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Subject: Comments For Public Consultation DOTE

Heiligenroth 16 October 2014

Page 12: Comments on CMR assessment

Annex XV Dossier by Austria does not substantiate the reproductive toxicity Cat. 1B, at any rate, not before 1 January 2015.

At the time of the submission of Annex XV SVHC Dossier by Austria (4 August 2014), DOTE was no candidate substance for the Authorisation List of REACH Regulation 1907/2006. Accordingly, a dossier was submitted for a non-SVHC substance.

Pursuant to Art. 59 (3) REACH, each Member State can prepare an Annex XV Dossier for substances, which in its opinion fulfil the criteria of Art. 57 REACH.

Art. 57 REACH concludingly defines the criteria for the inclusion in the Authorisation List. The criterion pursuant to Art. 57 c) REACH applies here. According to it, exclusively substances are to be included in the Authorisation List which meet the criteria for the classification in the hazard class reproductive toxicity category 1A or 1B in accordance with section 3.7 of annex I to regulation (EC) No 1272/2008, CLP.

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In annex I section 3.7, the CLP regulation stipulates over several pages under which conditions a substance or a mixture is to be classified as toxic to reproduction Cat. 1A or 1B. For the classification of substances, section 3.7 contains extensive explanations on the classification principles, the determination of the authenticity of the data, the determination of maternal toxicity, the admissible animal test data etc.

The Annex XV Dossier contains no details on the necessary information according to the CLP regulation for the correct classification as toxic to reproduction Cat. 1B. There is no evaluation as to how far DOTE corresponds to the criteria defined in annex I section 3.7 of the CLP regulation.

The Annex XV Dossier refers under 6.1 'CMR Assessment' merely to annex III of Regulation 944/2013/EU amending, for the purposes of its adaptation to technical and scientific progress, Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures. According to this regulation DOTE will be listed in Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Annex VI, part 3, of CLP Regulation as toxic for reproduction Repr. 1B, H360D (may damage the unborn child).

The classification of DOTE as toxic to reproduction Cat. 1B based on Regulation 944/2013/EU Art. 3 (3) only takes effect as of 1 January 2015. Therefore, the classification as toxic to reproduction Cat. 1B cannot be justified without any assessment only with a simple reference to a regulation applicable in the future. The intrinsic property of DOTE as toxic to reproduction Cat. 1B is not substantiated in the dossier and can therefore not be explicitly attacked within the scope of the consultation procedure.

Page 14: Comments on the Wide Dispersive Uses:

As downstream users of DOTE, we confirm that we use DOTE in an industrial setting only. We are not aware of any use of DOTE outside an industrial setting by professionals or consumers.

We confirm that our products fulfill the article definition under REACH. Any use of our products are part of the article life.

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Page 15: Comments on exemption from authorisation for DOTE

Regulatory basis for excluding uses of potential Annex XIV substance DOTE

Regulatory basis for excluding uses of potential Annex XIV substance DOTE: Article 58(2) of REACH for granting an exemption for authorisation, Regulation (EC) No 143/2011 amending Annex XIV to REACH, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Directive 2001/83/EC on the community code relating to medicinal products for human use and the convention on the elaboration and use of the European Pharmacopoeia (European Treaty Series 50, European Pharmacopoeia Version 8.0) and the protocol to the elaboration of the European Pharmacopoeia.

Pursuant to Articles 2(5) (a) REACH the provisions on authorisation under REACH do not in any event apply to medicinal or veterinary products. Use of DOTE in these products does not need to be exempted from authorisation under Article 58(2) of the REACH Regulation.

Pursuant to Article 58 (2) REACH the uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

The exemption from authorisation for DOTE similar to DEHP

The exemption from authorisation for DOTE is similar to the exemption of DEHP, BBP and DBP in immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Regulation 143/2011 and Directive 2001/83/EC. Regulation 143/2011 amends Annex XIV REACH:

Pursuant to the preamble 17 of Regulation 143/2011 DEHP, BBP, and DBP can be used in the immediate packaging of medicinal products according to Regulation (EC) No 726/2004 and Directive 2001/83/EC. The safety of immediate packaging of medicinal products which include additives like DEHP or DOTE has to be controlled for quality, stability, and safety. Therefore, risk to human health and the environment of DOTE is covered by Regulation (EC) No 726/2004 and Directive 2001/83/EC and the use of DOTE for immediate packaging of medicinal products should be exempted from authorisation (Art. 58 (2) REACH).

