KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

for

Dicyclohexyl phthalate

EC No 201-545-9

CAS No 84-61-7

Member State(s): Sweden

Dated: 20 March 2015

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.

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

After the first version of the RMOA (Feb 6, 2013) and the comments received Sweden submitted a CLH-dossier October 15, 2013 suggesting classification of dicyclohexyl phthalate and at the 31st meeting in the RAC-committé, Nov-Dec 2014 an agreement on classification for DCHP as Repr. 1B (H360D) and Skin Sens. 1 (H317) was reached.

Directive 2007/42/EC[1] limits the use of DCHP as a plasticiser for regenerated cellulose film to not more than 4 mg/dm2 of the coating on the side in contact with foodstuffs (the total quantity of plasticisers may not exceed 6 mg/dm^2).

Regulation (EU) No 10/2011 lays down the rules applicable to plastic materials and articles intended to come into contact with the food (the regulation has been in force since 2008 through directive 2007/19/EC – repealed by 10/2011). DCHP is not part of the list of authorized substances and therefore cannot be used in plastic food contact material.

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)	√
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP OF REGULATORY RISK MANAGEMENT ACTION AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

An Annex XV CLH-dossier has been produced and submitted to ECHA during 2014 and at the 31st meeting in the RAC-committé, Nov-Dec 2014 an agreement on classification for DCHP as Repr. 1B (H360D) and Skin Sens. 1 (H317) was reached.

[1] COMMISSION DIRECTIVE 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.

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

Further, in the hazard assessment for DCHP by the Australian government under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) it was concluded that "DCHP has a similar reproductive profile to the 'transitional' (C4-6) phthalates for which reproductive and developmental effects are recognised" (NICNAS, 2008a). The transitional phthalates BBP, DEHP, and DBP, as well as diisobutyl phthalate (DIBP), are already included in REACH Annex XIV (authorisation list) for being toxic for reproduction (*Article 57c*). DCHP is a potential substitute for these phthalates.

DCHP has been listed as an ED in the SIN list[2] and the Trade Union list[3], besides being listed in the EU-report and database of suspected endocrine disrupting substances mentioned above.

We have used Denmark (DK), and Germany-UK (DE-UK jointly made) proposals on criteria for the identification of EDs of regulatory importance. Human health relevant literature data for DCHP was searched and evaluated against the criteria proposed by DK and DE-UK. This work was part of a student's master degree project[4]. DCHP is identified as a 'potent ED' as per the DE-UK proposed criteria and is grouped under 'category 1 ED' as per the DK proposal.

As DCHP fulfills the CLP criteria for Repr. 1B it is an SVHC as defined by Reach *Article 57c*. We consider that there is an added value of also having DCHP on the candidate list according to *Article 57f* as special considerations may be applied to substances with endocrine properties with regards to evaluation of threshold and that if the substance is entered into Annex XIV the endocrine properties will also be considered in the authorisation process.

Professional workers use is reported as wide dispersive indoor use in closed and open systems. Consumer use is reported as wide dispersive outdoor and indoor use, examples of products are adhesives, sealants, paint, paint remover, finger paints, ink, toners, polishes, wax blends, polymer preparations, textile dye, finishing and impregnating products.

All of the above imply DCHP to be a substance of regulatory concern as a SVHC.

Inclusion into the Candidate list according to REACH *Article 57c* and *Article 57f* (ED properties) and subsequently into the authorisation list, seem to be appropriate risk management options for DCHP at this point in time. However, a final decision on whether to propose a SVHC for DCHP according *Article 57c* and/or *Article 57c* will be made in relation to the outcome of currently ongoing processes in the Member State Committee (MSC) and the Commission for other endocrine disrupting substances in general, and for the phthalates Bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) specifically.

The Swedish CA plan to submit a SVHC Annex XV dossier for DCHP in August 2015. The Swedish CA will ask for advice from ECHA:s expert group on endocrine disruptor (ED EG) during the preparation of the dossier.

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[2] http://www.chemsec.org/what-we-do/sin-list
[3] http://www.etuc.org/trade-union-priority-list
[4] The full project report can be retrieved via the following link: https://docs.google.com/file/d/0B42BFapq2KWaYXVBaHNfb2dYaXc/edit?pli=1, accessed 2012-10-12.

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

Not applicable

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A formal commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier shall be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor
Annex XV dossier for authorisation	08 / 2015	Swedish Chemicals Agency, Sweden