

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

TSCA CONFIDENTIAL BUSINESS INFORMATION DOES NOT CONTAIN NATIONAL SECURITY INFORMATION (E.O. 12065)

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. Ken McElrath Unidym, Inc. 16200 Park Row Houston, TX 77084

Dear Mr. McElrath:

Re: X-08-3

This letter responds to the above-referenced Low Release and Low Exposure exemption (LoREx) notice, received by the Environmental Protection Agency (EPA) on April 22, 2008. The notice review period expired on May 21, 2008. After that date, you became free to import this substance under the terms of the TSCA LoREx exemption (40 CFR 723.50(c)(2).

EPA is concerned that exposure of unprotected workers to, or environmental release of, this LoREx substance during manufacturing, processing, or use could present a risk of injury to health and the environment. This concern is based on Structural Activity Relationship (SAR) analyses derived from test data on analogous respirable, poorly soluble, particulates (see www.epa.gov/oppt/newchems/pubs/chemcat.htm) that show lung effects from inhalation exposure. EPA's concern for potential systemic effects from dermal exposure to the LoREx substance is based on test data for chemicals with similar physical properties.

EPA has, nevertheless, approved this LoREx due to the human exposure and environmental release controls provided in your exemption notice. You are required by 40 CFR 723.50(j) to maintain these controls. The conditions of manufacture, processing, use and disposal described in your LoREx application are legally binding for one year, until May 21, 2009. EPA views your commitment to this limit on the duration of manufacture as a legally binding and enforceable human exposure and environmental release control under 40 CFR 723.50(j). Thus, in order to continue uninterrupted manufacture after that date, you must submit a PMN for this substance and have the 90-day PMN review period expire before May 21, 2009.

You are required by 40 CFR 723.50(j) to ensure that the LoREx chemical substance is manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice. Therefore, to mitigate exposures, any workers who may be exposed to the substance during manufacturing, processing and use must use NIOSH-approved full-face respirators with N-100 cartridges, ANSI-rated 787 safety glasses, and impervious gloves and protective clothing. Your company must also maintain adequate records to verify these restrictions.

Further, 40 CFR 723.50(k) requires your Company to notify processors and industrial users of the exposure controls and use limitations specified in the exemption notice. According to 723.50(k)(2), you may distribute this LoREx substance only to persons outside your company who agree in writing to not further distribute the substance until it has been reacted, incorporated into an article, or otherwise rendered into a physical form or state in which environmental releases and human exposures above the eligibility criteria in 723.50(c)(2) are not likely to occur. If you learn that a customer is processing or using the substance in violation of such restrictions, you must immediately cease distribution of the LoREx substance to that customer or comply with the procedures specified in subsection 723.50(k)(3).

Thank you for your cooperation. If you have any questions or comments, please call the program manager of this LoREx, Zofia Kosim at 202-564-8733.

Sincerely,

Greg Schweer, Chief

New Chemicals Notice Branch

Chemical Control Division (7405 M)

TSCA CONFIDENTIAL
BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12065)