EASTMAN

July 12, 2010

Michael Babich, Ph.D.
Directorate for Health Sciences
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Re: CHAP Feedback on Non-Government Participants' Reports: Review of Exposure and Toxicity Data for Phthalate Substitutes
(as posted on http://www.cpsc.gov/about/cpsia/chap0410.html)

Dear Dr. Babich,

My colleagues and I have reviewed the documents that were provided to the CHAP members during the review in April. Specifically, I would like to submit for the panel's review and correction some comments regarding DEHT in the report titled "**Review of Exposure and Toxicity Data for Phthalate Substitutes".** The attached comments reference the specific page and context of the proposed corrections. A disk is also being attached with the comments and some additional published and peer reviewed data for your reference. In addition, there are a few Eastman specific studies show for additional support to the published information.

I am pleased that the CHAP is examining DEHT as a non-phthalate alternative used in children's toys and child care articles. As you know, DEHT (Eastman 168™ plasticizer) has been used in a variety of applications for over 40 years. There is significant published information regarding its safe use in these applications. Most recently the REACH registration for this product has been completed.

If you have any questions regarding our comments or about the use of Eastman 168™ plasticizer), please do not hesitate to call me at 423-229-2632.

Sincerely,

Dr. Steve Cullen
Business Manager, Plasticizers Business Unit
Eastman Chemical Company
P.O. Box 431, Bldg. 280
Kingsport, TN 37662
423-229-2632

Enclosure and Attachment

CHAP Feedback on Non-Government Participants' Reports:

Review of Exposure and Toxicity Data for Phthalate Substitutes

DEHT specific comments

Page i and page 12:
It is noted in the text that the "BCF is particularly high for DEHT, but for the other alternatives is lower than values observed for DEHP and DINP, indicating the potential for these chemicals to be metabolized by organisms." This quote is in reference to data in Table 2-1 on page 12 indicating DEHT has a BCF of 1,400,000. **The source of the BCF value was not provided in the report, but is incorrect. A BCF study has been performed on DEHT, which indicates that the BCF value is 393 (See Attachment 10: BCF and Elimination of DEHT in Oysters). This study was summarized as part of the OECD SIDS process (see below hyperlink) where all data were reviewed by subject experts from the various regulatory agencies participating in the OECD SIDS program.** Subsequent to the publication of the OECD SIDS dossier a new biodegradation study was completed. Results of that study show that DEHT is "readily biodegradable".

http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=C1534369-697F-46E5-83A6-626F8BC31554

Page ii:
It is stated that the "Acute oral toxicity for ATBC appears to be the lowest of the five chemicals, and it has been approved by the U.S. Food and Drug Administration (FDA) for use as a food additive and food contact substance."

While ATBC does appear to have the lowest acute toxicity potential, such a distinction is somewhat meaningless in light of the fact that the maximum allowable dose that a material can be administered in an acute toxicity study under current OECD guidelines is 5,000 mg/kg. This was the highest dose administered in the most recent acute toxicity study for DEHT and no evidence of toxicity was observed. This study was reviewed and summarized in the OECD SIDS program. **It should also be duly noted that DEHT has also been approved by the FDA for use in various food contact applications (See Attachment 11: DEHT Regulatory Clearances).**

Page 3, Section 1.3
It is stated that "Some of the most popular candidates include citrates, adipates, trimellitates, phosphates, benzoates, and vegetable oil derivatives." Why are terephthalates not also mentioned as they are subsequently reviewed for such a purpose, i.e., use as an alternative? **It is recommended that terephthalates be mentioned specifically as an alternative here.**

Page 7, Figure 1-2:
It is noted in this figure that DEHT is listed as having a "3" on a scale of "6" with regard to the amount of available toxicity information. This score seems very low when the amount of data available on this compound is taken into account. There are studies assessing its potential toxicity for essentially all major endpoints including a bioassay to assess its carcinogenicity potential. **It is recommended that this score be reconsidered.**

Page 8, Section 1.4.2:
It is noted that the OECD SIDS data base was a secondary source of information. DEHT has gone through the OECD SIDS process where all these data were reviewed by the US EPA as well as other governmental authorities. **The conclusion of that OECD review was that DEHT was deemed to be a chemical in low priority for further review.** However, it appears as if data found in the IUCLID and SIAR from that review are not included in the current review. For example, the LD50 for DEHT is noted to be >5,000 mg/kg in the OECD IUCLID. Whereas in the text on page 59 (section 6.4.2) it states: "The European Commission (SCENIHR, 2007) Safety Evaluation reported an oral LD50 of 5000 mg/kg, but did not provide a reference and no data matching this lethal dose were found during this review." **The data matching this LD50 can be found in the IUCLID dossier completed during the OECD review process at the following website:** http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=C1534369-697F-46E5-83A6-626F8BC31554,

Page 57, Section 6.1 Use:
It is stated in the last sentence of the first paragraph that DEHT is produced by Eastman Kodak Company. **This should be corrected to read Eastman Chemical Company.**

Page 57, Section 6.1 Use:
It is stated in the second paragraph that – "In contrast, available data indicate that metabolism of DEHT (as reported by Eastman) does not lead to significant formation of a monoester (McMillan, 2004), suggesting that it may not have health effects similar to *ortho*-phthalates." **The authors should remove "as reported by Eastman" and replace with the reference Barber et al. (1994) as this information has been published (See attachment 2: Metabolism of DEHT).**

Page 59, Acute Oral Toxicity:

See page 8 comment above about reference for acute toxicity.

Page 60, Skin Sensitization:
In this section it suggests that "DEHT has been shown to act as a sensitizer in guinea pigs…" **The sensitization potential of DEHT was reviewed by the OCED and the data for this endpoint are summarized in the IUCLID dossier (see above hyperlinks).** It should be noted that the particular study being cited to "classify" DEHT as a sensitizer had several flaws associated with it and the study was deemed as an invalid study for the review of this endpoint by the OECD. Thus, the results of this study should not be a part of this current review document. This study involved the use of pilot plant material and when reevaluated with more representative material did not show evidence of sensitization (See Attachments 12 & 13: Sensitization study 75-35, and 74-170, and sensitization section in the OECD hyperlink). In addition to the noted guinea pig studies, a human repeated insult patch test was conducted that demonstrated an absence of sensitization potential **(See Attachment 1: Sensitization manuscript HRIPT).** Eastman has no knowledge of any reported incidences of sensitization with this compound in the workplace. **As a chemical class, terephthalate esters are not associated with such a potential and sensitization hazard warnings are not present on the MSDS.**

Attachments (details on CD provided):

Published and Peer Reviewed Data Manuscripts

1. Sensitization (HRIPT)
2. Metabolism
3. Mutagenicity and chromosomal aberration
4. Mutagenicity
5. 21 day toxicity
6. 90 day toxicity study
7. Carcinogenicity
8. Developmental toxicity and Uterotrophic assay
9. Two-generation reproductive toxicity

Additional Unpublished Data

10. Bioconcentration study in oysters
11. Document showing various regulatory approval clearances
12. Sensitization study report 74-170
13. Sensitization study report 75-35