U.S. Department
of Transportation

**Research and
Special Programs
Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

OCT 23 1998

Ref. No. 98-0240

Mr. Yukawa Muneaki
Technical Department Manager
Musashino Chemical Laboratory, Ltd.
Yaesu-Daibiru Bldg.
1-1, Kyobashi I-Chome, Chuo-Ku
Tokyo 104 Japan 0031

Dear Mr. Muneaki:

This is in response to your letter dated August 18, 1998, regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to lactic acid and its derivatives. Specifically, you ask if lactic acid is a class 8 material as defined in the HMR. You also state that it is your understanding that lactic acid is a class 8 material based on the dermal irritation/corrosion classification contained in the 1992 Organization for Economic Cooperation and Development (OECD) Guideline for Testing of Chemicals.

Under § 173.136 of the HMR, class 8 materials are liquids or solids that cause full and irreversible thickness destruction of human skin at the site of contact within a specified period of time. A liquid that has a severe corrosion rate on steel or aluminum based on the criteria in § 173.137(c)(2) is also a corrosive material. A packing group is assigned to the material after evaluating data obtained from testing conducted in accordance with OECD Guidelines, and then determined from the criteria specified in § 173.137.

If your material has been tested for skin corrosion using a previously authorized test method and found to be not corrosive, there is no need to retest it. If you choose to have your material retested, however, and it meets, for example, class 8, packing group III, a proper shipping name then must be selected from the generic or n.o.s. descriptions corresponding to the specific hazard class and packing group for the material and it must be offered for transportation in accordance with the applicable requirements.

I hope this satisfies your inquiry. Also, I have enclosed some informational material. Please contact us if we can be of further assistance.

Sincerely,

Hattie L. Mitchell

Hattie L. Mitchell, Chief
Regulatory Review and Reinvention
Office of Hazardous Materials Standards

98-0240

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Musashino
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Stevens
§172.101 (L)
Lactic Acid

Date :August 18th, 1998
To :US Department of Transportation
Attn. :Mr. Edward T. MAZZULLO
Director, Office of Hazardus Materials
Statement

From :YUKAWA Muneaki/
Manager of Technical Department

Re :Lactic Acid

Dear Mr. Mazzullo,

We, Musashino Chemical Laboratory, Ltd., are a Lactic Acid Manufacture in Japan, and have been exporting Lactic acid and its derivatives worldwidely.

Recently we have had your opinion that lactic acid product, as tested, is not a corrosive material, based on the definition for "corrosive material" at 49 CFR 173.136, test criteria to determine the packing group of Class 8 material at 49 CFR 173.137.

However we understand that Lactic acid is a crrosive material based on the 1992 OECD Guide line for Testing of Chemicals Number 404 "Acute Dermal Irritation/Corrosion" which is attached.

We would like to take your comment whether Lactic acid is a corrosive or not.

Please inform us your opionion for Lactic acid.

Best regards
湯川宗昭
Yukawa M.

404
Adopted:
17.07.92

OECD GUIDELINE FOR TESTING OF CHEMICALS

OECD = Organization for Economic Cooperation and Development

Adopted by the Council on 17th July 1992

Acute Dermal Irritation/Corrosion

INTRODUCTION

1. OECD Guidelines for Testing of Chemicals are periodically reviewed in light of scientific progress. In the review, special attention is given to possible improvements in relation to animal welfare. This updated version of the original guideline 404 (adopted in 1981) is the outcome of a meeting of OECD experts held in Paris in May 1991.

2. The main differences between this and the original version of the guideline are: a) the inclusion of data from *in vitro* tests in the information on which a decision not to proceed to an *in vivo* test can be based; and b) the possibility to use one animal in a first step of the *in vivo* procedure allowing certain chemicals to be exempted from further testing.

3. Definitions used are set out in the Annex.

INITIAL CONSIDERATIONS

4. In the interests of animal welfare, it is important that the unnecessary use of animals is avoided, and that any testing which is likely to produce severe responses in animals is minimised. Consequently, test materials meeting any of the following criteria should not be tested in animals for dermal irritation/corrosion:

i) materials that have predictable corrosive potential based on structure-activity relationships and/or physicochemical properties such as strong acidity or alkalinity, e.g., when the material to be applied has a pH of 2 or less or 11.5 or greater (alkaline or acidic reserve (1) should also be taken into account);

ii) materials which have been shown to be highly toxic by the dermal route;

iii) materials which, in an acute dermal toxicity test (2), have been shown not to produce irritation of the skin at the limit test dose level of 2000 mg/kg body weight.

In addition, it may not be necessary to test *in vivo* materials for which corrosive properties are predicted on the basis of results from *in vitro* tests (3).

PRINCIPLE OF THE *IN VIVO* TEST

5. The substance to be tested is applied in a single dose to the skin of one or more experimental animals, untreated skin areas of the test animal(s) serving as control. The degree of irritation is read