



Plasticisers used in spectacular ways

See page 6 ...

in this issue

- ▶ Politicians welcome scientific certainty [2]
- ▶ Spreading the news: 'DINP/DIDP Safe for Use' [3]
- ▶ Industry working together for success [3]
- ▶ EU Risk Assessments: Facts & Figures [5]
- ▶ ECPI facilitates successful dialogue between scientific experts [5]
- ▶ Benefits drive plasticiser use in flooring [6]
- ▶ Specialty plasticisers – premium products meeting user needs [7]
- ▶ Laying the foundations for continued success [8]



Risk assessments confirm plasticiser safety

The European plasticiser industry is facing the future with confidence after the conclusion of the European Union's (EU) comprehensive safety assessments of the main general purpose phthalate plasticisers. With legislation on phthalates in toys now in place across Europe, the EU's conclusions on DINP, DIDP and DEHP provide a boost to the confidence of both users and producers in preparation for a new era in chemicals regulation.

For more than ten years, the EU has been conducting an in-depth review into the safety of the main phthalate plasticisers in line with the requirements of its Existing Substances legislation. The publication of the results for the assessments of DINP and DIDP in the EU's Official Journal and agreement at a European level on the results of the DEHP assessment finally offer users and regulators a scientific basis to judge the suitability of these substances across all their current applications. The results of the risk assessments for DINP

and DIDP, published in April 2006, show that these substances pose no risk to human health or the environment in any of their current applications. The use of the two substances in applications such as automotive, flooring, wall-covering, cable and wiring were all considered by EU experts as part of the comprehensive process.

The assessment for DEHP was concluded by national government experts and the European Commission in mid-2006 and now awaits final publication. Regulators have come to the conclusion that the level of exposure of the general population to DEHP is at least 280 times lower than safe limits. For the vast majority of key applications, further risk management measures are not foreseen. However, on the basis of the assessment, the European Commission will be examining measures to ensure that all converters (producers of flexible PVC items) have appropriate emission abatement technology. With regard to the use of DEHP in medical

devices the Commission is asking for more advice from a specialist scientific committee.



While the Existing Substances Regulation will be replaced by REACH in 2007, the fact that DINP, DIDP and DEHP are three of only a handful of chemicals to have gone through the existing assessment process puts the substances and their uses in an advantageous position. Indeed, the assessment process has contributed to the phthalates becoming some of the most well researched chemicals in the world. This body of knowledge will provide the foundation for the REACH registration of each of the substances. In the case of DEHP, the fact that the EU has already come to the conclusion that the substance can be safely used in its main applications will also provide the springboard for the industry's application for authorisation. ■

Politicians welcome scientific certainty

Key European Parliamentarians from across the political divide have welcomed news of the publication of the EU's Risk Assessments of DINP and DIDP as a firm foundation for policymaking with regard to these substances.

In the 11 years since the European Commission started its safety assessment process, phthalates have been subjected to often emotional debates within the European Parliament's Environment Committee. Unfortunately, for most of this period the assessments of the two substances were still under way and many Parliamentarians lacked clear guidance on their safety. Members of the European Parliament (MEPs) rarely have a scientific background and therefore tend to rely on the European Commission and



stakeholders such as NGOs and industry for assistance in understanding such issues. However, the situation has improved greatly with the completion of the risk assessments. As **Hans Blokland**, a Dutch MEP and current Vice Chair of the Environment Committee explained, the published Risk Assessments have vindicated those in the European Parliament who felt calls for legislation on phthalates were too often based on emotion rather than science. "The results clearly show that sometimes scare stories are not necessarily backed up by science."

stakeholders such as NGOs and industry for assistance in understanding such issues.

However, the situation has improved

With the restrictions on toys finally agreed and the results of the DINP/DIDP Risk Assessments published, MEPs now see the Risk Assessments as a key tool to inform policymaking with regard to the substances (see fig. 1). "The finalised assessments provide policymakers with some much-needed clarity as to the safety of these substances," **Caroline Jackson**, UK MEP and former Chair of the European Parliament's Environment Committee, commented.