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Safety of the immediate packaging which can include DOTE

Aspects of safety of the immediate packaging of medicines are covered by Directive 2001/83/EC and Regulation (EC) No 726/2004. The legislation of the Union provides for a framework to properly control risks of such immediate packaging materials by imposing requirements on the quality, stability, and safety of the immediate packaging materials. Immediate packagings have to be authorised with medicinal products. For authorisation of immediate packaging with medicinal products the stability, quality and safety of packaging must be controlled. For instance, it must be controlled if chemicals like DOTE can migrate from the package into the medicinal product and would change the quality and safety of the medicine. DOTE is listed in the European Pharmacopoeia and can be used as stabiliser immediate packagings. If DOTE will migrate from the packaging into the medicinal product and would change the quality, stability and safety this immediate packaging cannot be used for medicinal products.

It is therefore appropriate to exempt the use of DOTE in the immediate packaging of medicinal products from authorisation under Art. 58 (2) REACH. The exemption for authorisation of DOTE in immediate packaging of medicinal products is in line with the background document for bis(2-ethylhexyl)phthalate (DEHP) – document developed in the context of ECHA's first Recommendation for the inclusion of substances in Annex XIV. In this document the exemption for authorisation is accepted.

Pursuant to European Pharmacopoeia DOTE can be used as stabiliser in PVC films

In addition, DOTE is included in the European Pharmacopoeia Version 8.0 Chapter 3.1.11. MATERIALS BASED ON NON-PLASTICISED POLY(VINYL CHLORIDE) FOR CONTAINERS FOR DRY DOSAGE FORMS FOR ORAL ADMINISTRATION. DOTE is listed in the European Pharmacopoeia and can be used as stabiliser immediate packagings.

The requirements for plastic materials containing DOTE is covered by European Pharmacopoeia Version 8.0 Chapter 3.1.11. and the PVC films of our members of European Rigid PVC Film Association (ERPA) have to be in compliance with European Pharmacopoeia, Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.

Page 19: Comments on the likelihood of the release during article service life and waste phase:

We as the downstream users of DOTE agrees with the following statement:

In order to continue to stabilize the articles throughout its life-cycle stabilizers must not be washed off from the articles. Therefore those molecules are designed to have inherently low leaching rates and this is the case for octyltins which have a very low water solubility (high Octanol/Water partition coefficient).

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Moreover, DOTE are used extensively in rigid PVC films for food-contact and comply with the applicable Specific Migrations Limit of 6 µg/kg food, which confirms the low leaching rate in aqueous media. For many years in the USA, DOTE based stabilizers have complied with the strict guidelines set out by NSF/ ANSI 61 standards for use in drinking water applications.

Like all additives, leaching in contact with water is limited to a thin diffusion layer and does almost not affect the bulk of the material. This has been demonstrated indirectly by measuring the residual concentration of a tin stabilizer throughout the 6 mm wall of a 22-year old water pipe dug out. The depletion of tin was observed in the 1.5 micron boundary layer, representing 0.05 % of the pipe volume, whilst no depletion was observed in the bulk.

It is therefore the commentator's conclusion that it is unlikely for the release of DOTE during the article service life and waste phase. Additionally after many decades of use in these applications we are not aware of any reported adverse impact on users of articles containing DOTE.

Page 27: Comments on the Technical Feasibility of Calcium-based stabilizers as a substitute for DOTE:

Section 10.4 of the Annex XV dossier mentions Calcium/Zinc-based stabilizers as a substitute for DOTE. After extensive testing and formulation work, we have not been able to find an adequate technical substitute that is based on Calcium/Zinc to date.

Sincerely Yours,
Klöckner Pentaplast Europe GmbH & Co. KG

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