

ExxonMobil Chemical Company
13501 Katy Freeway
Houston, TX 77079-1398
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Patrick B. Henretty
Global Advocacy Director
Intermediates



November 22, 2013

Elliott Kaye
Acting Executive Director
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Dear Mr. Kaye,

I am writing to you today as a follow-up to Elissa Sterry's previous correspondence with the former Executive Director, Kenneth Hinson regarding apparent data gaps in the Consumer Product Safety Commission's (CPSC) Chronic Hazard Advisory Panel (CHAP) website pertaining to the DINP and DIDP toy restriction re-evaluation. As further background, our initial correspondence was prompted by a meeting with Commissioner Adler during which it was mentioned that the CPSC scientific staff appear to be missing some of the details behind the ExxonMobil submissions. We subsequently reviewed the CPSC website and did identify a number of critically important submissions which are not readily available or posted.

In Mr. Hinson's response letter, he offered to verify that the ExxonMobil information submitted to the CHAP is available on the CPSC website, and to make sure that information is "visible and accessible." I would appreciate your assistance in this matter as the CPSC website serves as the official record of the CHAP proceedings. It is important the website is fully inclusive and reflective of all significant information and data provided to the CPSC, whether by ExxonMobil or other third parties.

For your convenience, and to expedite the corrections to the website, we have attached a listing of the scientific studies ExxonMobil has submitted to the CPSC but which do not appear on the website (see addendum). We have also included information from the Hamner Institute and University of Edinburgh which we have been advised were previously submitted by their researchers as important for the CHAP members and CPSC scientific staff to consider but do not appear on the website.

We appreciate your timely consideration of this letter and our request to update the CHAP's website. If you have any questions, please feel free to contact me at 281-870-6760.

Sincerely,

A handwritten signature in black ink that reads "Patrick Henretty". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Patrick Henretty

cc:

Chairman Inez Tenenbaum

Commissioner Robert Adler

Commissioner Marietta Robinson

Commissioner Ann Marie Buerkle

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Addendum:

Below is a summary of the material submitted by or on behalf of ExxonMobil, to the CPSC for inclusion in the deliberations of the Chronic Hazard Advisory Panel (CHAP) which are not readily available or posted on the CPSC website. The second set of data include relevant third party studies which we have been advised were submitted but again, are not readily available or posted. Finally, for completeness, the last chart is of known submissions which are on the CPSC website.

Missing ExxonMobil Documents from the CHAP Record:

1. Chemical Industry Comments on State-of-the-Art Report on Mixture Toxicity

This document summarizes various methodologies to conduct a cumulative risk assessment. It recommends the hazard index (HI) approach. This highly conservative approach clearly demonstrates that even for highly sensitive populations such as children and women of reproductive age, the combination of six phthalates does not pose a cumulative risk to human health.

2. Endpoint Summaries for Mammalian and Environmental Toxicity Submitted in the REACH Registration Dossier for Diisononyl Phthalate (DINP)

Summary of the vast amount of toxicological data available for DINP and as compiled for DINP REACH registration. Concludes that DINP is not a reproductive toxicant, not an endocrine disruptor and is non-hazardous and therefore not classified as dangerous under EU CLP regulation.

3. European Union Risk Assessment DINP

Reports on the previous EU risk assessment for DINP, concluding that no hazard classification or risk management measures were required.

4. European Union Risk Assessment DIDP

Reports on the previous EU risk assessment for DIDP, concluding that no hazard classification or risk management measures were required

Important Recent Third Party Studies:

- **Hamner Institute** research on DINP:

Hamner Institute scientist Dr. Rebecca Clewell conducted **two** relevant experiments on DINP. Her work is the most comprehensive study on DINP to date. In 2011, Dr. Clewell appeared before the CHAP to present her preliminary findings. The studies were consequently published in *Reproductive Toxicology* in early 2013. Dr. Clewell submitted these published papers to CPSC in January 2013. It showed no evidence of the phthalate syndrome in adult male rats following fetal exposure to high doses of DINP and that:

- DINP is not a reproductive toxicant
- DINP is not an endocrine disruptor
- DINP is non-hazardous, different to the low molecular weight phthalate DBP.