Media outlets have widely echoed the 'no risk' conclusions of the EU assessment of DINP and DIDP. ■



Fig. 1, EU DINP and DIDP Risk Assessment Results

	Risk Reduction Measures foreseen by EU ⁽¹⁾	To note
Key Applications ⁽²⁾		
Automotive	None	
Cables	None	
Clothing/Footwear	None	
Flooring/Wall-covering	None	
Food Contact	None	Commission regulation proposed defining specific migration limits. Both phthalates may be used in repeat use materials in contact with all foods and in single use materials in contact with non-fatty foods only.
Roofing/buildings	None	
Toys	Measures adopted	EU Directive 2005/84/EC restricts the use of DINP and DIDP in toys and childcare articles that can be placed in the mouth.
General Population	None	
Workers	None	
Environment	None	

⁽¹⁾ The results of the Risk Assessments and a recommendation for risk reduction measures were published in the Official Journal on 13 April 2006 and are available at www.dinp-facts.com/ra and www.didp-facts.com/ra

⁽²⁾ The risk assessment examined many applications, including the key applications listed above. If you need further information on the regulatory situation in the EU concerning a specific application or use please contact info@plasticisers.org

Spreading the news: 'DINP/DIDP Safe for Use' – Official Advertising Campaign



The plasticiser industry has been proudly spreading the news about the results of the EU's assessments of DINP and DIDP. To raise awareness of the good news, the European plasticiser industry ran an advertising and advertorial campaign across the following publications during 2006.

- ▶ *Kunststoff Magazin – 1 June & 16 October editions*
- ▶ *Boden Wände Decker – 6 June & 2 November editions*
- ▶ *Plastiques et Caoutchouc Magazine – 8 June & 9 October editions*
- ▶ *Automotive News Europe – 12 June & 16 October editions*
- ▶ *Housebuilder & Developers Datafile – 15 June & 28 September editions*
- ▶ *Flooring Magazine – 16 June & 13 October editions*
- ▶ *ICIS Chemical Business – 9 June, 18 September & 25 September editions*
- ▶ *European Voice (European public policy weekly) – 9 June edition*

Copies of the advertisements, advertorials and the full risk assessment reports and summaries can be found at www.dinp-facts.com/ra and www.didp-facts.com/ra

Industry working together for success

Close collaboration between plasticiser producers and plastic converters at a European level has resulted in a positive outcome for the EU Risk Assessment of diethylhexylphthalate (DEHP).

The partnership that was forged between the European Council for Plasticisers and Intermediates (ECPI) and the European Plastics Converters (EuPC) meant that sufficient research data was provided to help convince the authorities that there are very few risks associated with the continued use of what is one of the best-known phthalate plasticisers.

The risk assessment report has concluded that there are no risks to children or adults associated with the use of DEHP in a wide

range of applications including flooring, wallcovering, PVC clothing and artificial leather-cloth (see fig. 2). This means there are also no risks from indoor air exposure, either from automotive use or from within buildings.

However, there had been concerns that DEHP emissions from converters' plants could pose a risk to children living nearby.

ECPI and EuPC worked together to provide the necessary data to challenge the generic models being used by the risk assessment authorities. Research conducted by the laboratories of IVL, the Swedish Environmental Research Institute, sampled the presence of DEHP around converter plants and found that the levels of DEHP were around 1,000 times lower than those

estimated by the authorities. This was sufficient to prevent a ban on outdoor applications which had been proposed as a risk reduction measure.

The European Commission will still propose controls to ensure that emissions abatement technologies are fitted as standard in all

▶ *Continued on page 4*

converter facilities using DEHP but converter industry research suggests that many DEHP users already have such controls in place. However, ECPI and the downstream industry will continue to work together to ensure that these meet the emission requirements.

The collaborative effort has been hailed by plastic converter industry representatives as a case study of how the plastics value chain can

work together to achieve common goals. "In Brussels as in business, we all benefit when supplier works with customer," stated **Geoffroy Tillieux**, Issues Manager at EuPC.

