



# Independent Lubricant Manufacturers Association

February 29, 2016

*Via Electronic Mail*

Dr. Yun Xie  
NTP Designated Federal Official  
Office of Liaison, Policy, and Review  
DNTP, NIEHS  
P.O. Box 12233, MD-K2-03  
Research Triangle Park, North Carolina 27709

**RE: NTP's Abstract and Poster Presentation at the Society of Toxicology Meeting**

Dear Dr. Xie:

The Independent Lubricant Manufacturers Association (ILMA or Association) recently obtained a copy of the abstract for the poster by Dr. Kristen Ryan and others that will be presented next month at the annual Society of Toxicology (SOT) meeting in New Orleans. ILMA has concerns with three statements in the abstract and how the National Toxicology Program's (NTP) conclusions from the 13-week inhalation studies of TRIM® VX, TRIM® SC210, SYNTILO® 1023 and CIMSTAR® 3800 will be presented during the SOT meeting.

First, the following statement excerpted from the abstract is misleading and requires revision in the abstract and poster: “[a]dverse health effects (respiratory symptoms, dermatitis, cancer) have been reported in exposed workers.” As currently written in the abstract, this statement suggests, or could potentially be interpreted as meaning, that adverse health effects have been reported in all or a significant number of exposed workers. This is not a true statement and should be clarified or limited to *some* workers exposed to *some* older metalworking fluid (MWF) formulations.

Second, the following statement also excerpted from the abstract is misleading and requires revision in the abstract and poster: “[w]hile known carcinogens have been removed from newer MWFs, recent studies in experimental animals indicate a continued health risk.” As currently written in the abstract, this statement suggests that all newer MWFs pose a continued health risk, which is false and scientifically unsubstantiated. As evidenced by ILMA's 2005 letter to Dr. Dan Morgan and NTP's MWF selection process that followed, each fluid is a unique formulation and, therefore, generalizations across the classes of MWFs are both inappropriate and scientifically unjustified.

Finally, the following is a mischaracterization in the abstract and must be corrected in the abstract and poster: “[t]hese data confirm that newer MWFs have the potential to cause respiratory toxicity in workers repeatedly exposed via inhalation.” As emphasized by ILMA and Master Chemical in their written and oral comments

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during the February 16, 2016 Peer Review Panel meeting on TRIM® VX, MWFs are inherently-unique, proprietary formulations. It is inappropriate to suggest that the conclusions reached in the 13-week studies of CIMSTAR® 3800, TRIM® SC210, SYNTILO® 1023 and TRIM® VX can be extrapolated and applied to all MWFs as a class. The Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard 2012 (HCS 2012) bridging principles fully support the Association's position. Further, the NTP Peer Review Panel encouraged the inclusion of limiting language in the executive summary to the final TR 591 that the results are specific to TRIM® VX and cannot be applied to any other MWFs.

ILMA echoes the sentiments of the Peer Review Panel and respectfully requests that NTP include limiting language in the final technical report, the poster abstract, the poster itself, and during any presentations during the SOT meeting, indicating that the conclusions are solely applicable to the four fluids included in the 13-week studies.

Sincerely,

A handwritten signature in black ink that reads "Holly Alfano". The signature is written in a cursive, flowing style.

Holly Alfano  
Chief Executive Officer