Clewell RA, Thomas A, Willson G, Creasy DM, Andersen ME. *Reprod Toxicol.* 2013 Jan;35:70-80. A dose response study to assess effects after dietary administration of diisononyl phthalate (DINP) in gestation and lactation on male rat sexual development.

Clewell RA, Sochaski M, Edwards K, Creasy DM, Willson G, Andersen ME. *Reprod Toxicol.* 2013 Jan;35:56-69. Disposition of diisononyl phthalate and its effects on sexual development of the male fetus following repeated dosing in pregnant rats.

- **University of Edinburgh** research into whether phthalates affect steroidogenesis in the human fetal testis:

University of Edinburgh clinical scientist Dr. Rod Mitchell together with Professor Richard Sharpe conducted human fetal testis xenograft studies with di-n-butyl phthalate (DBP). He showed that exposure of human fetal testes to DBP is unlikely to impair testosterone production as it does in rats and commented that this has important safety and regulatory implications. In 2011, Professor Richard Sharpe appeared before the CHAP to present the preliminary findings from his laboratory. The studies were consequently published in *JCEM (Journal of Clinical Endocrinology & Metabolism)* in 2012. Professor Sharpe submitted these published papers to CPSC in early 2012. **Mitchell RT, Childs AJ, Anderson RA, van den Driesche S, Saunders PT, McKinnell C, Wallace WH, Kelnar CJ, Sharpe RM *J Clin Endocrinol Metab.* 2012 Mar;97(3):E341-8. Do phthalates affect steroidogenesis by the human fetal testis? Exposure of human fetal testis xenografts to di-n-butyl phthalate.**

Known submissions vs. CPSC website postings

| Submissions Not Located on the CPSC Website (11/4/2013) | | |
|--|--|-----------------|
| Document | Source | Submission date |
| Clewell RA, Thomas A, Willson G, Creasy DM, Andersen ME. <i>Reprod Toxicol.</i> 2013 Jan;35:70-80. A dose response study to assess effects after dietary administration of diisononyl phthalate (DINP) in gestation and lactation on male rat sexual development. | Rebecca Clewell, Hamner Institute - by email | January 2013 |
| Clewell RA, Sochaski M, Edwards K, Creasy DM, Willson G, Andersen ME. <i>Reprod Toxicol.</i> 2013 Jan;35:56-69. Disposition of diisononyl phthalate and its effects on sexual development of the male fetus following repeated dosing in pregnant rats. | Rebecca Clewell, Hamner Institute - by email | January 2013 |
| Mitchell RT, Childs AJ, Anderson RA, van den Driesche S, Saunders PT, McKinnell C, Wallace WH, Kelnar CJ, Sharpe RM <i>J Clin Endocrinol Metab.</i> 2012 Mar;97(3):E341-8. Do phthalates affect steroidogenesis by the human fetal testis? Exposure of human fetal testis xenografts to di-n-butyl phthalate. | Richard Sharpe, University of Edinburgh - by email | January 2012 |
| Chemical Industry comments on State-of-the-art report on mixture toxicity | ExxonMobil Chemical | April 2010 |
| Endpoint Summaries for Mammalian and Environmental Toxicity Submitted in the REACH Registration Dossier for Diisononyl Phthalate (DINP) | ExxonMobil Chemical - by disk | July 2010 |
| EU Risk Assessment DINP | ExxonMobil Chemical - by disk | July 2010 |
| EU Risk Assessment DIDP | ExxonMobil Chemical - by disk | July 2010 |

