

Information on Material Safety Data Sheet

09.09.2016

Dear Sirs,

Please be informed that due to the following reason we do not issue the requested material safety data sheets as documentation to our products:

The area of application of MSDS is specified within Article 31 and Appendix II of the regulation (EG) No. 1907/2006 (REACH-regulation) in addition to § 6 Hazardous Material Regulation (GefStoffV). The regulations request the first distributing company or manufacturer of hazardous materials to issue MSDS.

According to the above mentioned regulations, none of our products is considered to be hazardous or to consist of any hazardous material.

The scope of the already cited legal regulation and the REACH-exemptions apply, where in § 1 Scope of Application it is stated:

.....
„(4) This publication is not valid for
.....

6. The provisions of Title IV shall not apply to the following preparations in the finished state, intended for the final user
.....

c) Medical devices which are invasive or used in direct physical contact with the human body in so far as
Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as Directive.1999/45/EG

Our products are Medical Devices in terms of the Medical Device Act § 3.

Thus, the requirements of the Hazardous Material Regulation do not apply.



(Dipl.-Chem. Markus Schmidtke)



(Werner Fretz QMB)