

## COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFICATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS

**Substance name:** 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 linear]

**CAS number:** -

**EC number:** -

**The substance is proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH**

**Regulation:** Endocrine disrupting properties (Article 57(f) – environment)

***Disclaimer:** Comments provided during public consultation are made available as submitted by the commenting parties. It was in the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a substance of very high concern. RCOM has not been agreed by the Member State Committee nor has the document been modified as result of the MSC discussions.*

### PART I: Comments and responses to comments on the SVHC proposal and its justification

#### General comments on the SVHC proposal

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
4945 2017/10/27	Finland, Member State	The Finnish CA supports the proposal to identify 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 linear (4-HPbl)] as a substance of very high concern having probable serious effects to the environment according to REACH Article 57(f). However, we note that another substance "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" is already included in the candidate list. Could this entry also cover the substance RP-HP?	Thank you for your support and your comments.  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 linear (4-HPbl)] are not covered by the candidate list entry for "4-heptylphenol, branched and linear" due to their substance identities that are different from the entry for 4-HPbl. In fact the name "Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear" refers to the result of the reaction of 4-

		<p>The support is based on a weight-of-evidence approach taking into account read-across to other alkylphenols (nonyl- and octylphenol) previously identified as SVHCs based on endocrine disrupting properties to the environment and on the precautionary principle, and on the fact that the constituent 4-HPbl has already been identified as an SVHC having endocrine disrupting properties to the environment and included in the candidate list.</p> <p>Nevertheless, the Finnish CA still has concerns on the reliability of the key study for 4-n-heptylphenol (Demska-Zakęś, 2005), as stated in the minutes of the MSC-51 meeting, and considers that the reliability is not possible to assign due to limitations in the study design and in its documentation. Based on the properties of the substance, it is expected that maintenance of test substance concentrations in the test medium is challenging. However, only nominal concentrations are available. No raw data is available (number of males, female, intersex in individual replicates) and details on histological determinations are missing. The number of replicates used in the study (2 or 3) is unclear. Therefore, the FI CA considers that the results from the study can be used only as supporting evidence.</p> <p>-</p>	<p>heptylphenol, branched and linear with two other starting materials.</p> <p>The concerns of the Finnish CA are noted. However, detailed arguments for the validity of the study by Demska-Zakęś (2005) have already been provided during public consultation of the SVHC identification process for 4-HPbl (see RCOM Document <a href="https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e180e22869">https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e180e22869</a>) and have been discussed during MSC-51 (see minutes <a href="https://echa.europa.eu/documents/10162/22837890/msc-51_minutes_en.pdf/9a506e8a-5e7d-80ed-0e6f-6ef8aa65a0de">https://echa.europa.eu/documents/10162/22837890/msc-51_minutes_en.pdf/9a506e8a-5e7d-80ed-0e6f-6ef8aa65a0de</a>) based on the detailed study explanations given in Annex II of the support document for 4-HPbl, that had been agreed during MSC-51 (support doc 4-HPbl: <a href="https://echa.europa.eu/documents/10162/f3dba6ab-8dd8-2457-4213-2f390b0539f1">https://echa.europa.eu/documents/10162/f3dba6ab-8dd8-2457-4213-2f390b0539f1</a>)</p>
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### Specific comments on the justification

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
4861 2017/10/19	ChemSec, International NGO, Sweden	ChemSec supports the inclusion of this substance to the REACH Candidate List, based on its endocrine disrupting properties in the environment.	Thank you for your support.
4870 2017/10/20	Germany, Member State	The German CA supports the Annex XV dossier and the identification of the 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 linear] as SVHC substance.	Thank you for your support.

