

Dr. Joachim Haselbach*Publicly Certified and Authorized Expert
for Toxicology of Cosmetics and User Articles**Attested by the Chamber of Commerce of „Mittlerer Niederrhein“
Expert Toxicologist („Fachtoxikologe“) DGPT/Eurotox Registered Toxicologist**Parkstraße 29
D-47829 Krefeld**Telefon: +49 (0) 2151 7842563**Telefax +49 (0) 2151 7842565**Mobile: +49 (0) 173 9635387**E-mail: joachim.haselbach@tox-consult.de**Internet: www.tox-consult.de*

Toxicological Risk Evaluation on Adverse Human Health Effects for Users from Oral Uptake of Foodstuff Contaminated with ANTIFROGEN® L

Executive Summary

**Clariant Produkte (Deutschland) GmbH
Industrieparkstrasse 1
D-84508 Burgkirchen**

Note, this executive summary is based on the detailed risk evaluation “*Toxicological Risk Evaluation on Adverse Human Health Effects for Users from Oral Uptake of Foodstuff Contaminated with ANTIFROGEN® L*” (dated 20/03/2012) performed for Clariant Produkte (Deutschland) GmbH.

Objective of the toxicological risk evaluation

The product ANTIFROGEN® L is marketed as

"Cooling brine for the food industry, antifreeze and corrosion inhibitor for refrigeration and heat pump systems, approved fire extinguishing agent".

Typically this product is used in closed systems only, but by accidental release some of the fluid when used in the food industry may get into contact with foodstuff and may then contaminate it. Therefore assessing the risks for potential adverse health effects for humans, who may have ingested such contaminated foodstuff, is necessary.

Execution of the toxicological risk evaluation

In summary potential adverse health effects have been toxicologically evaluated for all ingredient substances of the product ANTIFROGEN® L.

Also the amount of such ingredients humans might be exposed to by oral uptake of contaminated foodstuff has been calculated from very conservative exposure scenarios.

Thereafter the risk for potential adverse health effects has been determined by comparison of the calculated exposure concentrations with relevant effect levels for health hazards from the product's ingredient substances.

Conclusions from the toxicological risk evaluation

The toxicological risk evaluation which had been performed accordingly has shown that the safe use of the product ANTIFROGEN® L can be assured such that

ANTIFROGEN® L as a cooling brine for the food industry, antifreeze and corrosion inhibitor for refrigeration and heat pump systems has to be regarded as safe for the health of users when after unrecognized leakage a certain amount of foodstuff may have been contaminated with a certain amount of the ingredient substances of the product ANTIFROGEN® L

when taking into account the following elements of the toxicological risk evaluation:

- assessment of the relevant toxicity profiles of all ingredient substances considering the specific formulation (recipe) and
- assessment of the intended and reasonably foreseeable exposure conditions for users when additionally taking into account the specified use conditions of the product ANTIFROGEN® L.

Overall for the toxicological risk evaluation is very conservative with regard to its relevant input parameters, therefore the outcome is considered to be very robust.

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Dr. Joachim Haselbach
Expert Toxicologist DGPT
Eurotox Registered Toxicologist



Lothar Fruth
Specialist Pharmacist for
Toxicology and Ecology