Volume used in the scope of authorisation

The amount of RP-HP manufactured and/or imported into the EU is according to registration data (ECHA, 2018) in the range of 10-100 t/y.

All tonnage appears to be in the scope of authorisation.

2.3. Wide-dispersiveness of uses

Registered uses of RP-HP in the scope of authorisation include uses at industrial sites (e.g. formulation of lubricant additives, lubricants and greases, use in lubricants and greases in vehicles and machinery). The substances are also used by professional workers and consumers (e.g. in lubricants and greases in vehicles and machinery).

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

None.

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
RP-HP has endocrine disrupting properties with effects to the environment meeting the criteria of Article 57 (f) Score: 7	The amount of RP-HP used in the scope of authorisation is in the range 10 - 100 t/y. Score: 6	RP-HP is used at industrial sites, by professional workers and by consumers. Score: 15	28

Conclusion

On the basis of the prioritisation criteria RP-HP receive priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, RP-HP are recommended for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV⁸ and as further specified

⁸ General approach can be accessed at

in the practical implementation document⁹. The draft Annex XIV entries for all the substances that underwent public consultation are available at https://www.echa.europa.eu/documents/10162/13640/9th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf.

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for RP-HP:

Latest application date (LAD):	Date of inclusion in Annex XIV plus 21 months
Sunset date:	18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the “later” LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

ECHA made the final LAD allocation using all available relevant information including that received in the public consultation.

A summary of the information available is provided in Annex I.

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for RP-HP.

During the public consultation ECHA did not receive comments requesting upfront review period for specific uses.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of RP-HP.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for (categories of) uses of RP-HP on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

⁹ Practical implementation document can be accessed at

https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

During the public consultation ECHA did not receive any requests for exemptions for the substances.

ECHA therefore does not recommend exemptions for uses of RP-HP on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2 Exemption of product and process oriented research and development (PPORD)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of RP-HP for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substances.

No PPORD notifications had been submitted by the end of public consultation.

ECHA therefore does not recommend exempting any use of RP-HP for PPORD from authorisation.

4. References

Annex XV SVHC report (2017): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptyl-phenol, branched and linear [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear] ("RP-HP"). Submitted by Austria, August 2017.

<https://echa.europa.eu/documents/10162/5b061aeb-96d7-7e21-16df-5b976b233cd0>

ComRef (2019): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 5/09/2018 – 5/12/2018 on ECHA's proposal to include reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptyl-phenol, branched and linear [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear] ("RP-HP") in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_comref_rp-hp_en.rtf

ECHA (2018): Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptyl-phenol, branched and linear [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear] ("RP-HP"). ECHA's dissemination website on registered substances. Accessed on 5 December 2018.

<https://echa.europa.eu/search-for-chemicals>

RCOM (2019): "Responses to comments" document. Document compiling the responses to comments from commenting period 5/09/2018 – 5/12/2018 on ECHA's proposal to include reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptyl-phenol, branched and linear [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear] ("RP-HP") in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_rp-hp_en.pdf

Annex I: Further information on uses

Further details on the type of applications and functions

According to registrations, RP-HP are used industrially and by professionals in lubricants and greases in vehicles or machinery including filling and draining of containers. The lubricant is also applied to work pieces or equipment (by dipping, brushing or spraying), e.g. mould release agent, corrosion protection, slide ways. The consumer use of lubricants and greases in vehicles and machinery takes place in open systems.

No more detailed information on the types of industry branches using RP-HP is available. Besides the automotive industry, a wide range of industry branches using machinery may be concerned. Numerous gear oils containing RP-HP in concentrations up to 2.5% have been identified via web search (Annex XV SVHC report, 2017).

The presence of 4-Heptylphenol, branched and linear in consumer products has been verified by chemical analyses by the Environment Agency Austria (unpublished data) in nine out of ten gear oils purchased via internet. It is important to note that apart from environmental exposure resulting from the end uses, there is additional concern due to the environmental exposure during the formulation of lubricant additives and lubricants (Annex XV SVHC report, 2017).

According to the Substances in Preparations in Nordic Countries database (SPIN)¹⁰ the substance is used in e.g. repair of motor vehicles and motorcycles and manufacture of motor vehicles, trailers and semi-trailers. The function is described as gear oil, hydraulic oil, engine oil or lubricating grease.

Structure and complexity of supply chains

The following assumptions were made to allocate the substance to a specific LAD slot.

RP-HP are manufactured/imported by a limited number of registrants. The formulation into lubricant additives, lubricants and greases takes place within the EU. The number of formulation steps until the production of the final products is unknown. No information on the number, diversity, and spatial distribution of the actors of the supply chain is available (Annex XV SVHC report, 2017). No precise and up-to-date information is available on the number of industrial sites where the substances is currently used.

The supply chain can be characterised¹¹ by the following actors: formulators, users at industrial sites, professional workers, consumers (relevant life cycle stages: F, IS, PW, C).

RP-HP seems to be mainly used in the following Product Category: Lubricants, greases, release products (PC24).

It appears that there are potentially many sectors of end uses relevant. The only sector of use category currently given in registrations is SU0: Other 22 (public domain (administration, education, entertainment, services, craftsmen)). However, a wide range of industry sectors can be assumed (more than five).

¹⁰ SPIN database can be found at <http://spin2000.net>

¹¹ Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description:
https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

Some of the categories mentioned are not explicitly reported in registrations but could be derived from use descriptions in registration dossiers, information from the Annex XV SVHC report (2017) and from the SPIN database.