Confirmed posted on the CPSC Website (11/4/2013)

| Document | Source | Document Date |
|---|---|----------------------|
| Diisononyl Phthalate (DINP) Carcinogenicity Hazard Assessment, ExxonMobil Chemical Company, February 16, 2010 | Angela Rollins, ExxonMobil Chemical | 2/16/2010 |
| Approach to Cumulative Risk, ExxonMobil, 03232010 | ExxonMobil-- 03/23/2010 | 3/23/2010 |
| Plasticizers and the CPSIA | ExxonMobil Chemical | 7/16/2009 |
| Letter from Latham Watkins -- Request to present new Data to CHAP | ExxonMobil via Latham Watkins | 8/29/2011 |
| Letter from Latham Watkins on peer review | ExxonMobil via Latham Watkins | 3/14/2012 |
| Letter from Angela Rollins, EMC, 10272011 | Angela Rollins, ExxonMobil Chemical | 10/27/2011 |
| Letter from Latham & Watkins, legal arguments | ExxonMobil via Latham Watkins | 12/2/2011 |
| DiNP Dose-Response Studies: Gestation PK and Developmental Effects Postnatal Effects, | Rebecca Clewell, Hamner Institute (EM funded research) | JULY, 2011 |
| ExxonMobil Submission - Cumulative Risk, March 29, 2011 | Angela Rollins, ExxonMobil Chemical | 3/29/2011 |
| ECPI Submission, Pt 1 03012011 | ECPI, Maggie Saykali | 4/5/2011 |
| ECPI Submission, Pt 2 03012011 | ECPI, Maggie Saykali | 4/5/2011 |
| Letter from Latham to Cheryl Falvey on the Charge | ExxonMobil via Latham Watkins | 7/22/2011 |
| ExxonMobil Comment Submission to the CPSC CHAP - July 19, 2010 | Angela Rollins, ExxonMobil Chemical | 7/19/2010 |
| ExxonMobil DINP Comments | ExxonMobil Chemical | JULY, 2010 |
| Endpoint Summaries for Mammalian and Environmental Toxicity Submitted in the Reach Registration Dossier for Diisononyl Phthalate (DIDP) | ExxonMobil Chemical | JULY, 2010 |
| Review of Recent Scientific Data on DINP | ECPI: European Council for Plasticisers and Intermediates | JULY, 2010 |

Confirmed posted on the CPSC Website (11/4/2013), continued

| Document Name | Source | Document Date |
|--|--|----------------------|
| DINP and DIDP | Ammie Bachman, ExxonMobil | JULY, 2010 |
| Plasticizers and the CPSIA | ExxonMobil Chemical | 7/16/2009 |
| Clark database DINP DIDP | ExxonMobil Chemical | JULY, 2010 |
| Estimates of Exposure of Infants and Toddlers to DINP (Apart from Toys) and DIDP | ExxonMobil Chemical | 7/19/2010 |
| Cullen DINP Opinion | ExxonMobil Chemical | JULY, 2010 |
| Goodman DINP Opinion | Goodman, ExxonMobil Chemical | JULY, 2010 |
| HARD DINP Opinion | ExxonMobil Chemical | JULY, 2010 |
| Human Exposure to Diisononyl Phthalate (DINP) | Laura Winks, ExxonMobil Chemical | 9/16/2009 |
| DINP and DIDP are not endocrine disruptors | Nina Hallmark. CEFIC ECPI: European Council for Plasticisers and Intermediates | 7/26/2010 |
| Approach to Cumulative Risk, ExxonMobil, 03-23-2010 | ExxonMobil-- 03/23/2010 | 3/23/2010 |
| Proposed Approach to Conducting a Cumulative Risk Assessment for Six Phthalates (DINP, DIDP, DnOP, DEHP, DBP, and BBP) | ExxonMobil Chemical | 7/19/2010 |
| Uses of Phthalates and Other Plasticizers | Allen Godwin, ExxonMobil | 7/26/2010 |