Risk Management Option Analysis Conclusion Document

Substance Name: Terphenyl, hydrogenated

EC Number: 262-967-7

CAS Number: 61788-32-7

Authority: Finnish Safety and Chemicals Agency

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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

PBT/vPvB assessment

In accordance with Commission Regulation (EC) 465/2008, a soil degradation test (OECD 307) on a constituent of the substance (p-dicyclohexylbenzene) and a bioconcentration test (OECD 305) on another constituent of the substance (m,m-quaterphenyl) were submitted by the registrant.

The PBT/vPvB properties of Terphenyl, hydrogenated were discussed at the 2nd and 8th PBT EG meeting in 2012 and 2014, respectively. After both meeting discussions, the assessment went through written commenting procedures and it has been continuously refined based on the comments received. The PBT EG provides informal scientific advice on questions related to the identification of PBT and vPvB properties of chemicals. This advice is non-binding and does not anticipate or interfere with decision-making under the REACH Regulation, which exclusively remains the responsibility of the competent bodies designated in the REACH Regulation. The comments received from the PBT EG experts supported the identification of Terphenyl, hydrogenated as a vPvB substance or as a PBT/vPvB substance.

TPE

In accordance with a testing proposal evaluation decision (TPE-D-0000002727-68-05/F), the registrant submitted in 2014 a long term *Daphnia magna* test (OECD 211) on Terphenyl, hydrogenated (the registered UVCB substance) for risk assessment purposes.

RMOA

The risk management option analysis (RMOA) was discussed at the RiME meeting in May 2017, followed by a written commenting procedure. The RMOA was up-dated based on the comments.

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

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

As the substance appears to fulfil REACH Annex XIII criteria based on its PBT/vPvB properties, and it is currently not treated as a PBT/vPvB substance, further environmental risk management measures need to be considered.

An inclusion of Terphenyl, hydrogenated in the REACH Candidate List is considered an appropriate next risk management step, as it would clearly establish whether the substance fulfils the Annex XIII criteria or not.

Terphenyl, hydrogenated is manufactured in high tonnages. The known uses are within the scope of the authorisation process. Although its main use as a heat transfer fluid appears to be closed use with limited discharges, exposure cannot be overruled (e.g during renewal of the heat transfer fluids and disposal of the substance and used equipment). In addition, terphenyl, hydrogenated is used in a variety of other uses both industrial, professional as well as consumer uses.

On this basis, it is considered that Terphenyl, hydrogenated fulfils the SVHC roadmap 2020 criteria for being a relevant SVHC for inclusion into REACH Annex XIV. It is expected to score high based on the General Approach for prioritisation (13 for vPvB/PBT, 12 for volume, 15 for WDU).[2]

Although the hazard and use profile of the substance rises concern, it would probably be difficult to demonstrate Community wide risk, which is a prerequisite for preparing a REACH restriction proposal, because specific information on uses is limited and no measured data on discharges and/or environmental concentrations are available. Therefore, a REACH restriction is not considered a feasible alternative.

3.2 Other Union-wide regulatory measures

Based on its hazard properties Terphenyl, hydrogenated could also be considered a Priority Hazardous Substance under the Water Framework Directive (2000/60/EC).

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 dossier for SVHC proposal	02 / 2018	FI

[2] https://www.echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8