Recent years have seen an increased level of partnership between the plasticiser industry, its customers and the end-users of plasticised PVC at a European level. As **Tim Edgar**, Deputy-Director of ECPI explains, "Our work

with Brussels-based representatives of key end user groups such as automotive, flooring and medical, has two clear benefits. Firstly, we speak with a common voice based on our commitment to the science of safety. Secondly, key market segments for soft-PVC have access to the latest scientific information on the benefits and safety of plasticisers." ■

Fig. 2, EU DEHP Risk Assessment Results

	Risk Reduction Measures foreseen by EU ⁽³⁾	To note
Key Applications ⁽⁴⁾		
Automotive	None	
Cables	None	
Clothing/Footwear	None	
Flooring/Wall-covering	None	
Food Contact	Measures under consideration	Commission regulation proposed defining a specific migration limit. DEHP may be used in repeat use application in contact with non-fatty foods.
Medical	Measures under consideration	The European Commission is awaiting advice of specialist Scientific Committee (SCENIHR) on risks and benefits of DEHP in some medical applications.
Roofing/buildings	None	
Toys	Measures adopted	EU Directive 2005/84/EC prohibits the use of DEHP in all toys and childcare articles.
General Population	None	
Population near converter plants	Measures under consideration	Consideration of measures under Council Directive 76/769 EEC to ensure that emissions of DEHP from converter plants are adequately controlled through the use of abatement technologies.
Workers	Measures under consideration	To establish at a community level occupational exposure limits for DEHP according to Directive 98/24/EEC.
Environment	Measures under consideration	Consideration of EU wide Environmental Quality Standard for surface water of 1.3µg/l under the Water Framework Directive 2000/60/EC.

⁽³⁾ The measures foreseen reflect the draft recommendation agreed by Member States at the Risk Reduction Meeting of 6/7 June 2006. Where necessary, the European Commission will bring forward proposals to enact these measures in due course.

⁽⁴⁾ The risk assessment examined many applications, including the key applications listed above. If you need further information on the regulatory situation in the EU concerning a specific application or use please contact info@plasticisers.org

EU Risk Assessments: Facts & Figures

11	Years since the beginning of the Risk Assessment process for DINP, DIDP and DEHP
8	Drafts by Sweden of DEHP Risk Assessment before final agreement of 25 government experts
290	Pages in the DINP Risk Assessment Report
351	Studies referenced in the bibliography of the DINP Risk Assessment Report
130	Million Euro invested in research by industry as part of its long term commitment to its products
39	Chemical substances to have completed the EU Risk Assessment process out of the 100,204 existing substances in Europe
12	Percentage of substances to have completed the EU Risk Assessment process that are phthalate plasticisers

ECPI facilitates successful dialogue between scientific experts

Leading academic and government experts gathered in France recently to attend a workshop on the latest scientific developments on plasticisers. The workshop, facilitated by ECPI, built a greater common understanding between different parts of the research community on some of the latest topics addressed in international academic journals.

The workshop, held in early September outside Paris, saw two days of in-depth discussion between academics from both sides of the Atlantic, moderated by Professor **Richard Sharpe** of the UK's Medical Research Council.

As **Norbert Scholz**, Chair of ECPI's Technical Working Group explains, the event is part of an ongoing dialogue between industry and academia on the science and safety of plasticisers. "While phthalates are some of the most well researched chemicals in the world, new studies are constantly being conducted. An ongoing commitment to dialogue with all parts of the research community enables us to pool our knowledge and ensure that all new research meets the most rigorous scientific standards."

Among those attending the workshop were authors of papers that have led to media scare stories in the recent past. The event provided the opportunity for leading experts in relevant fields to challenge and discuss the results of these studies.

Key topics included the latest developments in our understanding of the mechanisms underlying the reproductive effects of phthalates in rodents and their relevance, if any, to humans; and the latest techniques for reliably measuring human exposure to phthalates.

One of the important outcomes of the workshop was an open exchange of views between epidemiologists, statisticians, toxicologists and exposure experts. It is hoped this will lead to an ongoing dialogue and to studies being designed more robustly so that their outcomes are accepted by researchers in all disciplines.

