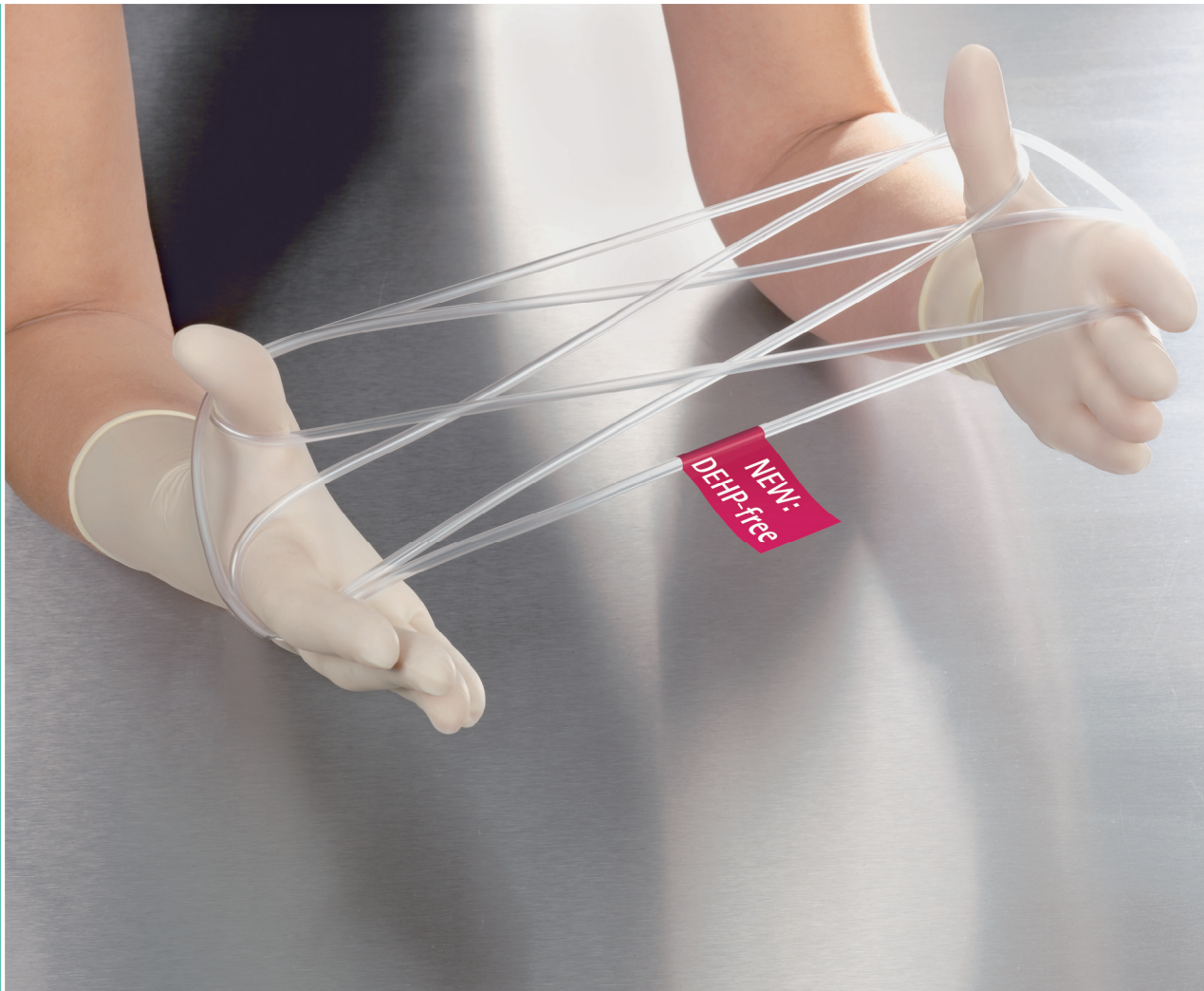


B. Braun infusion lines: Softness with safety



Safe IV Therapy

DEHP-containing medical products: Safety concerns for high risk patient groups

Infusion lines softened with the new generation of non-phthalate plasticizers.
Patient safety first.

DEHP-plasticized infusion lines

Medical products made of plastic are commonly used for patient treatment. Examples include flexible tubing for IV therapy and blood donation procedures. One of the plastics used the most frequently is polyvinyl chloride (PVC).

PVC is a polymer, its best performance can be achieved by making it softer and more flexible. This requires the addition of a plasticizer in order to achieve the properties required for various kinds of applications including IV therapy, enteral and parenteral nutrition, blood transfusions, etc.

Growing concern over exposure to DEHP plasticizer

Serious concerns have been raised about potentially harmful effects associated with the soft PVC material. An additive, DEHP di-(2-ethylhexyl)phthalate, is used most often as a plasticizer. DEHP is part of the chemical group of phthalates that are classified as SVHC - **Substances of Very High Concern**.

In animal studies, the leaching of DEHP out of PVC has been shown to adversely affect the development of the testes, liver, and kidneys. It is commonly believed that the results of the studies apply to humans too.

In humans, DEHP is suspected to be a reproductive toxicant that may impair fertility specifically in male unborn children, pregnant and feeding women, as well as critically-ill male neonates.

