



U.S. Department  
of Transportation

**Research and  
Special Programs  
Administration**

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

FEB 21 1997

Ref. No.: 02-0129

Ms. Carolina L. Mederos  
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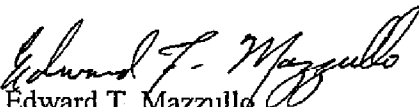
Dear Ms. Mederos:

This is in response to your letter to Alan I. Roberts, Associate Administrator for Hazardous Materials Safety, dated January 17, 1997, concerning the proper classification of unbuffered lactic acid under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). In particular, you requested confirmation that a lactic acid product is not a corrosive material and, assuming no other potentially hazardous attributes, is not a hazardous material under the HMR. The letter was sent via FAX transmission.

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, and test data and other information you submitted, it is our opinion that the lactic acid product, as tested, is not a corrosive material. Furthermore, if the material does not meet the definition for any other hazard class, it would not be subject to the HMR.

If we can be of further assistance, please contact us.

Sincerely,

  
Edward T. Mazzullo  
Director, Office of Hazardous  
Materials Standards



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WRITER'S DIRECT DIAL

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January 17, 1997

Alan I. Roberts  
Associate Administrator for Hazardous Materials Safety (DHM-1)  
Room 8420  
Research and Special Programs Administration  
U.S. Department of Transportation  
400 7th Street, S.W.  
Washington, D.C. 20590

Re: Request for Clarification

Dear Al:

I am writing to request guidance as to the proper classification of unbuffered lactic acid under U.S. Department of Transportation ("DOT") rules governing transportation of hazardous materials. 49 C.F.R. Parts 171-180. Lactic acid is marketed in the United States for a variety of uses, including as a preservative in foods. Based on the results of animal testing in accordance with OECD Guideline No. 404, the product does not have corrosive effects that would render it a "corrosive material" within the meaning of 49 C.F.R. §173.136(a). We request confirmation that the lactic acid product is not a "corrosive material" and, assuming no other potentially hazardous attributes, is not a "hazardous material" within the meaning of DOT's regulations.

DOT's regulations define "corrosive material" as: "[A] liquid or solid that causes full thickness destruction of human skin at the site of contact within a specified period of time."<sup>1</sup> Corrosive effect on human skin is to be inferred from testing on animals in accordance with the 1992 OECD Guideline for Testing of Chemicals, Number 404, "Acute Dermal Irritation/Corrosion." 49 C.F.R. §173.136.<sup>2</sup> Alternatively, a material is corrosive

<sup>1</sup> A liquid is classified as "corrosive material" if it causes observable destruction of intact skin tissue (1) within 60 minutes after exposure time of three minutes or less; (2) within 14 days after exposure time of between three minutes and 60 minutes; or (3) within 14 days after exposure time of between 60 minutes and four hours. 49 C.F.R. §§173.136(a),(b),(c)(1).

<sup>2</sup> Before October 1, 1995, DOT's regulations did not incorporate OECD Guideline 404. Instead, a material was considered "corrosive" if, when tested on the intact skin of an albino rabbit

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if its corrosion rate exceeds 6.25 mm a year on specified grades of steel or aluminum. 49 C.F.R. §173.136(a).<sup>37</sup>

The Netherlands Organization for Applied Scientific Research ("TNO") has tested unbuffered lactic acid (88%) for corrosive or irritative properties under Guideline 404. Pigs were dermally exposed to the acid at exposure intervals of 3 minutes, 60 minutes and 4 hours in accordance with Guideline 404.<sup>41</sup> TNO reported that no irritation or corrosion was observed to any exposed animal during the 21 day observation period. *Id.* at 8.<sup>38</sup> TNO concluded that, on the basis of these results, "lactic acid (88%) is not irritating or corrosive to skin" within the meaning of Guideline 404. *Id.* at 5.<sup>39</sup>

by a protocol set forth in the regulations, "the structure of the tissue at the site of contact is destroyed or changed irreversibly after an exposure period of 4 hours or less." 49 C.F.R. § 173.136(a)(1) [Oct. 1, 1994 ed.] In late 1994, DOT amended the regulation, establishing the three time periods discussed above, deleting the prescribed testing protocol using albino rabbits, and incorporating the OECD Guideline as the required test method, effective October 1, 1995. See 59 Federal Register 67508 (Dec. 29, 1994).