In order to ensure that the outcome of the workshop is widely disseminated within the research community, ECPI is seeking to publish a summary of the event and key findings in an appropriate international scientific journal. ■

Plasticisers used in spectacular ways

Plasticisers are being used in spectacular ways across Europe. From huge banners adorning EU institutions, to futuristic exhibitions centres, soft-PVC is proving to be a key material in innovative and striking structures and designs.



▲ PVC mesh containing plasticisers has recently been used for a huge banner hanging from the European Commission's Berlaymont building in Brussels.

Soft-PVC structures have been used for the visits of the Pope to Germany in both 2005 and 2006. The structure pictured was made using a soft-PVC membrane and covered the Pope for a papal address during his first visit to Germany in 2005. ▼



© mmw.no > Martin Sunde Skulstad

▲ A soft-PVC structure was recently used to create a spectacular art exhibition centre in Tullin, Norway. Known as 'The Frog', the exhibition structure is covered in a green and opaque PVC membrane and was part of the 100 year anniversary celebrations of Norway's independence.

Benefits drive plasticiser use in flooring

Why is soft-PVC the right choice for flooring?

After more than 50 years in our homes, soft-PVC continues to be one of the most popular choices for flooring in Europe. Valued by designers and users as a cost-effective material that combines comfort, style and durability, soft-PVC is a favourite for hard working family kitchens as well as bright new public spaces.

The use of attractive colour combinations is a positive addition to any working environment. Furthermore, the noise reduction properties of PVC flooring are widely appreciated, in hospitals, for example, where such qualities are important for patient comfort and well-being. In addition, soft-PVC floors are easy to clean, making them an ideal choice for environments where dust and dirt need to be kept to a minimum.

Which plasticisers are used in these applications?

General purpose phthalate plasticisers such as DINP and DEHP are used in many flooring

applications due to their cost-effectiveness and ease of processing. Lower molecular weight phthalates such as BBP, and DIHP, can also be employed. In cases where specific functional characteristics are needed, such as heightened stain resistance, the benzoate family of specialty plasticisers are often used.

What do regulators say about the safety of plasticisers in flooring?

The uses of the five main phthalate plasticisers, BBP, DBP, DEHP, DIDP and DINP, have all undergone comprehensive safety assessments by the EU over the course of the last ten years. In all cases, regulators have confirmed that the use of each of the substances in flooring poses no risk to either human health or the environment.

The assessments estimated that even were a person to spend twenty four hours a day, seven days a week in a room with PVC flooring, exposure to the plasticisers via both air and through the skin would be many thousands of times below levels which might be of any concern. ■

Specialty plasticisers – premium products meeting user needs

Specialty plasticisers' performance characteristics continue to ensure that for certain applications they remain the plasticisers of choice. Since 1999, European consumption of these valued products has remained constant at around 7-8% of the overall European plasticisers market.

By their very nature, specialty plasticisers are of course both numerous and diverse. They include adipates, alkyl sulphonates, benzoates, benzyl phthalates, linear phthalates, polymeric and trimellitates and are often chosen for PVC applications when a specific functional characteristic is required (see fig. 3). For example, trimellitates, because of their low

volatility and good thermal stability, are used in preference to general purpose phthalates in the production of cables operating at elevated temperatures. Adipates such as DEHA in conjunction with polymeric are often used in food packaging applications such as PVC cling film due to combination of flexibility at low temperature and low migration rates. Trimellitates and linear phthalates are often used in vinyl car interiors applications due to their antifogging characteristics.

Unlike many of the general purpose plasticisers, specialty plasticisers are also used to great effect in many non-PVC applications. For example, some alkyl

sulphonates and benzyl phthalates find a place in non-PVC sealing compounds and adhesive systems as well as industrial solvents. Similarly certain specialty plasticisers can be used in paint to assist in film formation and in inks to reduce the softening point.

