

AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION 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]
AS SUBSTANCES OF VERY HIGH CONCERN

According to Articles 57 and 59
of Regulation (EC) 1907/2006¹

Adopted on 30 November 2017

This agreement concerns

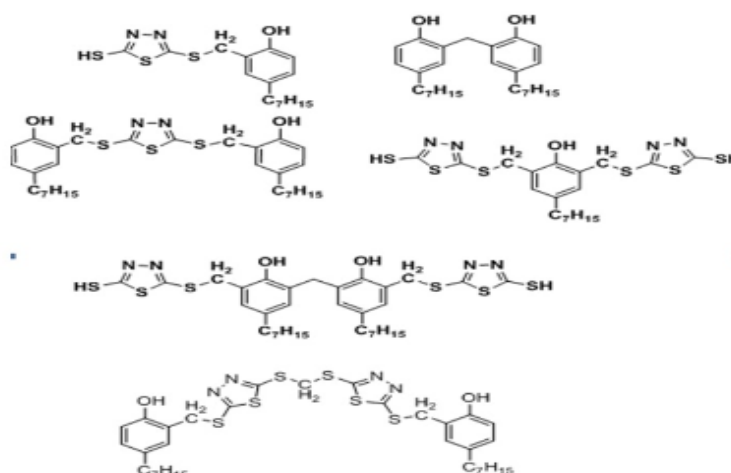
Substance name: Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP)²

EC/CAS numbers: -

Molecular formula: -

Structural formula:

(idealised structure³)



¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

² The full name of the entry as proposed for the Candidate List is: 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]

³ More details in the Support document.

Austria presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (29 August 2017, submission number SPS-013570-17) on identification of *Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP)*⁴ as substances of very high concern due to their 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 paragraphs (a) to (e) of Article 57 of REACH.

The Annex XV dossier was circulated to Member States on 5 September 2017 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 20 November 2017 and agreed in the written procedure of the Member State Committee with closing date of 30 November 2017.

Agreement of the Member State Committee in accordance with Article 59(8):

*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]* are identified as substances of very high concern 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 paragraphs (a) to (e) of Article 57 of REACH Regulation.

⁴ The full name of the entry as it is proposed for the Candidate List is: 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]

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN

Endocrine disrupting properties – Article 57(f):

The Member State Committee at its 51st meeting unanimously agreed that 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] meets the criteria set out in Article 57(f) of REACH⁵. The reasoning is laid down in the “Member State Committee support document for identification of 4-heptylphenol, branched and linear (4-HPbl) as a substance of very high concern because of its endocrine disrupting properties which cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB substances”, adopted on 14 December 2016⁶. ECHA has included 4-HPbl in the Candidate List for eventual inclusion in Annex XIV⁷.

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, are likewise identified as substances of very high concern due to their endocrine disrupting properties to the environment.

In summary, RP-HP are considered to give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH.

Conclusion: Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear with $\geq 0.1\%$ w/w of 4-heptylphenol, branched and linear, are 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 gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH.

Reference:

Support Document (Member State Committee, 30 November 2017)

⁵ <https://echa.europa.eu/documents/10162/843b45f2-fc7d-5a41-a1fd-fda3adb4db59>

⁶ <https://echa.europa.eu/documents/10162/f3dba6ab-8dd8-2457-4213-2f390b0539f1>

⁷ Decision of the European Chemicals Agency on the Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV:
<https://echa.europa.eu/documents/10162/0f8c5cf3-ccb7-3df6-c351-1c2df00cbc91>