

Labelling relative to phthalates in a medical device
Notice to manufacturers

NOTICE TO MANUFACTURERS

Labelling relative to phthalates in a medical device

ANSM, the French National Agency for Medicines and Health Products Safety, would like to remind manufacturers of their labelling obligations with respect to the presence of phthalates classified as carcinogenic, mutagenic or toxic to reproduction (CMR) of category 1A or 1B in accordance with regulation (EC) No. 1272/2008 in certain medical devices. ANSM would also like to specify that the presence of a residual level of phthalates in a medical device means that the device cannot be presented as "phthalate-free".

A control of products on the market¹, carried out by sampling in 2012, concerned a number of PVC medical devices containing a plasticiser other than DEHP². It was observed that devices supposed to contain no DEHP actually contained residual amounts of this phthalate. In addition, labelling of several analysed devices indicate the absence of phthalates. Considering these observations, ANSM asked the companies concerned to implement corrective measures.

DEHP is a phthalate classified as a category 1B reproductive toxicant according to regulation (EC) No. 1272/2008. CE marking according to the terms of amended directive 93/42/EEC concerning medical devices requires compliance with the essential requirements set out in annex 1 of this directive and, in particular, requirement 7.5, which stipulates a labelling obligation for certain medical devices containing phthalates known or presumed to be carcinogenic, mutagenic or toxic to reproduction in humans. The obligations are as follows:

If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC³, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.

If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

¹ Report dated November 2015 available on the ANSM website

² DEHP or bis(2-ethylhexyl) phthalate), a plasticiser used in the manufacture of certain medical devices

³ Directive 67/548/CEE has been since then replaced by regulation (EC) No 1272/2008. Categories 1 and 2 refer now respectively to categories 1A and 1B according to regulation (EC) No 1272/2008.

Hence any medical device meeting the above criteria must be labelled as containing phthalates pursuant to the above provisions.

The notion of a threshold value for the “presence of phthalates” labelling obligation is therefore not considered by the abovementioned modified directive 93/42/EEC.

On the other hand, the draft regulation revising the provisions applicable to medical devices proposes a threshold value of 0.1% for the labelling requirement for medical devices containing phthalates classified as category 1A or 1B CMR³. This draft regulation is still in the discussion stage.

Also considering,

-on one side, this future regulation and the threshold of 0.1% that this text provides for the obligation to mention the presence of phthalates in MDs,

-on the other side, the position shared between member states also in favor for the adoption of this threshold, despite the regulatory obligation provided for by the abovementioned essential requirement 7.5, ANSM has decided, at this time, not to take automatically a decision of sanitary police based principally or exclusively on the non-compliance of a labelling not stating the presence of phthalates classified as category 1A or 1B CMR for medical devices or parts of devices concerned by this requirement containing less than 0.1% mass by mass of the plasticised material.

ANSM will, however, carry out reinforced and precise surveillance of MDs affected, and of course reserves the right to exercise its policing powers in this area at any time and in accordance with the abovementioned provisions.

The use of the “phthalate-free” claim is only acceptable for medical devices that do not contain any phthalates, even in residual amounts.

Indeed, any device must present the characteristics claimed by the manufacturer. Hence, a “phthalate-free” claim is not compatible with the presence of residual levels of phthalates in the device, irrespective of the concentration. This claim cannot therefore be applied to the labelling, instruction leaflet or any other information document, promotional or otherwise, if phthalates are present in even residual amounts.

The attention of manufacturers is therefore drawn to the need to ensure the consistency of the information indicated on the labelling of their devices with respect to the presence of phthalates in view of the above.

Conclusion:

- 1) The absence of a statement informing of the presence of phthalates implies that the MDs affected by requirement 7.5 do not contain these phthalates, or, where applicable and taking into account the individual cases, contain a concentration of less than 0.1% mass by mass of the plasticised material.**
- 2) The presence of the “phthalate free” claim strictly implies that the MDs do not contain any phthalates, even in tiny and residual amounts.**

³ Category 1A or 1B according to regulation (EC) No 1272/2008