

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

Disclaimer: Comments provided during the 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.

Substance name: 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one

CAS number: 119344-86-4

EC number: 438-340-0

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)

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
5783 2023/10/16	Company, Netherlands	Inks are fed in the printing machine manually, all emissions from the equipment are locally captured and extracted, during maintenance adequate PPE are worn , no emission to water are expected since all liquid waste are treated externally	Thank you for this information on use and exposure. It is not directly related to the SVHC identification stage and will, when relevant, only be

			considered in the next steps of the authorisation process
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Specific comments on the justification

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5756 2023/09/27	Norway, Member State	The Norwegian CA supports that 2-(dimethylamino)-2-[(4-methylphenyl)-methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one should be identified as a substance of very high concern and should be included in the Candidate List.	Thank you for your support.
5774 2023/10/11	Health and Environment Alliance (HEAL), International NGO, Belgium	The Health and Environment Alliance thanks the Austrian competent authorities for their proposal to identify 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one as substance of very high concern (SVHC) under REACH article 57(c), which we fully support. In view of the upcoming inclusion of the substance in the 22nd ATP to Regulation 1272/2008 as a reprotoxicant 1B with the hazard statement H360Df "May damage the unborn child. Suspected of damaging fertility", we consider that the identification as a SVHC under REACH article 57(c) is unequivocal.	Thank you for your support.
5788 2023/10/16	Netherlands, Member State	NL supports the proposal to include 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one in the candidate list of SVHC in accordance with Article 57 (c) of Regulation (EC) No 1907/2006 (REACH).	Thank you for your support.
5797 2023/10/16	ChemSec, International NGO,	ChemSec supports the identification of the substance as an SVHC as it has been agreed to be classified as toxic to reproduction by RAC.	Thank you for your support.

	Sweden		
5801 2023/10/16	Germany, Member State	The German CA thanks the AT CA for preparing this SVHC proposal. We support the identification of 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one as toxic for reproduction category 1B.	Thank you for your support.
5807 2023/10/16	ANSES, National Authority, France	Considering that the substance will be covered by index number 606-158-00-2 of Regulation (EC) No 1272/2008 in Annex VI and it will be classified toxic for reproduction category 1B (H360D), the identification SVHC under article 57c is justified. Anses support the identification of the Substance as SVHC under article 57 (C) of REACH regulation.	Thank you for your support.
5821 2023/10/16	CHEM Trust Europe, International NGO, Germany	CHEM Trust supports the inclusion of 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one in the REACH candidate list due to its reprotoxic properties, based on article 57 (c). It will be important to follow up swiftly with risk management measures, ideally targeting the whole group of photoinitiators from the alkylaminoacetophenones (AAAPs).	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
5766 2023/10/10	Food Packaging Forum Foundation, International NGO, Switzerland	The Food Packaging Forum (FPF) is a charitable, science-based organization at the science policy interface dedicated to raising awareness for hazardous chemicals in, and environmental impacts caused by, all types of food contact materials and articles (FCMs). As our expertise is mainly on chemicals in food packaging, we	Thank you for providing additional