Reactions of health care authorities for safer plasticizers

The serious effects of DEHP on humans are currently "suspected" rather than "known". Nevertheless, in view of these concerns, health care authorities including the European Commission have already forbidden the use of DEHP in cosmetic articles, children's toys, and child care articles for precautionary reasons.

With respect to medical devices that contain DEHP, manufacturers have been asked to use alternative plasticizers. Thanks to REACH, the use of DEHP will be restricted through registration and authorization. The continued use of DEHP-plasticized PVC requires appropriate labeling of the products in order to allow medical personnel to balance the risks and benefits of products containing DEHP plasticizer.

Alternative plasticizers with low-risk profile

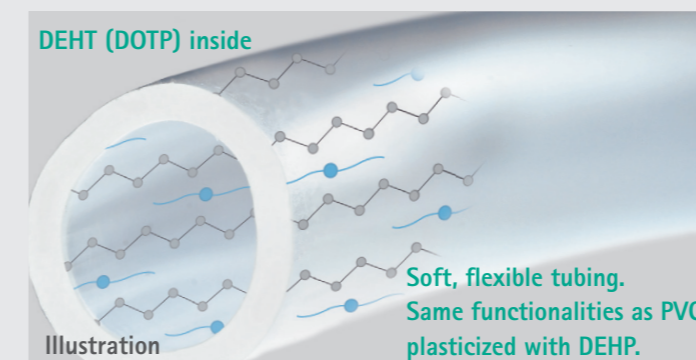
DEHP, which is currently the plasticizer used the most widely, will be replaced so that PVC tubing is safer. SCENIHR - The Scientific Committee on Emerging and Newly-Identified Health Risks of the European Commission - has analyzed and compared the toxicity data of a few available and potentially suitable alternatives. Amongst the available, positively evaluated options: DEHT [DOTP] = di-(2-ethylhexyl)terephthalate - a plasticizer with a significantly better toxicological profile than the disputed DEHP. Particularly of interest: there were no effects on male fertility.

The new formula for safety in IV therapy

B. Braun infusion lines: softened with DEHT-Eastman™ 168, a new generation of medically inert non-phthalate plasticizers.



DEHT plasticizer - DEHT-Eastman™ 168 - for safer patient care.



User benefits:

- No reproductive toxicity according to SCENIHR¹ of the European Commission.
- Comprehensive safety documentation.
- Not adversely listed by any government authorities.
- DEHT-Eastman™ 168: a plasticizer with over 35 years of use in many applications.
- 54% less leaching (with lipid 10%).
- TÜV product service tested with non-dedicated pumps.

¹ SCENIHR - Scientific Committee on Emerging and Newly-Identified Health Risks.

DEHT - the plasticizer alternative, toxicologically proven for intravenous application.

DEHT - the new plasticizer standard: universal in all B. Braun infusion lines for IV sets and accessory devices.



Examples of high risk patient groups.



Eastman™ is a trademark of EASTMAN Chemical Company, Kingsport, TN, USA

The B. Braun PVC infusion tubings now softened with non-phthalate DEHT plasticizer. Biocompatibility & functionality well described with toxicological and technical data. The safety evaluation at a glance:

	Fulfilment of ...
1. Biological, technical evaluation	<ul style="list-style-type: none"> - DIN ISO EN 10993-1 (biological evaluation of medical devices) - DIN ISO EN 8536-4 (infusion sets, gravity feed) - DIN ISO EN 8536-8 (infusion sets for use with pressure) - DIN ISO EN 1135-4 (transfusion sets)
2. Toxicity DEHT-Eastman™ 168 plasticizer /intravenous infusion of DEHT	<ul style="list-style-type: none"> - Summary Eastman, June 2009 - Toxicity summary for DEHT in medical devices, Dr. U. Rickenbacher, Medius AG - October 2009
3. Reproductive effects	SCENIHR report, Feb. 2008 – „biocompatibility of the alternative plasticizer DEHT after intravenous administration based on the animal testing study: subacute toxicity study in rats; intravenous infusion of DEHT for 12 hours daily for 3 weeks“, B. Braun internal study, 2009
4. Regulatory Status of DEHT-Eastman™ 168	Thoroughly evaluated by several government agencies around the world and placed on approved lists. For details product regulatory information sheet of Eastman. Regarding REACH regulation: pre-registered
5. Residual content of phthalates	Confirmed by analysis of laboratory SGS Institute Fresenius, Germany. Result: no phthalate content more than 0.1 % (w/w) recognizable. Conformity with REACH specification
6. Use on non-dedicated infusion pumps	Compatibility for selected infusion pumps confirmed by evaluation of TÜV Product Service, Germany

References:

1. Scientific Committee on Emerging and Newly-Identified Health-Risks (SCENIHR): "Opinion on the Safety of Medical Devices containing DEHP-Plasticized PVC or other Plasticizers on Neonates and other Groups possibly at risk", February 2008
2. "Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices", Center for Devices and Radiological Health U.S. Food and Drug Administration.
3. Guiseppe Latini et al. "Di(2-ethylhexyl)phthalate Leakage ... after Application in High-Risk Newborns", Neonatology, Jan. 2008
4. "Phthalate - Die unerwünschten Weichmacher mit den unerwünschten Eigenschaften", Umweltbundesamt (Germany), February 2007
5. Directive 93/42/EEC and its amendment 2007/47/EEC
6. B. Braun laboratory study "Intravenous infusion of DEHT plasticizer into rats", internal report, June 2009