Kemikalieinspektionen
Swedish Chemicals Agency

HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

Dicyclohexyl phthalate

EC No 201-545-9

CAS No 84-61-7

Member State(s): Sweden

30 July 2015

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Version 1.3

1. HAZARD SUBJECT TO ASSESSMENT

Dicyclohexyl phthalate was originally selected for hazard assessment in order to clarify suspected hazard properties:

For endocrine disruption/disruptor (ED)

2. OUTCOME OF HAZARD ASSESSMENT

The available information on the substance and the hazard assessment conducted has led the assessing Authority to the following considerations, as summarised in the table below.

Hazard Assessment Outcome	**Tick box**
According to the authority's assessment the substance is not an ED in accordance with the WHO (2002) definition based on the currently available information.	
According to the authority's assessment the substance is an ED in accordance with the WHO/IPCS (2002) definition.	√
According to the authority's assessment further information would be needed to confirm the ED properties but follow-up work is not relevant or carried out at present.	

This outcome is based on the REACH and CLP data as well as other available relevant information.

3. BASIS FOR REASONING[1]

Dicyclohexyl phthalate is a reproductive toxicant (Repr. 1B H360D) with findings in animal studies that show an endocrine mode of action, as confirmed by the opinion of the Risk Assessment Committee (RAC), adopted at the 31st RAC-meeting on 4 Dec, 2014 (http://www.echa.europa.eu/documents/10162/54ec6918-fb59-4640-b20f-ed7ebb41d20b). The overall findings indicate that DCHP causes developmental toxicity in male reproductive organs in the absence of marked maternal toxicity. A plausible mechanistic link between the toxic effects of concern and endocrine disruption (an anti-androgenic mode of action) is considered to be the explanation for the male reproductive system adverse effects.

Based on the available data we conclude that DCHP can be regarded as an endocrine disrupting substance for human health in accordance with the WHO/IPCS (2002) definition. Potential concerns for the environment have not been fully evaluated.

We have in this work not fully evaluated the data on fish and thus, a conclusion cannot at present be drawn on future action with regards to the environment. We do however consider

[1] Assessments of ED properties are based on the WHO/IPCS definition of an endocrine disruptor.

"An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations."

WHO/IPCS Report 2002: Global Assessment of the state-of-the-science of Endocrine disruptors, Executive Summary (Chapter 1) page 1 section 1.1

Under the REACH Regulation endocrine disruptors may be identified in accordance with Article 57(f) on a case-by-case basis as substances of very high concern (SVHCs), where there is scientific evidence of probable serious effects to human health or the environment, which give rise to an equivalent level of concern to CMR or PBT/vPvB substances.

information from studies in rodents to be relevant for mammals in general and thus part of the information package for the environment.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Taking into account the overall data, the input from the ED expert group and the ongoing discussions regarding ED properties for four other phthalates (BBP; DEHP; DBP and DiBP), the Swedish Chemicals Agency submitted an intention to put together a dossier for identification of DCHP as a substance of very high concern according to REACH Article 57 (c) and/or Article 57 (f). Planned submission date for the SVHC-dossier is August 3, 2015.

Follow-up action	**Date for intention**	**Actor**
SVHC	08 / 2015	Swedish Chemicals Agency