CPSC
CHAP-meeting
July 26, 2010

Comments on Hexamoll®DINCH
and
DPHP

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BASF
The Chemical Company

Overview

- Understanding data ownership rights versus need for transparency
- Misperception about availability and validity of data
- Clarification of Hexamoll®DINCH and DPHP database

Understanding conflicting laws
Fed Reg Vol 75, No 106 versus EU REACH

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FR 75, 106:

- **Any information** submitted to CPSC in response to this request will **become part of the public record**“
- „…CHAP **will not consider summaries of toxicological studies prepared by manufacturers** as substitutes for complete studies“

REACH

- Article 25 (3) of the REACH Regulation **protects** any such summary for a period of 12 years from being used for the purposes of registration by another manufacturer/importer **without compensation**
- In case a full study report is published elsewhere, any other manufacturer/importer has to observe applicable copyright laws but is not restricted otherwise

How can the need for information be reconciled with data ownership rights?

Data quality/quantity

- Wrong metric used for availability of information
  - Validity of the metric choosen „Toxline during September 2008“
  - NICNAS evaluation (August 2008) was missed

- Peer reviewed journals versus industry data summaries ?
  - EPA HPV program, OECD HPV program, REACH **all** use summaries authored by the investigators
  - In addition, validity of the data are scored based on criteria of GLP and use of standard protocols
  - GLP test facilities are subject to independent audit

Hexamoll®DINCH

- Very broad and solid phys-chem, eco- and toxicological data available
- Original study reports have already been evaluated in several notification processes worldwide by respective competent authorities/gremia/commissions, e.g.
  - Germany(UBA/BfR)/ Netherlands(RIVM) / Europe(SCENIHR)
  - Switzerland (BAG)
  - Australia NICNAS => full evaluation report available on web
  - Canadian competent authorities
  - NSF review

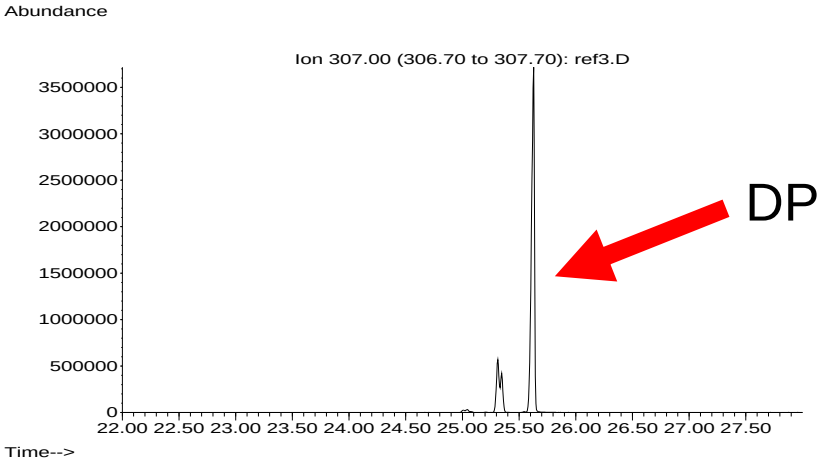
Hexamoll®DINCH

- Full phys-chem., ecotoxicological and toxicological data set
  - Negative genotoxicity (Ames, HPRT(CHO), in vitro CA(V79) and in vivo MNT)
  - Not a reproductive toxicant
    - Rats (1-gen Foster protocol + full 2 gen study)
    - OECD 414 in rats and in rabbits
      - No developmental toxicity
  - Chronic toxicity and carcinogenicity study (OECD 453, rat)
    - Thyroid adenoma, due to mechanism (enzyme induction) **not relevant to humans** based on EPA and IARC criteria.

Bis(2-propylheptyl)phthalate (DPHP)

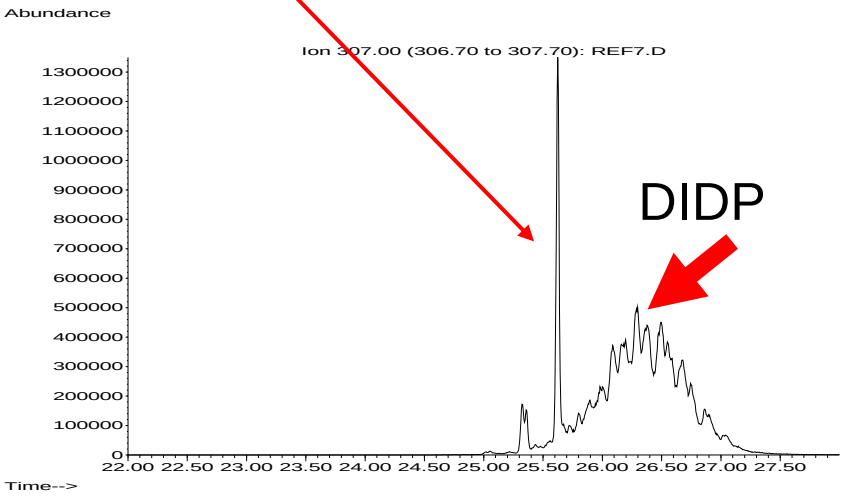
- Not genotoxic
- No developmental toxicity
  - OECD 414 (rat), GD 6 -19
- No reproductive toxicity
  - OECD 416
- Peroxisome proliferation

DPHP [53306-54-0] is not a DIDP [68515-49-1, 26761-40-0]



DPHP

DIDP spiked with DPHP



DIDP

Human Exposure

- Hexamoll®DINCH and DPHP
  - Human biomonitoring methods for urine are currently developed
- VWA and RIVM (NL) have currently evaluated migration of Hexamoll®DINCH and other plasticizers from toys
  - Report has been forwarded to CPSC