



Dr. Alan Weinrich  
American Conference of Governmental Industrial Hygienists  
1330 Kemper Meadow Drive, Suite 600  
Cincinnati, OH 45240

September 21, 2001

Dear Dr. Weinrich:

The Independent Lubricant Manufacturers Association (ILMA) appreciates the opportunity to respond to your July 12, 2001, request for further information regarding ACGIH's Proposed TLV and A2 Classification for Mineral Oil Mist. As mentioned in ILMA's June 19, 2001 letter, our members wish to play a constructive role in shaping future threshold limit values (TLV) involving or affecting their products. To this end, the Association's Safety, Health, Environmental and Regulatory Affairs (SHERA) Committee has prepared the following comments.

First, ILMA's fundamental concern with the TLV proposal is that, while ACGIH may not be "related to" or does not "advise" the federal government and its agencies, specifically the Occupational Safety and Health Administration (OSHA), its TLVs are adopted by OSHA in regulatory standards. For example, the Hazard Communication Standard specifically references the latest edition of "Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment" as a source for determining whether a chemical is "hazardous." 29 CFR 1910.1200(d)(3)(ii). It has been our experience that, regardless of ACGIH's intent, OSHA relies upon ACGIH's expertise and the rigorous, independent scientific approach used in the TLV process. OSHA and the regulated community, thus, have high expectations of ACGIH. Historically, ACGIH has met and has exceeded these expectations. It has provided TLVs that have been both protective of employees and scientifically supported. ACGIH should continue this tradition of excellence. To do so, however, ACGIH should reconsider its approach to the proposed Mineral Oil Mist TLV.

Second, in ACGIH's recent response to ILMA's concerns on the proposed TLV, a clarifying statement indicated "The 2001 Notice of Intent to Change (NIC) is for mineral oil mist and would not include mists from other sources, such as vegetable or synthetic sources." ILMA would ask that, if the proposed TLV is based on respiratory symptoms, how does ACGIH conclude that mineral oil

**President**

Stanley J. Ziemski  
American Oil  
& Supply Company

**First Vice President**

Gregory J. Foltz  
Milacron Marketing  
Company

**Second Vice President**

Paul P. Converso  
Battenfeld Grease & Oil  
Corporation of N.Y.

**Treasurer**

James A. Taglia  
Nor-Lakes Services  
Midwest, Inc.

**Executive Director**

Michael C. Metallo

**General Counsel**

Jeffrey L. Leiter  
Collier Shannon Scott

mists are more irritating than mists from vegetable and synthetic oils? Moreover, if more than one type of oil mist is generated in a workplace, and is aerosolized, the employer will be unable to determine which type of oil the sampling collects. An OSHA inspector would face the same challenge when visiting this workplace. We, therefore, lack the understanding necessary to advise our members on managing the proposal and differentiating the effects of various classifications of mists on the respiratory system.

Third, ACGIH appears to state that the proposed TLV “is based on respiratory symptoms among exposed workers, not primarily on the potential cancer risk from exposure.” ILMA queries if respiratory irritation is the issue, how does ACGIH make the scientific and intellectual leap to defend an A2 Carcinogen classification? Moreover, where carcinogenicity is an issue, ILMA’s position is that it is imperative to distinguish between carcinogenic and non-carcinogenic oils for which much data distinguishing the two are available.

Finally, ACGIH states “the proposed TLV for oil mist is intended to be compared with measures of airborne mineral oil mists, per se, regardless of the sampling and analytical challenges this may present.” For the sake of science, ILMA believes the ability to compare two values can only be based on stable, reproducible methodology. The limit of quantification for particulate determinations is greater than 0.2mg/m<sup>3</sup> in ACGIH’s proposed TLV. It appears to us that, if an industrial hygienist is required to parse a small, non-significant number into arbitrary fractions based on pure guesswork, how could two such values be compared? A sampling strategy dictates that the level of the substance monitored be compared with a quantifiable value (e.g., REL, PEL, or TLV), with which a specific substance has been tested and under which employees may be repeatedly exposed day after day, without adverse effect. It remains ILMA’s position that sampling and analytical methodologies are moot points unless exposure to a specific product can be identified. Unless this matter can be resolved, measurable results and known impact on workers cannot be established. Accordingly, it is ILMA’s opinion that ACGIH must help the industrial and scientific communities by addressing publicly these issues, such as through a symposium on the health effects of workplace exposures to mineral oil mists.

