

# CERTIFICATE OF COMPLIANCE

## Biocompatibility of the Test Material: "Electrolyte Foodlyte"

Manufacturer:  
HAMILTON Bonaduz AG

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### 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: 2010 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management system" - 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 Bio 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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