4878 2017/10/20	Norway, Member State	The Norwegian CA supports that 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 linear] should be identified as a substance of very high concern due to endocrine disruptor effects in the environment and should be included in the Candidate List.	Thank you for your support.
4884 2017/10/20	ANSES, National Authority, France	Heptylphenol, branched and linear (HPbl) has been identified as an SVHC due to its endocrine disruptive properties which cause probable serious effects to the environment. RP-HP contains HPbl above 0.1%. On this basis, the identification of RP-HP as an SVHC fulfilling article 57(f) due to its endocrine properties relevant for environment is supported for the following entry: RP-HP [with $\geq 0.1\%$ w/w 4-heptylphenol, branched and linear] .	Thank you for your support.
4897 2017/10/20	United Kingdom, Member State	<p>We thank the Austrian CA for the dossier on RP-HP and have the following comments.</p> <p><b>Identity</b> We understand that this proposed group entry covers UVCB substances containing 3 specific reaction products, 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear(4-HPbl), only if the level of 4-HPbl is <math>\geq 0.1\%</math> w/w (4-HPbl already being on the candidate list). We note that currently there is one registration using the identifiers 'Reaction product of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and phenol, heptyl derivs'. However the dossier indicates that other identifiers 'Formaldehyde, reaction products with branched and linear heptylphenol, carbon disulfide and hydrazine (EC No 300-298-5, CAS 93925-00-9) have been used previously – if similar UVCB substances are registered using the latter identifiers (there are 472 CLH notifications) they won't be covered by the proposed group entry. Have AT considered this?</p> <p><b>Proposed SVHC properties</b> This section appears to be largely copied over from the original supporting document for listing of the 4-HPbl as an SVHC. We do not feel it is necessary to include and consider this information all over again in the Report for RP-HP if the sole reason for this substance being listed is due to 4-HPbl as a component/impurity. The agreed Candidate Listing of 4-HPbl (from January 2017) stands by itself and the reasoning for it does not need</p>	<p>Thank you for your comments.</p> <p><b>Identity</b> The identifier "Formaldehyde, reaction products with branched and linear heptylphenol, carbon disulfide and hydrazine (EC No 300-298-5, CAS 93925-00-9)" had been used by the registrant of the 'Reaction product of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and phenol, heptyl derivs' prior to that registration. The identification and naming of the substance had been reviewed by the registrant during the registration process and changed. So, both reaction products are the same materials. It is now stated more clearly in the support document, that also the previously used description of the reaction product is covered by the entry.</p> <p><b>Proposed SVHC properties</b> The text taken from the support document for identification of 4-HPbl came from the version that had been unanimously agreed on in MSC-51. However, as the agreed Candidate Listing of 4-HPbl (from January 2017) stands by</p>

		to be repeated again. This is particularly the case since the original text included in relation to 4-HPbI includes a number of things which we previously commented on or disagreed with at the EDEG and during written commenting and MSC discussions on 4-HPbI. The text appears not to have been revised or updated to take account of these. We can provide a list of these comments again if necessary, however the easiest option would be to remove most of the detailed reasoning for 4-HPbI and instead just refer to its presence as a component or impurity in RP-HP at $\geq 0.1\%$ w/w.	itself, a link to the support document for 4-HPbI is sufficient. The quoted text has therefore been deleted.
4931 2017/10/20	Belgium, Member State	Belgium supports the proposal to identify "RP-HP with 0.1% w/w 4-HPbI" as SVHC, based on article 57(f) of the REACH Regulation due to the endocrine disrupting properties of 4-HPbI	Thank you for your support.
4934 2017/10/20	CHEM Trust, National NGO, United Kingdom	CHEM Trust supports the inclusion of 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 linear (4-HPbI) in the REACH candidate list based on the presented case by the dossier submitter. 4-heptylphenol, branched and linear, has already been identified as a group of substances with endocrine disrupting properties according to article 57 f and been included in the candidate list. Therefore, 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 linear, shall likewise be identified as substances of very high concern due to their ED properties.	Thank you for your support.

## PART II: Comments and responses to comments on uses, exposures, alternatives and risks

### Specific comments on use, exposure, alternatives and risks

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
4897 2017/10/20	United Kingdom, Member State	Please refer to our general comment above. We do not feel it is necessary to re-present in Part II Section 6.3 all of the original detailed reasoning for listing of 4-HPbI as a Candidate SVHC since this had already been agreed and that decision can simply be referred to. Instead reference is just required to its presence as a component or impurity in RP-HP at $\geq 0.1\%$ w/w.	Please see response to your comment above.