Risk Management Option Analysis Conclusion Document

Substance Name: Terephtalic Acid

EC Number: 202-830-0

CAS Number: 100-21-0

Authority: France

Date: January 2017

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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) other than this RMOA	
REACH Processes	Evaluation	☒ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri-ction	☐ Annex XVII[2]
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
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] Please specify the relevant entry.

- The decision on a compliance check required a chemical safety report ("CSR") for the registered substance, to be provided to ECHA by 29 April 2013.

- Terephtalic acid is regulated as a monomer for food contact plastics under Regulation (EU)10/2011 - on plastic materials and articles intended to come into contact with food. Terephtalic acid is a monomer of polyethylene terephthalate (PET) used as a resin for bottles, films and thermoformed packaging. The Regulation states a specific migration limit (SML) of 7.5 mg/kg.

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)	
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	X

3. NO ACTION NEEDED AT THIS TIME

The presently available information indicates that terephalic acid (TPA) is not expected to pose any health or environmental risks exept irritation does appear in different tissues depending on the route of exposure. Similar conclusions were made for DEHTP (parent substance, CAS No 6422-86-2).

Regarding endocrine disruption, 2 Member States experts agreed with France's conclusions based on the current available data (following ED Expert Group discussions the 2-3 September 2015): terephthalic acid is not considered as a reproductive or developemental toxicant and no alert was found on potential endocrine disruption properties.

Given that a multi-generation rat studiy have been submitted and show limited effects and irritative bladder effects also seen in other sub-chronic and chronic studies it is difficult to suggest this substance has a reproductive effect. Moreover,the bladder effects found in most of the studies are probably linked to irritating property of terephthalic acid and therefore not judged as apical finding to be considered for ED evaluation. Humans are generally considered to be less sensitive than rats to urolithiasis for anatomical reasons. It is possible that urolithiasis could occur in exposed humans; however it is extremely unlikely that humans could be exposed to the levels of TPA of the magnitude used in the rat toxicity studies, or for similarly long periods.

It is not possible to conclude on the endocrine disruptor character of terephthalic acid because there is no solid information on the other ED effects such as Androgen or thyroid transactivation or steroidogenesis in vitro (OECD TG 456). Furthermore some uncertainties remain: Anses' ED Expert Group concluded that the study Cui et al., 2004 misses some key parameters in sperm quality analysis and it is difficult to interpret some of the other parameters.

Considering the environmental fate and (eco)toxicity properties of TPA, and in accordance with the SIDS (SIAM 12, June 2001), no further work is recommended for this substance. This conclusion is supported by migration data showing a low potential to expose consumers from PET.

The irritating property observed in vivo via inhalation (Leach, 1987) xxx are in line with some self-classification (>20%). As this is not a priority endpoint, ANSES advise the registrant notifying irritant properties to submit a proposal or to discuss for an harmonization of the self-classifications.