5 September 2018

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

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-heptyl-phenol, branched and linear [with ≥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-heptyl-phenol, branched and linear [with ≥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 dossiers (as of the last day of the public consultation, i.e. 5 December 2018) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

[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*]

1. Identity of the substance

Identity of the substance as provided in the Candidate List[2]:

Name:	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear [with ≥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 entry[3].

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 authorisation[4]. 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 is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

2.1. Intrinsic properties

4-Heptylphenol, branched and linear[1] 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 ≥0.1%[5] w/w 4-heptylphenol, branched and linear[1] (**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.

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.

[2] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[3] Non-exhaustive list of numerical identifiers: https://echa.europa.eu/documents/10162/b33d78f4-946c-1d4d-e923-1ade7869c464
[4] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[5] Ref. to REACH, Article 56(6)a

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, it is proposed to prioritise RP-HP for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the public consultation. ECHA will apply the Annex XIV entries approach[6] and the criteria described in the implementation document[7]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

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

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 9th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for RP-HP.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to 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.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

[6] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[7] Practical implementation document can be accessed at https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[8]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[9], there is no need to propose an additional specific exemption.

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

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of RP-HP for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for RP-HP[10].

[8] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/b80fccc0-c055-7cd7-4743-8d3c26956b15, or in section C.2 in https://echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375

[9] https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

[10] As of 1 February 2018.

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 (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]. Submitted by Austria, August 2017.

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

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

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

RCOM (2017): "*Responses to comments*" document. Document compiled by Austria from the commenting period 05/09/2017 – 20/10/2017 on the proposal to identify reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptyl-phenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear] as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/896de311-33b2-0ea3-8750-71fcf5d3572e

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. as 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)[11] 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 are made based on currently available information and will be used, together with any relevant information from public consultation, to allocate RP-HP to a specific LAD slot in the final recommendation.

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 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 characterised[12] 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, however currently the information is missing to identify them. Therefore, the only relevant sector of use category assigned is SU0: Other (industrial manufacturing and public domain).

[11] SPIN database can be found at http://spin2000.net
[12] 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.