U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration

1200 New Jersey Ave, S.E.
Washington, D.C. 20590

JUL 2 3 2013

Ms. Suhey Francisco
Sr. Regulatory Affairs Specialist
Aceto Corporation
4 Tri Harbor Court
Port Washington, NY 11050

Ref. No.: 13-0073

Dear Ms. Francisco:

This is in response to your March 12, 2013 email requesting clarification on acute toxicity test requirements for inhalation toxicity in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

According to the information in your letter, you have classified your material Methylene-bis(4-cyclohexylisocyanate) or synonym Cyclohexane,1,1'-methylenebis[4-isocyanato- (CAS# 5124-30-1) using publicly available test data as UN2206, Isocyanates, toxic, n.o.s., 6.1, PG II. The acute toxicity test data values used in your classification are as follows:

LC_{50} Rat (male, head only exposure to an aerosol) inhalation 0.295 mg/L/4hr
LC_{50} Rat (female, head only exposure to an aerosol) inhalation 0.307 mg/L/4hr

After adjusting the four-hour exposure data in accordance with § 173.132(b)(3)(i) you indicate the one-hour exposure results as LC_{50} Rat (male) 1.18 mg/L/1hr and LC_{50} Rat (female) 1.228 mg/L/1hr. In accordance with the § 173.133(a)(1) table, this material is assigned to packing group II.

Specifically, you seek clarification on the suitability of test result data as the exposure was to an aerosol and not to either a dust or mist as prescribed in §§ 173.132 and 173.133 and if these results should be applied when classifying your material.

The answer to your question is yes. The test results would be applicable when exposure is administered as a liquid aerosol that emerges as a mist, if a mist is likely to be generated in a leakage of the transport containment as prescribed in § 173.132(b)(3)(iii). As provided in §173.22, it is the shipper's responsibility to make this determination.

In addition, you also request clarification that if the aforementioned test method is not appropriate for determining the toxicity of the material, would it still require classification as UN2206, Isocyanates, toxic, n.o.s., Class 6.1, because of its chemical family.

Under § 173.22 of the HMR it is a shipper's responsibility to properly classify a hazardous material. A poisonous material (liquid) is defined in § 173.132 as a material, other than a gas, which is presumed to be toxic to humans because it falls within one of the following categories when tested on laboratory animals: oral toxicity, dermal toxicity and inhalation toxicity. If your material meets the LC_{50} or LD_{50} criteria for any of these categories, it meets the definition of a Division 6.1 material. Thus, if your material meets the definition of a Division 6.1, or any other hazard class, then it must be classified accordingly, and the determination should not be based solely on its chemical family.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

Delmer Billings
Senior Regulatory Advisor
Standards and Rulemaking Division

Wiener
§ 173.132(b)(3)
Classification
13-0073

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U. S. Department of Transportation
Office of Hazardous Materials Standards Pipeline
and Hazardous Materials Safety Administration
1200 New Jersey Avenue, SE
Washington, DC 20590-0001

March 8, 2013

Re: Interpretation of test data values for LC50 inhalation rat in accordance to 49 CFR §173.132(b)(3).

Dear Sir or Madam:

Aceto Corporation is requesting from the Associate Administrator for Hazardous Materials Safety a clarification on the test result requirements for LC50 toxicity data values for inhalation rat.

Using publically available test data, we have classified our material *Cyclohexane, 11'-Methylenebis(4-isocyanato-* [CAS# 5124-30-1] as UN2206, Isocyanates, toxic, n.o.s., Class 6.1, PG II. However, it has come to our attention that because of the method of testing, this material may not be subject to the classification. The test data values we have are the following:

LC50 Rat (male, head only exposure to an aerosol) inhalation 0.295 mg/L/4hr
LC50 Rat (female, head only exposure to an aerosol) inhalation 0.307 mg/L/4hr

Once the test data has been adjusted in accordance with 49 CFR §173.132(b)(3)(i), the test data are LC50 Inhalation Rat 1.18 mg/L/1hr and LC50 1.228 mg/L/1hr respectively. This would place the material as packaging group II. However, due to the exposure as an aerosol and not a dust/mist as specified in the regulations, some sources have argued that this would exempt the material from its hazardous classification. Does the test method of exposure as an aerosol affect the toxic classification of the material?

Further to that, Aceto has classified the material as an isocyanate, which is specifically listed in the hazardous materials table. If the test method is not appropriate for determining toxicity of the material,

wouldn't it still require classification as UN2206, Isocyanates, toxic, n.o.s. because of its chemical family?

Aceto appreciates your attentiveness to this matter and looks forward to your response. If you have any questions or concerns, please feel free to contact me by phone at 516-627-6000, ext 596 or by email at sfrancisco@aceto.com.

Sincerely,

Suhey Francisco
Sr. Regulatory Affairs Specialist
Aceto Corporation