

Evonik Resource Efficiency GmbH 45764 Marl, Germany

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To our customers

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## **TROGAMID® CX7323 natural Biocompatibility**

Dear Sir or Madam,

Evonik Resource Efficiency GmbH has conducted a testing program with TROGAMID® *Care* MX73-A to investigate the biocompatibility of the material.

TROGAMID® *Care* MX73-A was tested concerning:

- Hemolytic Properties, Rabbit Blood Indirect Contact Test (ASTM F756-08)
- In Vitro Cytotoxicity, L929 Neutral Red Uptake Test (ISO 10993-5)
- Irritation and Skin Sensitization, Kligman Maximation Test (ISO 10993-10)
- Irritation and Skin Sensitization, Intracutaneous Injection Test (ISO 10993-10, USP <88> class VI)
- Systemic Toxicity, Intravenous and Intraperitoneal Injection Tests (ISO 10993-11, USP <88> class VI)
- Biological Reactivity *In vivo*, 1 Week Intramuscular Implantation Test (USP <88> class VI).

The test articles are considered non-hemolytic under the experimental conditions employed; the test articles are not considered to have a cytotoxic effect; the test articles are rated as a Grade I sensitization rate, which is not considered significant; the test articles meet the requirements of the Intracutaneous Test according to USP guidelines and ISO 10993-10 guidelines using extracts prepared with NaCl, CSO, EtOH, and PEG; the test articles

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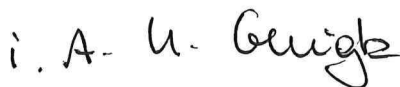
**Supervisory Board**  
Dr. Harald Schwager, Chairman  
**Managing Directors**  
Dr. Claus Rettig, Chairman  
Dr. Johannes Ohmer, Simone Hildmann,  
Alexandra Schwarz

meet the requirements of the USP guidelines and ISO 10993-10 guidelines for the Systemic Injection Test; the test articles meet the requirements of the USP guidelines for the Implantation Test.

Regarding the product composition there is in principal no distinction between TROGAMID® CX7323 natural and TROGAMID® Care MX73-A, except the fact that TROGAMID® CX7323 natural misses one additive. Therefore, the test results we got from TROGAMID® Care MX73-A can be transferred without any restriction to TROGAMID® CX7323 natural. The absence of one additive is of no concern in the above mentioned test systems.

Yours faithfully

Evonik Resource Efficiency GmbH



i. A. Dr. Ursula Gerigk



i. A. Dr. Kristin Kocher

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