Risk Management Option Analysis Conclusion Document

Substance Name: Tetraglyme
Bis(2-(2-methoxyethoxy)ethyl)ether

EC Number: 205-594-7

CAS Number: 143-24-8

Authority: Austria

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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

RMOA	☒ Risk Management Option Analysis (RMOA) - this assessment, Austria, May 2020	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restriction	☐ Annex XVII
Harmonised C&L	☒ Annex VI (CLP) - completed, RAC opinion adopted (06/2018), inclusion in CLP regulation is expected with next (15th) ATP	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes/ EU legislation	☐ Other (provide further details below)	

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:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	x
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

Tetraglyme has a harmonized classification as Repr 1B, H360FD (RAC opinion adopted). It is manufactured and used in the EU in medium tonnages (100-1000 tpa).

Tetraglyme is registered for uses as solvent for synthesis and extractions, gas absorption liquid, processing aid, solder flux, functional fluid and in inks. The registrations cover industrial and professional uses. Consumer uses were not registered.

There are several uses with high potential for exposure. The Austrian CA does not fully agree with the DNEL derivation by registrants, with the consequence that their might occur certain uses with RCRs close to one or even somewhat higher.

3.1 Identification as a substance of very high concern, SVHC (first step towards authorisation)

While in the discussion on SVHC identification, it is sometimes proposed that the setting of an OEL would be the more appropriate alternative, this RMOA comes to the conclusion that in the absence of general criteria - agreed at EU level - favouring the establishing of an OEL and for the reasons explained in the following paragraphs, authorisation is the best possible option for tetraglyme.

Tetraglyme fulfils the SVHC Roadmap 2020 criteria that have been defined for selecting substances that are relevant for identification as SVHC and thus it is desirable to substitute these substances on a long-term perspective.

Tetraglyme has a harmonized classification as Repr 1B, H360FD (RAC opinion adopted). It is registered in accordance with Article 10 of the REACH Regulation at medium tonnages with wide dispersive uses within the scope of authorisation. The substance is used as solvent and in functional fluids.

Tetraglyme belongs to the group of ethylene glycol ethers. The similarity in structure, technical function and uses between group members allows for the conclusion that substitution between them seems possible. Ethylene glycol ethers with longer initial alkoxy groups do not show reproductive toxicity and therefore could be promising candidates for alternative substances. In addition, several groups of substances have been identified, that have the potential to serve as suitable alternatives to tetraglyme.

The similar substances mono-, di- und triglyme (EC 203-794-9, EC 203-924-4, EC 203-977-3) are included in the candidate list. Diglyme is already included in Annex XIV. Tetraglyme might serve as an alternative to these lower MW glymes. As it has the same toxicological profile and potentially the same uses, substitution by tetraglyme would be inappropriate and thus it should be covered by authorisation in the same way as the other glymes.

The authorisation process provides incentives for the development of safer alternatives. Until substitution is achieved, the authorisation process aims at ensuring the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable (REACH Article 55). Therefore, the identification of tetraglyme as SVHC with subsequent inclusion in Annex XIV is considered a particularly appropriate measure in order to further stimulate substitution.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
Annex XV SVHC dossier for tetraglyme	August 2020	CA Austria