Risk Management Option Analysis Conclusion Document

Substance Name: Di ethyl hexyl terephthalate (DEHTP)

EC Number: 229-176-9

CAS Number: 6422-86-2

Authority: France

Date: January 2016

Version 2.1
October 2015

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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

Legal instrument	EU / national	Status of DEHTP
Plastics Regulation EU 10/2011on substances in contact with food	Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) -18th list of substances for food contact materials	In January 2008 the scientific panel on AFC from EFSA evaluated the safety of DEHTP. Based on EFSA opinion, the substance was then authorized to be used in food contact materials. A TDI of 1 mg/kg bw/day was derived.
European References	Harmonised Standards EN 71-3 (Safety of toys - Part 3: Migration of certain elements); EN 71-5 (Safety of toys - Part 5: Chemical toys (sets) other than experimental sets) and EN 71-9 (Safety of toys – requirements concerning organic chemical compounds)	DEHTP is not listed among the banned phthalates reported in the directives 1999/815/CEE and 2005/84.
Directive 2007/47/EC	**Directive on medical devices**	DEHTP is not listed among the banned substances in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967

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. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

No need for follow-up regulatory action at EU level.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

No need for action other than EU regulatory action.

5. NO ACTION NEEDED AT THIS TIME

DEHTP is a substance that has been developed to replace phthalates in various applications, especially in sensitive ones like medical devices or toys. In the framework on the French National Strategy on Endocrine Disruptors in 2014, the French Competent Authority requested ANSES to evaluate its toxicological profile and verify whether risk management measures should be necessary for this substance.

The presently available information indicates that DEHTP is not expected to pose any health or environmental risks. DEHTP is not considered as toxic for reproduction and no alert was found on potential endocrine disruption properties of the substance.
Nevertheless, some uncertainties remain.

First, further relevant experimental evidence for this compound would strengthen the environmental risk assessment, more specifically the PBT assessment (additional tests for the persistence of DEHTP in sediment and soil, bioaccumulative potential in aquatic vertebrates, toxicity to terrestrial organisms).

Secondly, the safety for 2-ethylhexanoic acid, a metabolite of DEHTP which is classified as Repro. 2 H361d, should also be judged, specifically for the environmental assessment. The 2-ethylhexanoic acid is being evaluated by Spain under the REACH substance evaluation procedure (CoRAP list 2012). Therefore, no further action is required for DEHTP until Spain states on this metabolite risk for environment. For human health, there is no evidence that 2-EHA is formed during DEHTP metabolism. As far as human health is concerned, this metabolite is not expected to pose any risk.

In conclusion, based on these information, and taking into account that DEHTP is developed as a substitute for phthalates, FR-CA believes that with the data in hands at this time, DEHTP requires no further risk management. Nevertheless, the evaluation of DEHTP may be reconsidered depending on the outcome of the evaluation of the metabolite (2-ethylhexanoic acid) by Spain.