

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

September 3, 2009

MEMORANDUM:

SUBJECT: Dietary, Drinking Water and Human Exposure Assessment for the Proposed New Product GLYCO-SAN (EPA Reg. # 42048-R)

TO: Tracy Lantz, Acting Product Manager
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DP Barcode: D362725 & D362726

PC Code: Lactic Acid (128929)

MRID #: 476814-11

DISCUSSION AND CONCLUSIONS:

An application for a new antimicrobial product, Glyco-San has been submitted to the Agency. This product contains L-Lactic Acid (12%) and the product is intended to be used to disinfect potable water tanks on aircrafts. The label states that the product is to be applied at a maximum of 1 part Glyco-San to 3 parts water, and once soaking commences, to rinse the system thoroughly. It also states that, "In order to determine whether the system is completely flushed, half fill a small glass with the rinse water, cap, and shake. If the water in the jar DOES NOT FOAM, the system has been thoroughly flushed."

Recently (2008), a Registration Review document for L-Lactic Acid has been completed and can be found at <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPP-2008-0383-0013>. The decisions presented in the case were utilized in support of this application for registration. The specific statements provided below are extracted from the document, "Summary of Human Health Effects Data for the L-Lactic Acid Registration Review Decision Document," and were utilized to justify a qualitative human exposure assessment (Memorandum from N. Mottl to E. Blair and D. Isbell, 5/14/08, DP Barcode 352773).

Dietary and Drinking Water

As provided in the summary of human health effects memorandum, dietary (food and drinking water) exposures of concern are not anticipated for L-lactic acid. The Food and Drug Administration (FDA) considers L-lactic acid as generally recognized as safe (GRAS) for use in foods under 21 CFR 184.1061. According to the FDA website, <http://www.cfsan.fda.gov/~dms/opascogd.html>, the Select Committee concludes that: 1.) there is no evidence in the available information on L (+) calcium lactate that demonstrates or suggests reasonable grounds to suspect a hazard to the public when they are used at levels that are now current or that might reasonably be expected in the future, and 2.) there is no evidence in the available information on either of the isomers of lactic acid, their calcium salts, and their racemates that demonstrates or suggests reasonable grounds to suspect a hazard to individuals beyond infancy when they are used at levels that are now current or that might reasonably be expected in the future.

In addition, the lactate turnover rate in man has been estimated to be of the order of 2 gm per kg per day. Based on all of these findings, the amounts of L-lactic acid in sanitizers and disinfectant products are not expected to significantly impact the current lactate concentrations in man. Lastly, all subchronic, and chronic toxicity and mutagenicity data requirements have been waived on the basis of the natural occurrence of L-lactic acid in plants and animals as well as its role in glucose metabolism for cellular energy production.

The registrant has provided a risk assessment along with supplementary documentation, including a copy of the aforementioned memorandum. A quantitative assessment was not conducted, as the findings in the registration review documents illustrate that there are no anticipated dietary and drinking water concern resulting from the new use of lactic acid in potable water tanks on aircraft carriers.

Human Exposure

As provided in the Registration Review Decision Document, all of the toxicity data requirements for lactic acid have been satisfied. The acute toxicity studies for oral, dermal, inhalation, dermal irritation and skin sensitization demonstrate the low toxicity potential of the active ingredient. While lactic acid is identified as a severe eye irritant, exposure can be mitigated by the use of protection on the label. The proposed label directs the user to wear protective eyewear and gloves when handling this product, which effectively addresses any potential toxicity issues involving eye irritation.

In addition, existing labels considered for registration review have been concluded to contain a low concentration of lactic acid, identified at <35% (*current proposed label, 12%*) which in turn can be assumed to be diluted enough per label direction to minimize any irritant effects. Risk and exposures that may result as a result of the proposed use are expected to be minimal or non-existent on the basis of the lower concentration of active ingredient than found in the registered products, and the limited evidence of any adverse subchronic or chronic systemic effects.