

INFORMS

NEW: Sempercure Vinyl



With the new Sempercure Vinyl, Sempermed offers examination gloves that not only comply with the REACH Regulation, but are also free from DOP

What does “DOP-free” mean?

DOP (Diocetyl-phthalate), often also referred to as DEHP (Diethylhexyl-phthalate), is a so-called PVC softener. Softeners are used to give the essentially hard and brittle raw material PVC (polyvinyl chloride) its rubber-like properties, making the material malleable and elastic for glove production, while at the same time keeping it dimensionally stable. However, because PVC and softeners do not bond chemically, the softener can gradually dissolve out of the product again when it is used, and as a result of evaporation, washing or abrasion it can get into the environment and into the human body.

After extensive investigations, the EU has classified DOP as a hazardous substance for reproduction (Category 2: toxic to reproduction and development) and included it in the so-called “SVHC Candidate List” as a “**substance of very high concern**” (SVHC) in October 2008. This list contains the first 15 substances proposed as being SVHC. These substances are expected to be included in Annex XIV to the new EU Chemicals Regulation REACH in June 2009. This “SVHC List” will then be subject to a process of permanent development, which means that in future the use of SVHC will require authorisation by the EU for every single purpose. Such authorisations are possible if no alternative substances can be used.

Sempermed medical gloves contain neither DOP nor any other substance included in the SVHC list (version dated 28.10.2008). Instead, Sempermed uses the isomer blend DINP (Di-isononyl-phthalate) as a PVC softener, which is not classified as hazardous to health by the EU based on the results of the risk evaluations carried out to date.¹ Therefore the new Sempercure Vinyl gloves in the orange or red packaging design, which will be available from March onwards, will be labelled “DOP-free”:



The new Sempercure Vinyl powder-free



The new Sempercure Vinyl powdered

Those manufacturers of medical gloves who continue to use DOP, on the other hand, will soon have to use a different label: Due to the classification of DOP as toxic to reproduction, medical devices containing DOP will have to be labelled in accordance with the new EU Directive 2007/47 probably as of March 2010. - Therefore you should look out for “DOP-free” already!

¹ EU Commission Communication in the Official Journal of 13 April 2006, 2006/C90/04

What does REACH mean?

The new EU Chemicals Regulation REACH 1907/2006 has been in force since June 2007. REACH stands for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **C**hemicals.

The most important **objectives** of this Regulation are to reduce substances of very high concern (SVHC) and to gradually replace them, as well as to provide a reliable flow of information about SVHC throughout the supply chain.

Essentially, chemicals that are carcinogenic, mutagenic and toxic to reproduction (so-called CMR substances), substances that are environmentally harmful, persistent, very bio-accumulative or toxic (so-called PBT substances) and substances that can cause similar damage (e.g. substances with hormone-like effects) are considered to be substances of high concern.

The **purpose** of REACH is to register the chemicals used in the EU systematically with regard to their environmental and health impact. The manufacturers must submit safety data (registration dossiers) for every chemical produced or marketed in quantities of >1 tone per year in the EU (about 30,000 substances). In the case of a "substance of very high concern" included in the SVHC list, every single use has to be authorised by the European Chemicals Agency ECHA. Thereby the manufacturers have to declare that they can "adequately control" the health and environmental risks, otherwise the ECHA can refuse authorisation or restrict use of the substance.

In accordance with the principle "no data, no marketing" REACH calls upon the industry, at its own responsibility, to market only those chemical substances that have been registered in the central database of the ECHA. The ECHA in Helsinki, which was established specifically for this purpose, examines the submitted safety data, assigns registration numbers and monitors the use of SVHC. (The evaluations are carried out by the EU Member States.)

REACH also provides for an **information obligation** for products that contain an SVHC in a concentration of >0.1% by weight. Every supplier is obliged to provide adequate information to the buyers of products containing SVHC. (As a minimum requirement, the chemical name of the SVHC must be provided.) This aims to ensure the information flow for the safe use of chemicals from the producer right down to the end consumer and back.

Sempermed complies with the statutory requirements of REACH and does not use any SVHC in the production of medical gloves.