



Risk Management Option Analysis Conclusion Document

Substance Name: 4,4'-Isobutylethylidenediphenol

EC Number: 401-720-1

CAS Number: 6807-17-6

Authority: Swedish Chemicals Agency

Date: 2018-04-05

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 2020¹.

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

The substance 4,4'-Isobutylethylidenediphenol (Index no 604-024-00-8) has a harmonised classification as reprotoxic in category 1B.

Since 4,4'-Isobutylethylidenediphenol has a Repr. 1B classification it is covered by entry 30 in Annex XVII of the REACH Regulation (EC) No 1907/2006. This means that it is restricted as such and in mixtures placed on the market for sale to the general public.

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:	x
<i>Harmonised classification and labelling</i>	
<i>Identification as SVHC (authorisation)</i>	x
<i>Restriction under REACH</i>	
<i>Other EU-wide regulatory measures</i>	
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)

4,4'-Isobutylethylidenediphenol is classified as reprotoxic in Category 1B and would therefore be considered as an SVHC for inclusion in the Candidate List according to Article 57 (c) of the REACH Regulation (EC) No 1907/2006.

Candidate listing might be useful for providing further information on the potential presence of 4,4'-Isobutylethylidenediphenol in articles that are produced in or imported to the EU, due to the information requirements in the REACH regulation article 33. Such information could be useful when assessing whether a restriction of 4,4'-Isobutylethylidenediphenol is justified as an additional risk management measure.

4,4'-Isobutylethylidenediphenol is an analogue to 4,4'-isopropylidenediphenol (Bisphenol A, BPA). BPA is harmonised classified as Repr. 1B and included in the Candidate List for being toxic for reproduction and for having endocrine disrupting properties. Some of BPA's uses, e.g., in thermal paper, are restricted under Annex XVII of the REACH Regulation (EC) No 1907/2006. There are indications that 4,4'-Isobutylethylidenediphenol may be used as an alternative to BPA in thermal paper.

Based on structural similarity and similar uses as BPA, a grouping approach is considered appropriate in order to prevent inappropriate substitution of BPA and other similar bisphenols with 4,4'-Isobutylethylidenediphenol.

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
e.g. Annex XV dossier for restrictions	Month / Year	Member State
Candidate list	August 2018	Sweden