

## Non-PVC and DEHP-free summary information

In November 2023, BD issued an Urgent Product Defect Correction notice about mislabelled infusion sets affecting Alaris pumps. In response to several requests for information about medicines that require non-PVC or DEHP-free infusion sets, the following information is provided to assist local decision-making about suitable infusion sets for these medicines. Questions about the suitability of specific infusion sets can be directed to the product manufacturer.

### BACKGROUND AND RATIONALE

**Polyvinyl chloride (PVC)** is a plastic that is used to make IV bags, infusion sets and other medical equipment.

**DEHP** (di (2-ethylhexyl) phthalate) is a plasticiser used in some PVC products.

Some medicines interact with PVC or DEHP. There are two main mechanisms for interaction:

**Adsorption:** drug moves out of the infusion solution and onto the surface of the plastic. This means less drug is delivered to the patient.

**Leaching:** an excipient (e.g. castor oil, polysorbate) in the medicine extracts the DEHP from the plastic into the infusion solution. This means DEHP is administered to the patient.

The amount of DEHP leached from the container depends on the amount of excipient in the solution and the time in contact with the plastic. The presence of polysorbate in a formulation does not automatically mean a DEHP-free line is required as the total amount in the infusion solution, the infusion time and length of the tubing are important factors.

DEHP has potentially toxic effects, particularly in neonates, pregnancy, and breastfeeding women.

### EXAMPLES OF NON-PVC CONTAINERS

- polyolefin
- polyethylene (PE)
- ethylene-vinyl acetate (EVA)
- glass

### EXAMPLES OF NON-PVC INFUSION SETS

- polyurethane (PUR)
- polyethylene (PE)

### EXAMPLES OF DEHP-FREE INFUSION SETS

- polyurethane (PUR)
- polyethylene (PE)
- DEHP-free PVC

### LOW-SORBING INFUSION SETS

Low-sorbing sets are made with:

- polyurethane (PUR), or
- PVC outer with polyethylene lining (PE-lined).

Low-sorbing sets are designed specifically **to reduce adsorption** of the drug to PVC. They can be used if adsorption is the only mechanism of interaction with PVC. Some drugs also adsorb to PUR.

Some low-sorbing sets contain DEHP and may not be suitable for medicines that require a DEHP-free set. See the table below.

For a limited number of medicines (\*) there is evidence to support the use of a PE-lined low-sorbing set, for the concentrations and infusion duration stipulated in the monograph.

- 'non-PVC' is also DEHP-free
- 'DEHP-free' may contain PVC
- 'low-sorbing' infusion sets may contain DEHP
- low-sorbing infusion sets are not always suitable substitutes for non-PVC infusion sets.

DRUG <sup>1-3</sup>	Bag or container	Infusion sets	Reason	Filter
<b>Amiodarone if &gt; 24 hours</b>	non-PVC	DEHP-free	adsorption leaching of DEHP	
<b>Blinatumomab</b>	polyolefin, EVA or DEHP-free PVC	polyolefin <b>or</b> DEHP-free PVC	incompatible with DEHP	yes
<b>Cabazitaxel*</b>	non-PVC	non-PVC <b>or</b> low-sorbing (PE-lined) do not use PUR	leaching of DEHP possible adsorption to PUR	yes
<b>Carmustine</b>	non-PVC	non-PVC <b>or</b> low-sorbing (PE-lined) do not use PUR	adsorption	
<b>Ciclosporin</b>	non-PVC	non-PVC	leaching of DEHP	
<b>Clonazepam if &gt; 4 hours</b>	non-PVC	non-PVC <b>or</b> low-sorbing	adsorption	
<b>Diazepam</b>	non-PVC	non-PVC <b>or</b> low-sorbing	adsorption	
<b>Docetaxel*</b>	non-PVC	non-PVC <b>or</b> low-sorbing (PE-lined)	leaching of DEHP	
<b>Etoposide (NOT ETOPOPHOS)</b>	non-PVC	non-PVC	leaching of DEHP	
<b>Fat Emulsion</b>	N/A	DEHP-free	leaching of DEHP	yes
<b>Glyceryl trinitrate</b>	non-PVC <b>or</b> use PVC and titrate to effect	non-PVC <b>or</b> low-sorbing <b>or</b> use PVC and titrate to effect	adsorption	
<b>Letermovir</b>	EVA <b>or</b> polyolefin	PE <b>or</b> DEHP-free do not use PUR	incompatible with DEHP and PUR	yes
<b>Nicardipine</b>	see monograph	see monograph	varies between brands	
<b>Nimodipine</b>	non-PVC (e.g. polypropylene syringe)	PE <b>or</b> PUR	adsorption	
<b>Paclitaxel*</b>	non-PVC	non-PVC <b>or</b> low-sorbing (PE-lined)	leaching of DEHP	yes
<b>Plitidepsin</b>	polyolefin	non-PVC <b>or</b> DEHP-free	leaching of DEHP adsorption	yes
<b>Tacrolimus</b>	non-PVC	non-PVC	adsorption leaching of DEHP	
<b>Urokinase</b>	see monograph		adsorption (in glucose)	

**PE** polyethylene, **PUR** polyurethane, **EVA** ethylene-vinyl acetate

#### REFERENCES

1. Product information. Available from [www.tga.gov.au](http://www.tga.gov.au).
2. ASHP Injectable drug information 2021. Bethesda, MD: American Society of Health-System Pharmacists; 2021.
3. Cabazitaxel. In: IV index [internet]. Trissel's 2 clinical pharmaceuticals database (parenteral compatibility). Ann Arbor, MI: Merative. Accessed 14/11/2023.