Risk Management Option Analysis Conclusion Document

Substance Name: (1-methyl-1,2-ethanediyl) bis[oxy(methyl-2,1-ethanediyl)] diacrylate

EC Number: 256-032-2

CAS Number: 42978-66-5

Authority: Swedish Chemicals Agency

Date: 12 July, 2017

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

TPGDA has a Harmonised Classification in Annex VI of the CLP legislation (EC) No 1272/2008.

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
607-249-00-X	(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)] diacrylate	256-032-2	42978-66-5	Skin Irrit. 2 Skin Sens. 1 Eye Irritant 2 STOT SE 3 Aquatic Chronic 2	H315 H317 H319 H335 H411	STOT SE 3; H335: C ≥ 10%	

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	No
Harmonised classification and labelling	-
Identification as SVHC (authorisation)	-
Restriction under REACH	-
Other EU-wide regulatory measures	-
Need for action other than EU regulatory action	No
No action needed at this time	Yes

3. NO ACTION NEEDED AT THIS TIME

Harmonised Classification and Labelling: TPGDA has a harmonized classification as Skin Sens. 1 which requires that products containing ≥ 0.1 % TPGDA are labelled. The overall available animal data indicate that TPGDA is a potent sensitiser that may be classified as Skin Sens. 1A. This is further supported by evidence from a cross-sectional work-place study. Updating the classification to Category 1A would enforce labelling of products containing ≥0.01% TPGDA and would potentially allow workers to avoid lower levels of TPGDA than what is currently possible. However, data from the Swedish product register indicate that the large majority of the products on the market contain ≥ 0.1 % TPGDA and are thus already subject of labelling requirements according to CLP. Hence, the risk reducing effects from an updated classification are likely to be minor. It has been suggested that changing the classification to Skin Sens. 1A would facilitate more transparent communication that TPGDA is a strong sensitiser and may allow further decision making by the industry to move to less potent skin sensitizers. The Swedish Chemicals Agency agrees but considers that the time and effort to produce a CLH-proposal is not proportional to the reduction of risk. Hence, at the moment we have no intention to propose a harmonized classification as Skin Sens. 1A for TPGDA.

Identification as SVHC for inclusion on the Candidate list: Identification of SVHC under Reach article 57(f) must include an assessment of whether the substance is of equivalent level of concern (ELoC) to CMR substances category 1A/1B. ECHA's general approach paper[2] for identification of SVHC under article 57(f) can be used as support in

[2] "Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example": http://echa.europa.eu/documents/10162/13657/svhc_art_57f_sensitisers_en.pdf

the ELoC assessment taking the factors described below into account. These ELoC factors should be considered together in one package, rather than making comparisons one factor at a time. The table below gives an overview of the ELoC assessment for 2-EHA including the ELoC factors described in ECHA's general approach.

Table. Overview and conslusions of the ELoC assessmen for TPGDA

ELoC factor	**Available evidence to justify ELoC to CMR-substances**
Possible serious health effects?	Yes: The overall data from animals indicate that TPGDA has a strong skin sensitising potency. This is supported by human evidence from one work-place study. Aside from that, there is one reported case that we consider as severe, involving exudative lesions and scaling of the skin that required medical care and treatment with glucocorticoids.
Irreversibility of health effects?	Yes: TPGDA can cause irreversible contact allergy.
Delay of health effects?	Yes: Contact allergy is per se a delayed health effect. One case report describe a patient that were exposed to TPGDA for two years before seeking medical care.
Is derivation of a 'safe concentration' possible?	No: It was not possible to derive an EC3 value for TPGDA from the available studies. Hence, a threshold for sensitisation could not be derived.
Quality of life impaired?	Likely: TPGDA can cause occupational allergic contact dermatitis which is generally associated with a negative impact on quality of life. The two case reports on TPGDA we found describe that the patients had to change work routines to avoid the allergen. Given the strong potency of TPGDA and reports of adverse effects following occupational exposures. It can be assumed that affected individuals experience a negative impact on quality of life.
Societal concern?	Uncertain: There are no reliable data describing how common occupational contact dermatitis to TPGDA is in the EU.

In conclusion, the Swedish Chemicals Agency considers that the available evidence demonstrate that TPGDA is of equivalent level of concern to CMR substances category 1A/1B and fulfil the SVHC Roadmap to 2020 criteria.

Restriction under REACH: There is evidence that TPGDA has the potential to cause allergic skin reactions in humans. However, there are no reliable data describing how common contact dermatitis to TPGDA is in the EU. It is therefore not possible to accurately estimate the societal costs from contact allergy to TPGDA. Thus, there is no *prima facie* evidence that the current uses TPGDA pose an unacceptable risk which has to be addressed by a ban on an EU-wide basis.

EU workplace health and safety legislation: The EU directives for occupational health and safety only mention substitution of substances with other hazardous properties than CMR to safer alternatives in general terms [3]. We believe that REACH is more efficient to achieve substitution of hazardous substances at the work-place because it enables EU wide regulations of specific hazardous compounds.

The Directives for Indicative Occupational Exposure Limit Values include IOELs for four

[3] The Chemical Agents Directive (98/24/EC) and the Carcinogens and Mutagens Directive (2004/37/EC).

skin sensitising acrylates (n-butyl acrylate, methyl methacrylate, methylacrylate and ethylacrylate). However, these air levels have not been set in order to protect against skin exposure. Setting an IOEL for TPGDA would therefore most likely not be an efficient means to minimize allergic skin reactions to TPGDA at the work place.

Overall conclusion: Contact allergy from exposure to potent (meth)acrylates such as TPGDA is a problem that may call for regulatory action. However, it is currently not clear how to best manage the risk of skin sensitising substances under REACH. The available data show that TPGDA is a potent skin sensitiser with the capacity to cause serious and irreversible health effects in humans. In our view, TPGDA can be considered to be of equivalent level of concern to CMR 1A/1B substances and therefore be subject to SVHC identification. However, in light of a previous case where the European Commission and the Member States decided not to identify the potent skin sensitizer hexamethylene diacrylate (HDDA) as an SVHC primarily because there were no reported cases of permanent skin damage in humans[4], we do not anticipate that identification of TPGDA as an SVCH is likely. Further discussions among Member States and the Commission will hopefully lead to useful new insight or practice so that further work to regulate TPGDA based on its skin sensitising properties could be initiated. Since meth(acrylates) are structural analogues with possibly similar technical and toxicological profiles and also for which cross-reactivity may be an issue, it might be a good option that the future needs and possibilities for risk reducing measures for TPGDA are addressed in a wider scope. At the moment, the Swedish Chemicals Agency takes no further action on TPGDA.

[4] Commission Implementing Decision (EU) 2016/2091