

1 July 2015

Background document for diisopentylphthalate

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: Diisopentylphthalate
EC Number: 210-088-4
CAS Number: 605-50-5
IUPAC Name: Bis(3-methylbutyl) 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

Diisopentylphthalate (DIPP) 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

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

1272/2008 as toxic for reproduction, Repr. 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.

2.2. Volume used in the scope of authorisation

The amount of diisopentylphthalate manufactured and/or imported into the EU is according to registration data in the range of 10 - 100 t/y. All tonnage appears to be in the scope of authorisation.

2.3. Wide-dispersiveness of uses

According to registration data diisopentylphthalate (DIPP) is used in the scope of authorisation at industrial sites (use in the production of propellants and explosives, and to coat them to regulate the rate of burn). Use of DIPP by consumers to coat the propellant and regulate the rate of burn is also reported but is expected to be limited to applications where the concentration is below the concentration limit specified in the generic restriction on the use of CMRs by the general public. Therefore, the use appears to be outside the scope of authorisation. The use reported as consumer use might however also apply to professionals (Annex XV report, 2012). The tonnage for that use is expected to be very low. Furthermore, according to the Annex XV report propellants containing DIPP are used in articles (ammunition).

2.4. Further considerations for priority setting

Due to similar structure and physical-chemical properties DIPP can potentially be used in similar applications as other phthalates already on Annex XIV (e.g. DBP, DIBP). Examples include use in propellants in manufacture of ammunition (registered use of DIPP), use as plasticiser for PVC products and other polymers (non-registered use but confirmed as potential application of DIPP).

Owing to its relatively high volatility, in comparison with other phthalates, DIPP could be used in conjunction with higher molecular mass esters in a similar manner as Dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) (linear and branched C4 esters) in PVC formulations, principally for ease of gelation (Annex XV report, 2012).

With regards the use in propellants it seems that DIPP is not a very common additive. DEHP can also be used in such application while Dibutylphthalate (DBP) seems the most common phthalate used in ammunition. Applications for authorisation have been received for DEHP and DBP for those uses (ECHA, 2014).

2.5. Conclusions and justification

Verbal descriptions and Scores			Total Score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Diisopentylphthalate is classified as toxic for reproduction 1B meeting the criteria 57c Score: 1	The amount of diisopentylphthalate used in the scope of authorisation is in the range of 10 - 100 t/y Score: 6	Diisopentylphthalate is used at industrial sites Initial score: 5 Furthermore, the substance may be used by professional workers in volumes <10 t/y. Mixtures containing DIPP can be used in articles (ammunition) Refined score: 7	14	Grouping with phthalate(s) already on Annex XIV

Conclusion

On the basis of the prioritisation criteria, diisopentylphthalate did not receive priority for this round among the substances in the Candidate List (see link to the prioritisation results above). However, based on grouping considerations, diisopentylphthalate is recommended for inclusion in Annex XIV.

3. Further information on uses

DIPP has been registered for its specific use in the production of propellants and their coatings to regulate the rate of burn. Propellants containing DIPP may be further used by producers of ammunition or used directly by professional users to manually reload empty cartridges. The reloading of cartridges may be done at many different sites (Annex XV report, 2012). The propellants are used for the production of ammunition which is mostly for military uses; however a part is also used for civil applications.

It can be assumed that the supply chain of DIPP within EU consists of a low number of industrial users and potentially a high number of professional users (mixtures and articles) and consumers (articles).

DIPP may have a potential to be used as plasticiser for plastics. However this use is not covered by the current registrations.

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 XIV². 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.

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. Diisopentylphthalate. Submitted by Austrian competent authorities, September 2012.

<http://www.echa.europa.eu/documents/10162/b33d9431-e823-43fd-bf4b-d554b6aef968>

ECHA (2014): Adopted opinions and previous consultations on applications for authorisation

<http://echa.europa.eu/en/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations>

² Document can be accessed at

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