

C E R T I F I C A T E

Cytotoxicity of the Test Material:
"Electrolyte Friscolyt B (Paste)"

Manufacturer/Distributor:
Mettler Toledo GmbH

Scientific Background and Normative Requirements

"Electrolyte Friscolyt B (Paste)" is a gelled component used in electrodes for pH measurement (e.g. In-Pro3100 family) for example in bioreactors in the pharmaceutical industry. Based upon this intended use, and in accordance with DIN EN ISO 10993-1: 1998 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing - the biological risk of cytotoxicity was evaluated under conditions of industrial use.

The following results were obtained:

Assessment

Cytotoxicity

The potential of cytotoxicity of the aforementioned test material was investigated by using the elution test method in accordance with DIN EN ISO 10993-5 and USP 27, 2004, Chapter 87 (mdt report 05z062). None of the extract-concentrations of the electrolyte Friscolyt B (Paste) showed any cytotoxic reaction.

Conclusion

According to the provision of the manufacturer the 100% extract concentration is identified to be the worst case situation in the industrial use of the tested chemical "Electrolyte Friscolyt B (Paste)". The worst case is defined as a complete depletion of "Electrolyte Friscolyt B (Paste)" contained in a pH electrode into the content of a bioreactor of minimum size utilized in the pharmaceutical industry.

Based upon the study results obtained, and considering the provisions of the harmonised standard DIN EN ISO 10993-1 it is concluded that the intended use of the "Electrolyte Friscolyt B (Paste)" causes no cytotoxic effects in its industrial application environment.



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mdt medical device testing GmbH
Grenzenstraße 13 • 88416 Ochsenhausen



Dr. Ingrid Rapp, 19.08.2005
Study director of cytological laboratory

Michael Ohnmacht Dipl.-Ing. (FH), 19.08.2005
Quality Assurance Unit