

PRESS RELEASE

Report shows there are numerous safe plasticisers for PVC medical devices

The PVCMed Alliance is pleased to have contributed to the report *"Alternatives to classified phthalates in medical devices"* which outlines the benefits of plasticised PVC for medical applications.

27 March 2014, Copenhagen, Denmark - The Danish Environmental Protection Agency, the Danish Health and Medicines Authority and the PVC Information Council Denmark (a PVCMed Alliance partner) are coming together today to present the results of the report *"Alternatives to classified phthalates in medical devices"*.

The Danish Environmental and Health authorities are presenting the conclusions of this report which is based on the evaluation of ten existing PVC plasticisers¹. *"The report concludes that most of the alternatives to DEHP that we evaluated for their human health and environmental hazard profiles are considered to be appropriate alternatives, but data are lacking for some of the alternatives, before a toxicological assessment can be carried out"*, says Shima Dobel from the Danish Environmental Protection Agency.

The PVCMed Alliance partners provided data on these plasticisers to the Danish authorities. *"Many different plasticisers have been developed and are increasingly being used in a wide array of medical applications allowing medical professionals to benefit from PVC's unique properties for patient comfort, economic affordability and hospital hygiene. We encourage the value chain to commit to continuous improvement of safety in order to develop innovative products for all PVC healthcare applications"*, stresses Brigitte Dero, PVCMed Alliance representative.

Furthermore, the report outlines the need for certain types of medical devices to be *"extremely soft and flexible"* and *"be able to offer the most efficient and qualitative treatment of patients"*. PVC-based healthcare applications have a fundamental role in ensuring this quality of healthcare thanks to PVC's technical properties including flexibility and resilience, softness, sterilisability, chemical stability, biocompatibility, clarity and transparency, durability and dependability, resistance to chemical stress cracking, low cost, and many others.

The conference will convey the views of environmental and health authorities, medical device companies, medical professionals, NGOs and hospital facility managers on the latest developments on the use of plasticised PVC in medical devices. *"PVCMed believes this is a crucial discussion in order to continue ensuring patient safety and quality healthcare, even more so at a time of on-going review of the EU medical devices legislation and the SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) scientific opinion on the use of phthalates in medical devices"* explains **Ole Grøndahl Hansen, Director of the PVC Information Council Denmark and project manager for the PVCMed Alliance**.

For more information, please contact: Ole Grøndahl Hansen – PVCMed Alliance - ogh@pvc.dk

About the PVCMed Alliance:

PVCMed is an alliance of the PVC medical industry chain represented by PVC resin & plasticiser producers and PVC converters to proactively engage in PVC and healthcare related debates. The Alliance's aim is to provide a focal point for communication with healthcare professionals and regulators about PVC-based healthcare applications.

¹ ASE - Sulfonic acids, C10-21-alkane, Ph esters (CAS No 91082-17-6); ATBC - tributyl O-acetylcitrate (CAS No 77-90-7); BTHC - butyl trihexyl citrate (CAS No 82469-79-2); COMGHA - glycerides, castor-oil-mono-, hydrogenated, acetates (CAS No 736150-63-3); DEHT - bis(2-ethylhexyl) terephthalate (CAS No 6422-86-2); DINA - diisononyl adipate (CAS No 33703-08-1); DINCH - Diisononyl cyclohexanedicarboxylate (CAS No 166412-78-8); DOA - Bis(2-Ethylhexyl) Adipate (CAS No 103-23-1); ESBO - Epoxidized soybean oil (CAS No 8013-07-8); TOTM/TEHTM - trioctyl trimellitate/tri-(2-ethylhexyl)- trimellitate) (CAS No 3319-31-1)