Risk Management Option Analysis Conclusion Document

Substance Name: Tributyl citrate (TBC)

EC Number: 201-071-2

CAS Number: 77-94-1

Authority: France

Date: September 2016

Version 2.1
October 2015

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

Harmonised Classification in Annex VI of the CLP

There is no existing Harmonised Classification for TBC.

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.

For each conclusion selected in the table below a justification needs to be provided in section 3 of this document. Reasons outlining why a particular risk management option was not considered appropriate can also be included in the relevant section; otherwise subsections can be left blank/deleted if not relevant.

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

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

TBC is an alternative to phthalates in various applications, including sensitive ones like toys. In the framework of the French National Strategy on Endocrine Disruptors in 2015, the French Competent Authority requested ANSES to evaluate its toxicological profile and check whether risk management measures should be necessary for this substance.

There is very limited data available on TBC for human health and environment risk assessment. In order to meet the requirements as described in annexes VII, VIII, IX and X, a read-across has been proposed by the registrant with other citrate esters (ATBC, ATEHC, TEC, ATEC).

Based on expected similar hydrolysis between ATBC and TBC, an analogue approach seems plausible for systemic effects on sub-chronic toxicity, reproductive toxicity, genotoxicity and cancerogenicity and on endrocrine disrupting effects. However, a detailed description of the in vivo toxicokinetic profile of TBC, its metabolites including their proportion in urine are judged necessary to confirm the read-across hypothesis. In particular, steric hindrance of substances plays a major role on nuclear receptor binding.

The read-across for effects at site of contact such as skin or eye irritations and skin sensitisation cannot be supported. Indeed, TBC may be more reactive than ATBC at the site of contact due to the absence of acetyl. This small change in the structure may impact properties such as permeability or protein binding.

As detailed in the RMOA of ATBC, ATBC is not considered as toxic for reproduction and no alert was found on potential endocrine disruption properties, in particular on estrogenic and androgenic activity. However, there is a concern for activation of the PXR

pathway but it is currently unclear which adverse effects this may lead to. So, it is not possible to conclude on the endocrine disruptor character of ATBC because there is no solid information on the other ED effects (thyroid, …).

Danish EPA, Swedish chemical agency (KEMI) and Ireland agree with France's conclusions based on the current available data (following ED Expert Group discussions the 2-3 September 2015). In particular, Ireland considers that PXR/ SXR interaction is not endocrine disruption.

With regard to the environment, TBC does not fulfill the criteria for a PBT nor vPvB-substance. Considering all available data of the acute toxicity tests on aquatic organisms, the substance does not have to be classified. Regarding endocrine disruptor concern, there is not enough data to conclude an alert for environment.

The toxicokinetic study cannot be requested in a compliance check (CCH) as this is not a requirement of REACH annexes. It could therefore be requested during substance evaluation (SeV). As conclude for ATBC on its potential endocrine disruption properties, TBC is judged of low priority for SeV.

As read-across is not supported for skin or eye irritation and skin sensitisation, there is a datagap for these endpoints.

ATBC is on the ECHA list of substances potentially subject to compliance checks (ECHA list December 2015). Therefore, a concomittent CCH on TBC dossier would be the most suitable option.

In conclusion, taking into consideration the data available today, the best management measure is to perform a CCH on TBC.