

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

Substance name: 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone

CAS number: 119313-12-1

EC number: 404-360-3

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

Regulation: Toxic for reproduction (Article 57c)

***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.*

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

Specific comments on the justification

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5326 2019/10/09	ChemSec, International NGO, Sweden	ChemSec agrees to inclusion of this substance to the Candidate List based on it being officially classified as a reprotoxic chemical 1b.	Thank you for your support.
5331 2019/10/11	Health and Environment Alliance (HEAL), International NGO, Belgium	The Health and Environment Alliance (HEAL) thanks Austria and Slovakia for proposing the identification of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone as SVHC based on article 57(c) and fully supports this identification. Considering the existing classification as toxic to reproduction 1B under the CLP regulation (regulation 1272/2008), we consider the proposed SVHC identification unequivocal.	Thank you for your support.

5336 2019/10/17	CHEM Trust Europe, National NGO, Germany	CHEM Trust supports the inclusion of 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone in the REACH candidate list owing to its classification as reproductive toxicant 1B which fulfills the criterion of article 57 c).	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
5336 2019/10/17	CHEM Trust Europe, National NGO, Germany	The dossier includes important information on potential alternatives, highlighting that several potential replacements are structurally very similar. This means that any future regulatory approach should include a relevant grouping approach to avoid a replacement of one reprotoxic chemical with potentially other harmful ones.	Thank you for your remark, which is noted.
5355 2019/11/04	Germany, Member State	Table 7: In order to get a detailed description of the use, we would suggest to provide more information about the use and way of application by including the PROC as well.	Thank you for your remark. The following PROCs have been indicated by the registrants according to ECHA website (https://echa.europa.eu/de/information-on-chemicals/registered-substances/-/disreg/substance/100.100.600) Formulation: PROCs 1, 2, 3, 5, 8a, 8b, 9, 15, 19, 22,

			<p>24, 27a, 27b Uses at industrial sites: PROCs 0, 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 15, 19, 21, 24, 25 Uses by professional workers: PROCs 0, 5, 8a, 10, 11</p> <p>Please note that at this stage of the process of SVHC identification changes to Part II of the Annex XV Report are not foreseen. However, information regarding use, exposure, alternatives and risks will, when relevant, be considered at later stages of the risk management process.</p>
--	--	--	---