ILMA also offers the following comments to ACGIH’s request for assistance on specific issues. These comments correspond to the “bullets” that begin on page 3 of your July 12, 2001 letter.

1. ACGIH recognizes the “confusing aspects of the three major studies forming the primary basis for the proposed mineral oil mist TLV.” ILMA feels this confusion exists because the draft TLV Documentation has relied almost exclusively on the science developed to evaluate the health effects of *metal working fluids* (MWFs). Such fluids are not 100% oil mist. It is confusing because these are not the appropriate studies upon which to base a TLV for *oil* mist. ACGIH typically addresses substances for which the available data point to a TLV in a straight and unequivocal way. ILMA believes the problem is with the data, which do not and cannot support such a TLV. The type of data ACGIH needs to support a TLV for mineral oil mist cannot be found in existing MWF studies; rather it is ILMA’s hope that ACGIH will gather and evaluate scientific data relevant only to mineral oil mist

exposure for purposes of threshold implementation and not rely on data that involve MWFs.

2. ILMA cannot support relying upon epidemiological studies from MWF exposure as justification for a mineral oil TLV. As noted by the American Petroleum Institute (API), the results of these epidemiological studies relate to mixtures; they do not provide a sound basis for establishing an oil mist TLV. In addition, there are no complete studies on in-use fluids and how contamination affects employee exposure. It is our hope that ACGIH will join with ILMA in the opinion that it is imperative that quantifiable research be done on oil mists in question, rather than mists of MWFs, before any lower TLV for oil mist can be established.
3. ILMA is not aware of any data regarding workers occupationally exposed to highly refined mineral oil mists.
4. Regarding data on how *in vitro* tests for carcinogenicity may be used, ILMA feels a symposium would better address how such *in vitro* tests for carcinogenicity may be used and applied in field situations for formulated products.
5. NIOSH states that there have been a small number of epidemiological studies that have adequate exposure characterization, and that the MWF constituents responsible for the site-specific cancer “remains to be determined.” ILMA believes that none of the studies, including the epidemiological study by Eisen, et.al., has adequate exposure characterization. Those studies that reported statistically significant effects found only very weak effects. None of the studies met Hill’s criteria for establishing a cause-effect relationship. It is our opinion that more studies should be conducted to establish whether there is truly a statistically significant cause-effect relationship supportable by science before recommendations for TLV thresholds are put forward.

As we understand cause-effect studies, those studies that report findings should link a strong association between exposure and an effect. Epidemiologists recognize risk ratios greater than 3 as strong. Risk ratios of 1.2-1.5 are classed as weak. This is the range reported in the study with the best design. Given this situation, ACGIH’s primarily reliance on one study of health effects of MWFs to support an A2 designation for mineral oil mist is not appropriate. ILMA would be pleased to present a critical review of this paper as it relates to justification of the proposed A2 carcinogenicity designation at a future symposium. ILMA strongly encourages ACGIH to sponsor a symposium designed to provide an open forum for interested parties to discuss the proposed TLV and to assist ACGIH gather scientific data on analytical methods to measure mineral oil mist and other such important data.

ILMA members are committed to the goals of employee health and safety and the safe use of their products. Members of the Association welcome the opportunity to participate in a symposium that would ultimately further these goals. We appreciate the opportunity to dialogue with the distinguished members of the ACGIH.

Once again, thank you for considering our comments. Please contact either myself, or the SHERA manager Cathy Barmoy at 703/684-5574 regarding this letter or ILMA's participation in and support of the symposium.

Sincerely,



Michael C. Metallo  
Executive Director

cc/ ILMA Board of Directors  
SHERA Committee  
Jeffrey L. Leiter  
Stephanie Siegel

bcc/ API  
ORC