

Phthalate free medical devices?

- A Danish survey

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In short

In 2010 EcoForum and University of Southern Denmark conducted a survey for The Danish Ministry of Environment in 2010 that resulted in a list of medical device products free from the phthalates that require labelling according to the 'Medical Devices Directives' (Directive 93/42/EEC with amendments).

The aim of the list is to support the hospital purchasing officers – and others involved in the selection of medical devices – in the identification of medical devices free from the phthalates demanding labelling.



Background details

The REACH system operates with 'Substances of Very High Concern' - SVHC - substances such as potentially carcinogenic, mutagenic or toxic to reproduction. SVHC substances are the same as the substances on the candidate list, which are substances that are candidates for approval scheme under REACH. Several phthalates are SVHC / on the candidate list due to their classification as potentially teratogenic

Medical supplies and drugs are not covered by REACH, but the 'Medico-directive, which provides for compulsory marking of articles if they contain substances classified as carcinogenic, mutagenic or toxic for reproduction:

An amendment to the Medical Devices Directive (2007/47/EC), which came into force in spring 2010, defines in section. 7.5:

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/EEC, 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.

Method:

Data was collected by a simple spreadsheet format supplied to 58 suppliers of medical devices together with an explanatory note.

Results:

The survey included responses from 22 suppliers covering totally 813 products or product families.

It turned out that the suppliers operated with different statements regarding their performance – see graph **Main result...**

A number of suppliers provided information on the substitute plasticizers – see graph **Substitute plasticizers...**

The substitute plasticizers were assessed for effects on health and environment based on readily available information – see box **Assessment of ...**

This assessment indicates that some of the plasticizers replacing the original phthalates are, in fact, quite problematic – indicating that the producers have difficulties selecting appropriate substitutes.

Application of these findings in purchasing requirements:

In practice purchasers always wants to maintain competition between vendors – typically the requirement is that three or more bidders can supply a certain product quality. Hence it is recommended to make mandatory requirements - at different levels dependent on the actual situation.

Combining the present survey with the SEMCo purchasing requirements for 'Anaesthesia and Intensive Care' (SEMCO 2012) provided the lists to the right. (New categories identified in the Danish EPA survey are indicated by **blue text**).

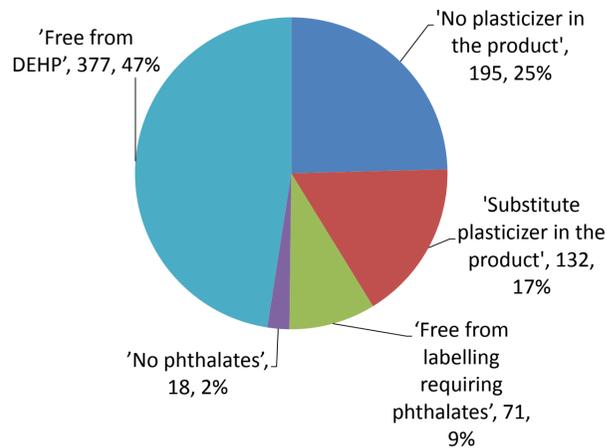
Conclusion

Overall the survey showed:

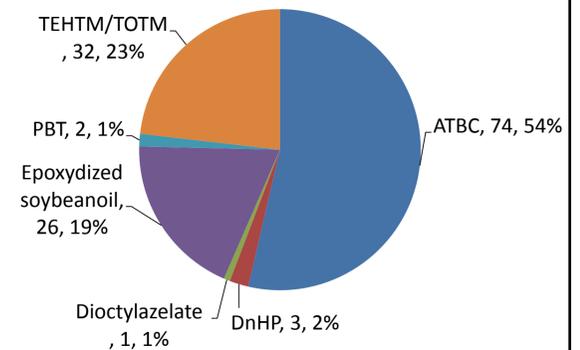
- That producers are quite focused on being able to deliver products that do not require labelling, but
- There seem to be some difficulties in selecting appropriate alternative softeners for the PVC based products.
- Some retailers involved in the survey had difficulties getting access to the full specification of the products.

Based on these findings it is recommended that the producers consider developing a common product declaration with respect to health and environmental aspects – including the issue of phthalates.

Main results regarding content of plasticizers/phthalates (number of products with the different responses)



Substitute plasticizers applied for the products where the supplier provided that information



Assessment of the substitute plasticizer:

ATBC (CAS: 77-90-7):	Intravenous exposure affects the central nervous system and blood in laboratory animals – slowly bio-degradable
DnHP (CAS: 84-75-3)	Phthalate. Will probably be labelled harmful to reproduction in the near future
Diocetylazolate (CAS: 2064-80-4)	No available info
Epoxydized soybeanoil	Probably OK
PBT (CAS: 24968-12-5)	No available info
TEHTM/TOTM (CAS: 3319-31-1)	Toxic to laboratory animals through inhalation – slowly bio-degradable

References: Danish EPA 2011, Lowell Center 2011



Different requirements for different product groups:

**** Three or more suppliers can deliver product

free from plasticizers

Anaesthetic hose kit
 Anaesthetic lime CO₂ (absorbent container)
 Bite blocks/rings
 Breathing balloons (rescue balloons, ventilators)
 Breathing ventilators (anaesthetic ventilators, test lungs)
Central vein catheters
 Filters and moisture/heat exchanger and accessories
 Heating blankets
 Hoses, anaesthetic/anaesthesia/respiration/reservoir
 Laryngeal tubes
 Masks, anaesthesia, multi-use
 Masks, face pocket for emergency care
 Moisture bottles (bubble bottles)
 Nasal tubes (cantrells)
 Speech valves
 Tooth guards

... Three or more suppliers can deliver products

free from plasticizers

Expiration gloves

..Three or more suppliers can deliver products

free from phthalates requiring labelling

Products for enteral nutrition
Drainage catheters
Gastronomi catheters and tubes
Infusion sets
Urinary catheters

. Three or more suppliers can deliver products

free from DEHP

Extension hoses ('cut-to-size') on roll
 Flex tubes and flex hoses
 Aspiration catheters

References:

Danish EPA (2011): Shima Dobel personal communication
 Lowell Center for Sustainable Production (2011): Phthalates and Their Alternatives: Health and Environmental Concerns, Technical Briefing, January 2011
 SEMCo 2013: <http://www.msr.se/> Upphandling/Kriterier/Sjukvard-och-omsorg/
 Anestesi-och -intensivvard/Forbrukningsartiklar/