	<p>focus our remarks on this aspect to provide context on any follow-up to the listing of 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one as an SVHC Candidate.</p> <p>2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one has been measured in food contact materials. We found evidence from four studies demonstrating the presence of 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one in migrates from FCMs or that have been directly extracted from food packaging or other food contact articles (Geueke et al., 2022). These four studies measured the chemical under consideration in aluminum, multi-material, paper/board, multilayer plastic, polypropylene (PP), and polystyrene (PS) food contact materials.</p> <p>The studies in question were published between 2012 and 2016, including a study from the German government, which demonstrates relatively recent potential consumer exposure to this chemical that the authorities in Austria have concluded is toxic for reproduction.</p> <p>Concerns for EU FCM safety</p> <p>As of October 10, 2023, 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one is not included in Annex 1 of EU 10/2011 on plastic materials and articles intended to come into contact with food. Yet, as mentioned above, it is still found in plastic and other types of food packaging. REACH demands the substitution of SVHCs by safer alternatives in industrial products, processes, and in consumer articles solely based on their intrinsic hazard properties, not based on their risk (where both hazard properties and exposure levels would be taken into account). Authorization under REACH can be granted for specific uses and time periods in case the applicant demonstrates that the risk from using the substance is adequately controlled. Alternatively, the applicant can show that socio-economic benefits of using the substance outweigh the risks and that there are no suitable alternative substances or technologies. However, the human health effects of FCMs are excluded from the REACH authorization process. A stricter ban of SVHCs from all possible areas of use, including FCMs, would further reduce the overall burden of these chemicals, facilitate compliance with Article 3 of the FCM Framework Regulation and help to improve public health.</p>	<p>information on the presence of the photoinitiator in food packaging or other food contact articles. As this information is not directly related to the SVHC identification stage it will, when relevant, only be considered in the next steps of the authorisation process.</p>
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		<p>Thank you for the chance to provide input into the consideration of candidate SVHCs.</p> <p>Best regards, FPF staff</p> <p>Studies detecting 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one in FCMs Stuttgart, Chemisches und Veterinäruntersuchungsamt. (2012). Ausmaß der Migration von Druckfarbenbestandteilen aus Verpackungsmaterialien in Lebensmittel. BLE. Retrieved from https://service.ble.de/ptdb/index2.php?detail_id=20498&site_key=141&stichw=09HS007&zeilenzahl_zaeher=1&pId=20498&dId=116610</p> <p>Lago, M. A., & Ackerman, L. K. (2016). Identification of print-related contaminants in food packaging. <i>Food Additives & Contaminants: Part A, Chemistry, Analysis, Control, Exposure & Risk Assessment</i>. https://doi.org/10.1080/19440049.2015.1136435</p> <p>Bentayeb, K., Ackerman, L. K., Lord, T., & Begley, T. H. (2013). Non-visible print set-off of photoinitiators in food packaging: detection by ambient ionisation mass spectrometry. <i>Food Additives & Contaminants: Part A, Chemistry, Analysis, Control, Exposure & Risk Assessment</i>. https://doi.org/10.1080/19440049.2012.762694</p> <p>Crespo, M. Á. L. (2016). Printing inks for food packaging: study of the key parameters in the migration of photoinitiators (Doctoral dissertation). Retrieved from https://minerva.usc.es/xmlui/handle/10347/14928</p> <p>Other</p> <p>Geueke B, Groh KJ, Maffini MV, Martin OV, Boucher JM, Chiang Y-T, Gwosdz F, Jieh P, Kassotis CD, Łańska P, Myers JP, Odermatt A, Parkinson LV, Schreier VN, Srebny V, Zimmermann L, Scheringer M and Muncke J (2022) Systematic evidence on migrating and extractable food contact chemicals: Most chemicals detected in food contact materials are not listed for use. <i>Critical Reviews in Food Science and Nutrition</i>, 1-11. https://doi.org/10.1080/10408398.2022.2067828.</p> <p>Geueke, B., Wagner, C., and Muncke, J. (2014) Food contact substances and</p>	
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		chemicals of concern: a comparison of inventories, Food Additives & Contaminants: Part A, 31:8, 1438-1450, DOI: 10.1080/19440049.2014.931600 Geueke, B., and Muncke, J. (2018) Substances of Very High Concern in Food Contact Materials: Migration and Regulatory Background. Packag. Technol. Sci., 31: 757–769. https://doi.org/10.1002/pts.2288 .	
5783 2023/10/1 6	Company, Netherlands	Substance cas 119344-86-4 is identified as a component of ink used in UV printing process. The inks are specifically used to print on polymer surfaces (PVC or ABS) , cured in UV curing oven and covered by a special transparent varnish and/or a specific plastic layer (PVC). Main use is for smart cards printing (Sim card, bank card, ID card) Current use is evaluated in 10 kg/y for a final weight on the card of 0,2 ppm for 50M cards/year This use will cover almost the 75% of the total manufacturing of a smart card manufacturing location Printing process is highly automated, exposure to workers is controlled, all liquid waste are sent for external waste treatment, air emissions from the printing process are treated and regularly monitored The substance is present in all major inks, at present no supplier is able to propose alternative free of the substance	Thank you for this information on use, alternatives and exposure. It is not directly related to the SVHC identification stage and will, when relevant, only be considered in the next steps of the authorisation process.