Rear Admiral William S. Stokes
Director, National Toxicology Program Interagency Center
for the Evaluation of Alternative Toxicological Methods
National Institute of Environmental Health Sciences
P.O. Box 12233 (Mail Code K2-16)
Research Triangle Park, NC 27709

Dear Admiral Stokes:

Thank you for the letter to Secretary LaHood from Linda Birnbaum, Director, National Institute of Environmental Health Sciences which forwarded toxicological test method recommendations to the U.S. Department of Transportation (DOT) from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The DOT is one of several Federal agencies that received the toxicological test method recommendations for consideration. The letter was referred to the Pipeline and Hazardous Material Safety Administration (PHMSA), the agency within DOT responsible for regulating the transport of hazardous materials in commerce and participation in ICCVAM. Dr. Birnbaum requested that we send the DOT response directly to you, not later than 180 days after receipt of the recommendations.

We reviewed the test method recommendations for the reduced murine local lymph node assay (rLLNA), an updated LLNA test method protocol, and LLNA test method performance standards. As noted, the LLNA is a test method used to assess the potential for chemicals and products to cause allergic contact dermatitis.

The DOT administers the Hazardous Materials Regulations and regulates the transportation of hazardous materials in commerce (HMR; 49 CFR Parts 171-180). The HMR include, among others, materials that meet the definition for Gas poisonous by inhalation (Division 2.3), Poisonous material (Division 6.1), and Corrosive material (Class 8).

The rLLNA test method and the related performance standards are not applicable to the HMR. The test method and related standards do not possess the capability to determine if a material is hazardous in accordance with the HMR and, therefore, subject to the HMR.
I hope this information is useful. If we can be of further assistance, please contact Ms. Patricia Klinger, Director of External Communications at 202-366-4461.

Sincerely,

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Magdy El-Sibaie
Associate Administrator
for Hazardous Materials Safety