

1 July 2015

Background document for N-pentyl-isopentylphthalate

Document developed in the context of ECHA's 6th recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of Registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

1. Identity of the substance

Chemical name:	N-pentyl-isopentylphthalate
EC Number:	--
CAS Number:	776297-69-9
IUPAC Name:	n-pentyl-isopentyl phthalate

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation¹. Results of the prioritisation of all substances included in the Candidate List by June 2013 and not yet included or recommended in Annex XIV of the REACH Regulation is available at http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf

The prioritisation results of the substances included in the draft 6th recommendation have been updated as necessary after the public consultation. The updated results are available at http://echa.europa.eu/documents/10162/13640/updated_prioritisation_results_6th_axiv_rec_en.pdf.

2.1. Intrinsic properties

N-pentyl-isopentylphthalate was identified as a Substance of Very High Concern (SVHC) according to article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360FD: "May damage fertility. May damage the unborn child.", and was therefore included in the candidate list for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

¹ Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

2.2. Volume used in the scope of authorisation

There are no registrations for N-pentyl-isopentylphthalate under Regulation (EC) No 1907/2006 (REACH).²

2.3. Wide-dispersiveness of uses

There are no registrations for N-pentyl-isopentylphthalate under Regulation (EC) No 1907/2006 (REACH).

2.4. Further considerations for priority setting

N-pentyl-isopentylphthalate has similarities in terms of structure and physico-chemical properties with other phthalates of carbon backbone lengths of C4-C6, some of which are already included in Annex XIV (e.g. dibutyl phthalate (DBP), diisopentyl phthalate (DIPP)). There are indications on the potential for using the substances in the same types of application (e.g. plasticisers in plastic material) (Annex XV report, 2012).

2.5. Conclusions and justification

On the basis of grouping considerations, N-pentyl-isopentylphthalate is recommended for inclusion in Annex XIV.

3. Further information on uses

N-pentyl-isopentylphthalate has not been registered in the EU. Further details on potential types of application of N-pentyl-isopentylphthalate can be found in the Annex XV report (2012).

4. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV³. The draft Annex XIV entries for substances included in the 6th recommendation are available at http://echa.europa.eu/documents/10162/13640/6th_axiv_recommendation_july2015_en.pdf. The section below provides background for allocation of the substance to the Latest Application Dates slots.

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV but more slots can be considered on a case-by-case basis).

Prioritised phthalates have been considered to be placed in the same slot as they may fulfil the definition of a group according to section 1.5 of Annex XI of REACH.

Allocation of (group of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively high number of uses. Substances with no registration requirement are also allocated to the later slots.

² Number of registrations as of 1 December 2014

³ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

The time required to prepare applications for authorisation related to the prioritised phthalates may be relatively lower than for other (groups of) substances prioritised for this recommendation, considering e.g. the number of registered uses (six of the prioritised phthalates are not registered).

Therefore this group of substances is assigned in the 1st slot (LAD 18 months after inclusion in Annex XIV).

5. References

Annex XV report (2012): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. N-Pentyl-isopentyl phthalate, Submitted by Federal Office for Chemicals, Germany, August 2012.

<http://echa.europa.eu/documents/10162/48f63323-2ed7-453b-b1ca-c42987d0453f>