

**RISK MANAGEMENT OPTION ANALYSIS
CONCLUSION DOCUMENT**

for

**1,2-Benzenedicarboxylic acid, di-C6-10-
alkyl esters**

with ≥ 0.3 % of 1,2-benzenedicarboxylic acid, dihexyl ester (EC no 201-559-5) and/or 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear (EC no 271-093-5)

**EC No 271-094-0
CAS No 68515-51-5**

Member State: Sweden

Dated: 05 December 2014

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new 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 other 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>

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

For 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC no 271-094-0, CAS no 68515-51-5) there are no completed or ongoing legislative processes. For some of its possible constituents/impurities there are several relevant regulations:

- Dihexyl phthalate (EC no 201-559-5) is included in the candidate list.
- Dihexyl phthalate branched and linear (EC no 271-093-5) is included in the candidate list.
- Dihexyl phthalate (EC no 201-559-5) is harmonised classified as Repr. 1B according to Annex VI CLP.²
- There is a RAC opinion for dihexyl phthalate branched and linear (EC no 271-093-5) proposing harmonised classification as Repr. 1B.³
- Dihexyl phthalate (and dihexyl phthalate branched and linear) is anticipated to be listed in REACH Appendix 6, meaning that it would be restricted according to REACH Annex XVII, entry 30, and should not be placed on the market or used as substance, as constituent of other substances or in mixtures for supply to the general public.
- Di-n-octyl phthalate (EC no 204-214-7) is included in REACH Annex XVII, entry 52, restricting its use in toys and childcare articles.
- Dioctyl phthalate was prioritised in the existing substances regulation, but no risk assessment was carried out.

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
Harmonised classification and labelling	possibly
Identification as SVHC (authorisation)	x
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

² Dihexyl phthalate (EC no 201-559-5) is included in the Commission Regulation (EU) No 944/2013 (ATP05), where article 3 states that the amendments shall apply from 1 January 2015, meaning that the harmonised classification enters into force 1/1 2015.

³ Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, dihexylester, branched and linear EC number: 271-093-5 CAS number: 68515-50-4 CLH-O-0000002695-67-03/F Adopted 7 June 2013 <http://echa.europa.eu/documents/10162/18d3ed6d-91c5-48d0-844a-8383ab5723b3>

3.1.1 Harmonised classification and labelling

Due to potential hazard concern of asymmetric phthalates such as hexyl octyl phthalate, a constituent in 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters, the Swedish Chemicals Agency intends to further look into possibilities of classification of the substance in 2015.

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

The substance meets the SVHC Roadmap 2020 criteria since

- it fulfills REACH article 57 (c)
 - o because it becomes classified as Repr. 1B when it contains dihexyl phthalate ≥ 0.3 % (detailed explanation below),
 - o when it contains dihexyl phthalate branched and linear ≥ 0.3 % since there is a RAC opinion for dihexyl phthalate branched and linear proposing harmonised classification as Repr. 1B (detailed explanation below),
- there is a full registration,
- all of the uses registered are within the scope of authorization and
- there are uses not already regulated that provides pressure for substitution.

There is potential exposure to the substance from mixtures and articles, both to consumers, professional workers and workers at industrial settings.⁴

Inclusion in the candidate list can be a driver for substitution prior to the inclusion in Annex XIV. Inclusion of *the substance* in Annex XIV would require that manufacturers/importers and users consider replacement by suitable alternative substances.

The substance is to be treated in the same way as the group of phthalates already included in the candidate list in order to ensure uniform regulation of phthalates exhibiting similar dangerous properties and to avoid inappropriate possible substitution of phthalates on the candidate list with *the substance*. Inclusion would also ensure information to both consumers, users (including workers) and to ECHA about the substance contained in articles.

1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters is not itself listed in Annex VI of Regulation (EC) No 1272/2008, i.e. there is no harmonised classification for the substance. However, according to Article 10(1) of the CLP Regulation, specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance (or in a mixture) as an identified impurity, additive or individual constituent leads to the classification of the substance (or mixture) as hazardous.

For dihexyl phthalate (EC no 201-559-5) no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining classification of substances (or mixtures) containing dihexyl phthalate. The generic concentration limit for reprotoxic substances, Repr. 1B, is 0.3 %, as set out in Table 3.7.2 in Part 3 of Annex I to the CLP Regulation.

For dihexyl phthalate branched and linear (EC no 271-093-5) no specific concentration limits are set in the RAC opinion and therefore (after decision of the European Commission confirming the classification, and inclusion in the list of harmonised

⁴ ECHA dissemination site. Manufacture, use and exposure of EC no 271-094-0. <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>. Accessed 2014-07-10.

classifications (Annex VI to the CLP Regulation)) the generic concentration limit is to be used for the purpose of determining classification of substances (or mixtures) containing dihexyl phthalate branched and linear.

Therefore, on such basis, the classification of *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters where it contains dihexyl phthalate ≥ 0.3 %* will (from the 1/1 2015)⁵ be as seen in Table 1.

Table 1 Classification of *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters where it contains dihexyl phthalate ≥ 0.3 %* according to Art. 10 and Table 3.7.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of the entry with index number for dihexyl phthalate in Part 3 of Annex VI to CLP Regulation (as from 1/1 2015)

Substance name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard Statement Code(s)	Suppl. Hazard statement code(s)		
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters with dihexyl phthalate $\geq 0.3\%$	271-094-0	68515-51-5	Repr. 1B	H360FD	GHS08 Dgr	H360FD	-	-	-

H360FD = May damage fertility. May damage the unborn child.

Following the same principle, the classification of *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters where it contains dihexyl phthalate branched and linear ≥ 0.3 %* will be as seen in Table 2.

Table 2 Classification of *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters where it contains dihexyl phthalate branched and linear ≥ 0.3 %* according to Art. 10 and Table 3.7.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of a future anticipated entry with index number for dihexyl phthalate branched and linear in Part 3 of Annex VI to CLP Regulation

Substance name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard Statement Code(s)	Suppl. Hazard statement code(s)		
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters with dihexyl phthalate branched and linear $\geq 0.3\%$	271-094-0	68515-51-5	Repr. 1B	H360FD	GHS08 Dgr	H360FD	-	-	-

H360FD = May damage fertility. May damage the unborn child.

⁵ Dihexyl phthalate (EC no 201-559-5) is included in the Commission Regulation (EU) No 944/2013 (ATP05), where article 3 states that the amendments shall apply from 1 January 2015.

3.1.3 Restriction**3.1.4 Other Union-wide regulatory risk management measures****4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL****4.1 No need for regulatory follow-up at EU level****4.2 Other actions****5. 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 intention	Actor
Annex XV dossier for identification as a SVHC	February / 2015	Sweden
Investigate potential hazard concern and possibilities of classification of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters	2015	Sweden