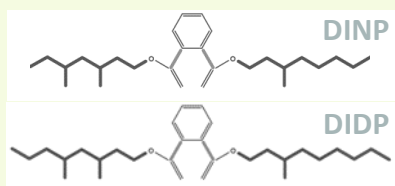


## CASE STUDY

### DINP and DIDP plasticisers for flexible and safe vinyl articles

*Latest news: EU scientific agency concludes DINP not classifiable for reproductive effects*



**Additives:** High Molecular Weight Orthophthalates

#### Key benefits

- › Formulate flexible PVC with DINP and DIDP
- › DINP and DIDP deemed safe for use in all current applications by the European Chemical Agency (ECHA)

## The Challenge

February 2015. A proposal for the classification of **DINP** was submitted to the European Chemicals Agency (ECHA) by Denmark. It triggered a scientific debate on the proposal for classification. Consequently, a complete re-analysis of the raw data on a key study in the dossier conducted by scientists at the Danish Technical University was made.

After 3 years work on the proposals from Denmark to classify DINP as a Category 1B Reproductive Agent, the Risk Assessment Committee (RAC) review process involved a rapporteur and co-rapporteur working in-depth on the Danish proposal one year before the decision was taken by the full committee. During this period, the rapporteurs reviewed all the relevant data including original scientific reports, the re-analysis of statistics from a key study, and peer-reviewed published papers by academic and industry scientists. The producers of DINP worked proactively via Cefic European Plasticizers to provide the data on DINP into the public consultation and to

respond in a timely manner to the specific requests from ECHA RAC with regard to the original scientific reports. The aim was to provide robust, scientific data to support the evidence and data provided.

March 2018. The ECHA RAC carried out a robust scientific weight of evidence evaluation taking into account all of the relevant data.

## The Outcome

---

The RAC concluded that “Contrary to the proposal from Denmark, RAC agreed not to classify DINP for reproductive toxicity”. Di-isononyl phthalate (DINP) did not warrant classification for reprotoxic effects under the EU’s Classification, Labelling and Packaging (CLP) regulation. Given Denmark’s view that DINP should be classified as a Category 1B Reproductive Agent, this case underlined the critical importance of regulators (and industry) conducting robust, weight of evidence assessments taking into account all of the relevant data including the quality of the data. Together with the prior EU Risk Assessment Report and the ECHA evaluation of new data (2013), both concerning reproductive effects, this now gives **DINP a clean bill of health on current uses**.

### › No significant adverse reproductive effects

RAC also concluded that **DINP does not show any significant adverse reproductive effects** in the extensive animal studies (both industry and academic studies) available. In the absence of adverse effects, DINP then cannot be considered an endocrine disruptor for the topic of relevance to low molecular weight phthalates such as DEHP, namely reproduction, since the definition of endocrine disruptor requires three criteria to be met: 1) an adverse effect and 2) an endocrine mode of action, and 3) a plausible biological relationship between the two.

**“Overall, RAC concluded that no classification for DINP for either effects on sexual function and fertility, or for developmental toxicity is warranted.”**

### › Safe for use in all current applications

RAC undertook a stringent hazard assessment following the rules of the EU Classification and Labeling program (CLP) regulation, with the conclusion that, given the lack of evidence of adverse effects, classification is not required. Amongst prior regulatory assessments, the ECHA evaluation of new scientific evidence – endorsed by the European Commission in 2014 – concluded that **DINP can be safely used in all current applications** (restrictions in mouthing toys maintained). All relevant data are included in the DINP REACH registration dossiers, which were updated in 2015 and 2016.

DIDP has also been extensively evaluated with conclusions on no hazard classification required (EU Risk Assessment Report) and safe for use in current applications (ECHA re-evaluation). There is no new data after these assessments to warrant any further assessment of DIDP. Like DINP, DIDP has extensive reproduction studies and has shown no adverse reproductive effects and hence classification for such effects is not required.

The extensive regulatory assessments of DINP and DIDP over the last 20 years concluded that there is no need for hazard classification and that DINP and DIDP are safe for use in current applications. Taking into account the clearly demonstrated safety, as well as the sustainability benefits from flexible vinyl applications, together with

available life cycle assessment information, as well as the extensive recycling and reuse, then the value chain, regulators and consumers can be reassured with respect to the safety and sustainability of flexible vinyl made with DINP and DIDP

---

*“Absence of any further risks”*

*“Tasks called for by the review clause are satisfied and fully completed”*

*European Commission confirms ECHA conclusions (Jan 2014)*

---

**Low molecular weight (LMW)**  
**DEHP, BBP, DBP**



C3 to C8 alcohol + Phthalic Anhydride

- Cat 1B Reproductive Agents
- Risk reduction required
- REACH Candidate List
- Endocrine Disrupters
- Subject to REACH Authorisation and Restriction

**High molecular weight (HMW)**  
**DINP & DIDP**



C9 & C10 Alcohol + Phthalic Anhydride

- Not CMR
- Not classified and labelled
- No risk reduction required in current uses (mouthing toy restrictions)
- Not Endocrine disrupters for reproductive effect

**PVC+DINP, DIDP: safe, flexible, durable, cost effective**