While specialty plasticisers are a small part of the overall plasticiser market, they fulfil an important function for their users. As part of its commitment to providing a knowledge centre for all those interested in plasticisers, the European Council for Plasticisers and Intermediates will launch a specific section of its web site focused on specialty plasticisers in the course of 2007. ■

Fig. 3, Specialty plasticiser families and their key performance characteristics

Plasticiser Family	Efficiency	Ease of processing	Low volatility	Low migration	Low temperature flexibility	High temperature performance	High saponification resistance	Stain resistance	Fire resistance	Key PVC end use application	Use in other polymers
Adipates					✓					Food Packaging, Medical	
Alkyl Sulphonates		✓					✓			PVC products that come into contact with water or alkalis	PU, NR, SBR, SBR/BR, IIR, NBR, CR
Benzyl Phthalates	✓	✓						✓		Floor covering, sealants	CR, PU, PVAC, NBR, SBR Acrylates, Polisulfides
Linear Phthalates			✓		✓	✓				Construction, cables, car interiors, out door applications, Automotive electric cables	
Polymeric			✓	✓		✓				Food packaging, PVC in contact with oils, fats and hydrocarbons	PVA, NBR, Acrylics
Trimellitates			✓	✓	✓	✓				High Temperature electrical cables, Automotive electric cables, Anti-fogging PVC for automotive applications, Medical devices	HNBR, CPE

BR Polybutadiene rubber
CA Cellulose acetate
CPE Chlorinated polyethylene
CR Polychloroprene rubber

HNBR Hydrogenated nitrile rubber
IIR Butyl rubber
NBR Nitrile rubber
NR Natural rubber

PV Polyurethane
PVA Polyvinyl alcohol
PVAC Polyvinyl acetate
SBR Styrene butadiene rubber



Laying the foundations for continued success

The publication of the EU Risk Assessments of DINP, DIDP and DBP, along with the finalisation of the assessment of DEHP, bears testimony to the investment made by the plasticiser industry over the last ten years in Europe. Through the research conducted and the results achieved, I believe that we have lived up to our promise of being committed to the science of safety. Above and beyond this, the good results of these assessments justify our longstanding belief in our products, their safety and the value they bring both to plasticiser users and society as a whole.

The EU's conclusions do not diminish the need for us to work together as an industry with users, the research community and regulators. Nor do they absolve us of our responsibilities under Product Stewardship. Indeed, the Risk Assessments provide a strong foundation to succeed in our next set of challenges. Chief among these is the new European chemicals regime (REACH).

Without doubt the data created by the Risk Assessment process will prove invaluable when we seek to register many of the general

purpose phthalate plasticisers under REACH. However, in my view the experience that we have gained from the Risk Assessment process is equally as important to our products' continued success. Very few parts of the wider chemicals industry can claim the expertise that resides within our industry in navigating complex regulatory processes, communicating with users about this process and managing media and NGO attention. Even a cursory examination of the REACH Regulation suggests that all of these attributes will be in increased demand as we enter the REACH era.

Of course, REACH will not only affect general purpose plasticisers but for the first time will involve many of the specialty products that fall under the ECPI umbrella. Phthalates represent around 93% of the overall plasticiser market in Europe. Yet many specialty plasticisers, such as adipates, citrates and trimellitates, have specific properties that make them the plasticisers of choice for certain PVC and non-PVC applications. While ECPI has necessarily focused much of its attention on the general purpose plasticisers in the past, our ability to communicate the benefits of all our products is likely to become increasingly important in the future.

Since its creation, ECPI has become a trusted source of information for all those seeking to know about the performance and safety of plasticisers. Indeed, the sheer numbers of unsolicited emails that arrive via our comprehensive set of European websites each day attest to this. We have only been able to achieve such success through working together as an industry with users, the research community and regulators. As we face our next set of challenges, we will only continue to be successful if we build upon these existing partnerships.

Luca Bielli
Chairman, ECPI

*Business Line Director
PA, TMA & Plasticizers
Polynt S.p.A.*



European Council for
Plasticisers and Intermediates
COMMITTED TO THE SCIENCE OF SAFETY

The European Council for Plasticisers and Intermediates (ECPI)

Avenue E. Van Nieuwenhuysse 4, Box 2, B-1160 Brussels, Belgium, telephone: + 32 2 676 7260, fax: + 32 2 676 73 92, e-mail: ccr@cefic.be