

CERTIFICATE OF COMPLIANCE

Biocompatibility of the Test Material: "Electrolyte Foodlyte"

**Manufacturer:
HAMILTON Bonaduz AG**

Scientific Background and Normative Requirements

The "Electrolyte Foodlyte" is a liquid component used as reference electrolyte for pH-electrodes for example in bioreactors in the biotechnology and in the pharmaceutical industry.
Based upon this intended use, and in accordance with DIN EN ISO 10993-1: 2003 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing - the biological risk of cytotoxicity was evaluated under the conditions of industrial use.

The following results were obtained:

Biocompatibility Assessment

Cytotoxicity

The potential of cytotoxicity of the test material was investigated in compliance with international GLP regulations, using the elution test method in accordance with DIN EN ISO 10993-5 and USP 31, 2008, Chapter 87 (mdt report 08z118, 08z128).

In summary, no growth inhibition was caused by the test material diluted 1:100 (v/v) and higher. Therefore, it is concluded that the test material can be evaluated to have no cytotoxic potential under the conditions of industrial use.

Conclusion

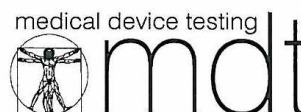
According to the provision of the manufacturer the 1:100 (v/v) dilution is identified to be the worst case situation in the industrial use of the tested chemical "Electrolyte Foodlyte". The worst case is defined as a complete depletion of the "Electrolyte Foodlyte" contained in a pH electrode into the content of a bioreactor of minimum size (e.g. an "Easyferm Food 120" sensor used for a 500 ml batch reactor) utilized in the pharmaceutical industry.

Based upon the study results obtained and considering the provisions of the harmonised standard DIN EN ISO 10993-1, 2003, it is concluded that the intended use of the "Electrolyte Foodlyte" causes no cytotoxic effects in its industrial application environment.



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