<sup>37</sup> Testing by the Metaalinstuut of the Netherlands Organization for Applied Scientific Research demonstrated that 80% lactic acid has corrosion rates an order of magnitude lower than the DOT limits – 0.15 mm/year on steel and 0.1 mm/year on aluminium. See TNO Report No. 85M/014560/WIJ/RAN, "The Corrosion Resistance of Steel and Aluminium in 80% Lactic Acid at 55° C" (19 Nov. 1995) (unpublished). We see no basis for inferring that 88% lactic acid would have materially greater corrosion rates. (A copy of this study is enclosed; we have previously submitted to your office copies of the other scientific materials cited in this letter.)

<sup>41</sup> TNO Report No. V 87.405/270419, "Acute Dermal Irritation/Corrosion Study With Lactic Acid (88%) In Pigs (Nov. 1987) (unpublished) at 7.

<sup>38</sup> The 1981 Guideline required that a single patch containing the test substance be applied to the skin of each of three test animals for four hours, and that the exposed areas then be examined for signs of irritation at intervals of 30-60 minutes, 24 hours, 48 hours after patch removal. The 1992 Guideline requires that three patches be applied to the test animal, to be removed sequentially after 3 minutes, one hour and four hours. TNO's 1987 test followed this latter procedure, with the exposed locations being examined 60 minutes, 1 day, 2 days, 3 days, 7 days, 14 days and 21 days after patch removal. 1987 TNO Report at 7.

<sup>39</sup> In 1986 Inversk Research International ("IRI") exposed guinea pigs to 88% lactic acid, without corrosive effects. J.A. Cuthbert and S.M.A. Carr, "Lactic Acid Q88: A Skin Corrosivity Test in Guinea Pigs," Inversk Research International, IRI Report No. 3625 (Sept. 1986) (unpublished). Unlike the 1987 TNO testing, the 1986 IRI test report does not specifically reference OECD Guideline 404 as the test protocol followed. However, our review of the IRI report indicates that

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TNO performed this study under the 1981 version of Guideline 404. However, based on our review of the 1981 and 1992 versions of Guideline 404, the principal substantive changes in the 1992 version relate solely to animal welfare issues, i.e., the new version requires sequential rather than simultaneous testing of three animals and cautions against in vivo testing of very low pH liquids. Therefore, TNO's 1987 findings appear valid for purposes of 49 C.F.R. §173.136.

Although both the 1981 and 1992 versions of OECD Guideline 404 state that the albino rabbit is "the preferred species" for use in skin exposure testing, the Guideline says that "several mammalian species may be used." The skin of the albino rabbit is, in fact, significantly more susceptible to corrosive effects than that of humans, whereas pig skin is quite similar to human skin. Surveying a number of studies on the permeability of human skin and that of various animal species, Wester and Maibach (1977) conclude:

"Comparative studies in vivo on percutaneous absorption have shown the skin of monkey and pig to be most relevant to the skin of man. The skin of the rabbit and rat was highly permeable when compared to human skin." <sup>71</sup>

They note further that "especially in the rabbit, skin penetration is greater than that observed in man." *Id.* at 116-117. As observed by Winter (1971), "porcine skin resembles human skin more closely than does the skin of any of the common small laboratory animals." <sup>72</sup> Thus, pig skin provides more representative results than does rabbit skin in modeling the effects of lactic acid on human skin.

In conclusion, we believe that the TNO test, in which pigs exposed to lactic acid showed no adverse effects, demonstrates that this product is not a "corrosive material" within the meaning of 49 C.F.R. §173.136(a). If you agree with our conclusion, we ask that you

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the exposure times – 3 minutes, 1 hour, and 4 hours – and the observation intervals – 1, 24, 48 and 72 hours after patch removal – were substantially identical to those in the TNO test, and thus closely replicated Guideline 404. *Id.* at 4-5. Based on its observations, IRI concluded that "Lactic Acid Q88 is not corrosive to guinea pig skin." *Id.* at 6.

<sup>71</sup> Wester, R.C. and H.I. Maibach, *Percutaneous Absorption in Man and Animal: A Perspective*, in *Cutaneous Toxicity* 111-126 (V.A. Drill and P. Lazar eds., Academic Press Inc., New York 1977), at 125.

<sup>72</sup> Winter, G., *Epidermal Regeneration Studied in the Domestic Pig*, in *Epidermal Wound Healing* 71-112 (H.I. Maibach and D.T. Rovee eds., Yearbook Medical Publishers, Chicago 1971), at 71.

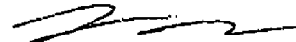
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provide confirmation that the material would not be a hazardous material, assuming no other hazardous attributes. Please do not hesitate to contact me if you have questions about this letter or require further information. We greatly appreciate your assistance in this matter.

Sincerely,



Carolina L. Mederos  
Transportation Policy Consultant