

**1 September 2014**

## Draft background document for Diisopentylphthalate

### Document developed in the context of ECHA's sixth 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 authorisation<sup>1</sup>. 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](http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_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 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.

<sup>1</sup> Document can be accessed at

[http://echa.europa.eu/documents/10162/13640/gen\\_approach\\_svhc\\_prior\\_in\\_recommendations\\_en.pdf](http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

### 2.3. Wide-dispersiveness of uses

According to registration data Diisopentylphthalate 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 Di-n-butyl 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 propellant 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 the following uses of DEHP and DBP (ECHA, 2014):

- Use of DBP in propellants in manufacture of ammunition for military and civilian uses, and pyrocartridges for aircraft ejection seat safety systems
- Use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles
- Use of DEHP in manufacture of solid propellants and motor charges for rockets and tactical missiles

## 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 didn't receive priority for this round among the substances in the Candidate List (see link to the prioritisation results above). However, on the basis of grouping considerations, it is proposed to recommend diisopentylphthalate 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 coating 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 are 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 XIV<sup>2</sup>. The draft Annex XIV entries for substances included in this draft recommendation are available at [http://echa.europa.eu/documents/10162/13640/draft\\_axiv\\_entries\\_summarytable\\_6th\\_en.pdf](http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_summarytable_6th_en.pdf) The section below provides background for allocation of the substance to the Latest Application Date slots.*

The LAD slots are set in 3 months intervals (i.e. 18, 21 and 24 months after inclusion in Annex XIV). 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 (provision allowing submitting common applications for authorisation).

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 but the time differences between the LADs set out in a recommendation (i.e. 3-6 months) can be considered as minor compared to the total time reserved for the potential applicants to prepare their applications.

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

Therefore this group of substances is assigned in the 1st slot.

## 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>

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<sup>2</sup> Document can be accessed at

[http://echa.europa.eu/documents/10162/13640/draft\\_axiv\\_entries\\_gen\\_approach\\_6th\\_en.pdf](http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf)