

## EUCOMED Q & A on PVC/DEHP

### GENERAL INFORMATION

Q1 What is a phthalate?

A1 Phthalates are a group of compounds used to soften PVC and make it more flexible. The highest volume phthalate produced is DEHP which represents between 50 and 90% of the total phthalate production. In 1997, at least 93% of DEHP produced was used as an additive for PVC plastic. In addition to medical products, phthalates, and DEHP in particular, are applied in PVC (vinyl) floorings, wallpaper, cable coatings, toys, packaging, cosmetics and fashion goods.

Q2 What is DEHP?

A2 DEHP stands for di-(2-ethylhexyl) phthalate. It is the plasticiser most commonly used to soften the otherwise hard PVC and it can be readily mixed with it. PVC plasticised with DEHP is recommended for use in blood and plasma transfusion equipment by the European Pharmacopoeia ("quality specifications for pharmaceutical preparations and their ingredients")

Q3 Why do the medical industry use DEHP to manufacture products if DEHP is not safe?

A3 DEHP has been widely used and tested with scientific evidence indicating that it is acceptable for use in medical devices. Medical PVC that contains DEHP has been safely used for more than 40 years without any adverse effects.

The reason why the medical industry uses DEHP is that the PVC polymer itself is very rigid and relatively sensitive to deterioration. By adding DEHP, PVC will become a soft and flexible material extremely suitable for medical applications. This is why PVC plasticised with DEHP was chosen to replace the traditional materials in the medical sector such as glass and rubber.

Q4 Do you agree with claims that DEHP is toxic for human beings?

A4 No, we disagree with these claims. Numerous studies conclude today that there is no toxic risk for humans. Claims that DEHP causes cancer and affects reproduction are mainly based on rodent studies. However, as rodents have a different metabolism and different response mechanisms to DEHP compared with humans, claims that DEHP poses health risks to humans are not correct. This position has been supported by numerous scientific committees around the world, such as:

- The European Union Scientific Committee on Toxicity, Ecotoxicity and the Environment which stated on May 23, 2000 that phthalates do not pose a sufficient risk to justify a ban.
- The American Council on Science and Health that stated in its 1999 Koop Report: "It is important for the medical community and the public to understand that removing the phthalate would actually pose a significant health risk to individuals who depend on these devices."
- The International Agency for Research on Cancer (IARC) has stated that DEHP is not classifiable as a human carcinogen and that the mechanism by which phthalates such as DEHP increase the incidence of hepatocellular tumours in rats and mice is not relevant to humans

- Q5 If it is true that all phthalates and DEHP in particular are only carcinogenic to rats, then, why have Health Authorities banned their use in babies' toys?
- A5 We would like to emphasise the fact that DEHP does not pose a health risk to humans. Statements about the carcinogenic and hormone disrupting character of DEHP for humans are mainly based on rodent studies. However, as the metabolism and response mechanisms of rodents are different compared to humans, these statements are not applicable. This is also fully supported by The American Council on Science and Health, which stated in its 1999 Koop Report that "there is a critical difference between the toxicology and mechanisms for the chemicals between rodents and humans. It is therefore incorrect to extrapolate directly from studies on rats and mice to possible effects on human."
- The Chairman of the EU Scientific Committee on Toxicity, Ecotoxicity and the Environment stated that phthalates do not pose a sufficient risk to justify a ban on baby toys. Nevertheless, the EU has imposed a ban on baby toys containing six types of phthalates. Despite the ban, the CSTEE has re-iterated its view that this threat to health is trivial.
- Q6 Why is the medical industry mainly using DEHP as a plasticiser for PVC?
- A6 The medical industry uses the most appropriate materials that are fit for ultimate medical performance and successful therapeutic results. DEHP is the most tested and authorised plasticiser with proven performance qualities. In some other products the medical industry uses other plasticisers which have been scientifically tested and proven fit for use.
- Q7 What is the link between PVC, DEHP and dioxins?
- A7 There is no direct link. Dioxins are only formed in trace amounts during the PVC production process. However, the PVC industry has taken significant steps (Responsible Care Programmes and Industry PVC Charters) in recent years to control processes so that dioxin formation is minimised well below the limits set by the authorities. Dioxins can be formed if any chlorine-containing material (such as PVC) is incinerated under improper conditions. When PVC is incinerated at temperatures of 800 degrees centigrade (or over) and with proper residence time in the combustion zone, the production of dioxin is negligible. Since there are many other sources of chlorine in waste fed to incinerators, some dioxin will be produced even without the presence of PVC. The key is the use of correct incineration conditions, regardless of whether PVC is present. Since DEHP does not contain chlorine it is not linked to dioxin formation.
- Q8 What is the impact of DEHP on the environment?
- A8 DEHP has no known significant impact on the environment, but risk assessments for the purpose of determining the best method of disposal are currently underway within the EU.
- Q9 Are there any additional risks linked to the contact with PVC?
- A9 During the last 40 years of medical use – as approved by the regulatory authorities – there have been no identified risks associated with medical products containing PVC, only positive benefits.
- Q10 What is a hormone disrupter?
- A10 Usually referred to as endocrine disrupters (EDs), they are chemicals which disrupt human hormone production. For example, they may result in production of too little male hormone or they can lead to birth defects in the genital area of male babies.

European Union authorities are still trying to identify the exact composition of an endocrine disrupter.

Q11 Is DEHP an endocrine disrupter?

A11 There is no proven link between endocrine disruption and DEHP. Indeed the UK Environment Agency has not listed DEHP, or any other phthalate, among the chemicals to be included in its action and surveillance programme for potential endocrine-disrupting substances.

### EUCOMED AND THE ISSUE

Q12 Does EUCOMED agree with the adverse statements made about the risks of using PVC-containing products?

A12 No. These criticisms have originated from some Environmental Non-Governmental Organisations. Medical products containing PVC plasticised with DEHP were specially chosen to replace natural rubber and glass because they are considered safe, are not toxic for humans and have essential physical and functional properties such as being easy to sterilise, transparent, flexible and chemically stable. In addition to the above, PVC plasticised with DEHP is recommended for use in blood and plasma transfusion equipment by the European Pharmacopoeia ("quality specifications for pharmaceutical preparations and their ingredients").

Q13 According to various sources, PVC has been proven to cause several health risks such as dioxin emission, hormone disruption and cancer. Why has the medical industry not withdrawn its PVC-containing products?

A13 There is no rationale for withdrawing such products, as these claims are groundless. Medical products containing PVC were specially chosen to replace the traditional materials in the medical sector because they are considered safe for human use as well as having attributes of easy sterilisation, transparency, flexibility and chemical stability. In addition, PVC plasticised with DEHP is recommended for use in blood and plasma transfusion equipment by the European Pharmacopoeia ("quality specifications for pharmaceutical preparations and their ingredients"). In cases where another material has proven to be superior for its application and regulatory clearance is obtained, it is normal for companies to offer the alternative.

Q14 Is EUCOMED conducting research to further investigate the potential risks?

A14 EUCOMED, as well as regulatory authorities, relies on the large amount of scientific evidence on the safety of medical PVC. Nevertheless, member companies are continually analysing risk and research data as required by the Medical Device Directive.

Q15 Why has the medical industry abandoned the use of reusable products to manufacture disposable PVC products?

A15 The medical products industry manufactures both disposable products and reusable ones - for example glass bottles. The production and distribution of disposable products answers the medical need to avoid cross-contamination and ensure patient safety that cannot be met by traditional reusable products. Regulations on medical devices specifically restrict the reuse of products in order to contribute towards safeguarding the health of both patients and medical personnel.

Q16 Was the medical industry aware of the health hazard when it started to use PVC for the manufacturing of its products?

A16 There is no health hazard according to all available scientific research and PVC has been successfully used for over 40 years without any reported adverse effects

### THE ISSUE IN EUROPE

Q17 Why has the European Union decided to ban the use of phthalates in babies toys and not in medical products?

A17 The risk/benefit analysis for medical products is very different to that for toys.

It must not be forgotten that many medical products are life saving, or improve the quality of life, and have a long history of safe use, including the treatment of newborn babies and infants. The same principle cannot be applied to toys.

In any case, the ban on phthalates in babies' toys occurred despite the view of the EU Scientific Committee on Toxicity, Ecotoxicity and the Environment that phthalates do not pose a sufficient risk to justify a ban.

Q18 Is EUCOMED co-operating with the European Health Authorities to further investigate the risks linked to PVC-containing products?

A18 EUCOMED works with the Health Authorities of all countries to share information about various subjects, one of them being environmental and safety issues.

Q19 Is the medical industry considering the option of manufacturing recyclable products to replace their existing PVC-containing products?

A19 All medical PVC-containing products are recyclable. However, it will be necessary to take into account the risk of contamination (patient and public safety), the cost and environmental impact of decontamination and the compliance with the requirements for the safe handling of medical waste. We would only recommend recycling when the risks associated with safe handling and the high costs of decontamination are overcome

Q20 What is the impact of DEHP on the environment?

A20 DEHP has very little impact on the environment. It does not accumulate in water, soil or air and breaks down very quickly.

Q21 What does EUCOMED do to ensure that hospitals incinerate their used medical products in the best way to limit emission of dioxins?

A21 The waste incineration process, in particular for medical waste, is strongly regulated by the authorities at both local and national government level throughout Europe. If the incinerators are operated according to these requirements then the process is safe, eliminating the possibility of dioxin formation. Eucomed fully supports such regulations