

1 September 2014

Draft background document for Bis-(2-methoxyethyl) phthalate (DMEP)

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:	Bis(2-methoxyethyl) phthalate (DMEP)
EC Number:	204-212-6
CAS Number:	117-82-8
IUPAC Name:	Bis(2-methoxyethyl) 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

2.1. Intrinsic properties

Bis(2-methoxyethyl) phthalate (DMEP) 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, H360Df: "May damage the unborn child. Suspected of damaging fertility", and was therefore included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

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 Bis(2-methoxyethyl) phthalate under Regulation (EC) No 1907/2006 (REACH).²

2.3. Wide-dispersiveness of uses

There are no registrations for Bis(2-methoxyethyl) phthalate under Regulation (EC) No 1907/2006 (REACH).

2.4. Further considerations for priority setting

Bis(2-methoxyethyl) phthalate has structural similarities with other phthalates already included in Annex XIV. There are indications on the potential for using the substances in the same types of application (applications similar to e.g. DBP include plasticisers in PVC products, use in paints, lacquers, varnishes, adhesives, printer inks, film coatings) (Annex XV report, 2011; Annex XV report DBP, 2008).

2.5. Conclusions and justification

On the basis of grouping considerations, Bis(2-methoxyethyl) phthalate is proposed to be recommended for inclusion in Annex XIV.

3. Further information on uses

Bis(2-methoxyethyl)phthalate (DMEP) has not been registered. Information about potential types of applications of Bis(2-methoxyethyl)phthalate (DMEP) can be found in the annex XV report (2011).

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 this draft recommendation are available at 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.

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, however 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.

² Number of registrations as of 21 May 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 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 uses (six of the prioritised phthalates are not registered). Therefore this group of substances is assigned in the 1st slot.

5. References

Annex XV report (2011): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Bis(2-methoxy) phthalate, Submitted by Germany, September 2011.

<http://echa.europa.eu/documents/10162/38458518-7e1d-49ff-b53d-d07963c1bceb>

Annex XV report DBP (2008): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Dibutyl phthalate. Submitted Austria, June 2008.

<http://echa.europa.eu/documents/10162/d9d7265f-b7c9-4dcf-8554-f92ae6170d66>