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October 21, 2005

Dr. Daniel L. Morgan
Respiratory Toxicology
NIEHS

P.O. Box 12233
Research Triangle Park, NC 27709

Dear Dr. Morgan:

I am writing this letter to follow-up on the July 27, 2005 meeting between staff from the National Toxicology Program (NTP) and representatives from the Independent Lubricant Manufacturers Association (ILMA). At this meeting, we discussed the status of NTP's Cancer Bioassay studies of nine metalworking fluids (MWFs) and explored ways that ILMA could assist NTP with its research endeavors by providing practical insights about these products and their commercial uses.

Thank you for hosting the meeting. It went a long way to establishing open lines of communication between ILMA and NTP. We learned a great deal and look forward to assisting NTP as much as possible.

At the meeting, we agreed to a mutual information exchange. To assist NTP in designing further studies, ILMA agreed to provide technical product specifications on shelf life and fluid stability, insights on dilution, and to explore whether we could provide information *related* to product formulation, short of the actual product formulas. (We are pleased that NTP recognizes that the disclosure of actual product formulas would be exceedingly difficult because they are trade secrets in a highly-competitive market.)

NTP agreed to provide ILMA a summary of the factors and underlying reasoning that it considered in selecting the nine fluids for study (NTP's "selection criteria"). As we noted at the meeting, the plurality of products in the MWF market (in terms of chemical composition and application) precludes identifying a "representative" sampling of MWFs. The fluids are unique in the truest sense of the word. ILMA agreed, nevertheless, to provide some feedback on NTP's selection criteria. Several weeks ago you shared the selection criteria with us.

Product Specifications

The following matrix addresses shelf life and product stability for the nine fluids assuming normal storage conditions:

PRODUCT LINE	SHELF LIFE	STABILITY
Castrol Industrial North America, Inc.	24 months	Concentrates stable within a range of 40° F to 120° F; dilutions stable for approximately 90 days under laboratory conditions (though water hardness and evaporation may have an impact)
Master Chemical Corporation	12 months	Concentrates are stable within a range of 50° F to 90° F
Milacron Marketing Company	12 months	Products are stable in ambient temperatures

As the information in the matrix suggests, a good “rule of thumb” might be that concentrates kept at room temperature for up to a year will likely be in good shape for NTP’s purposes.

Dilution

Soluble oil product concentrates, in contrast to other water-dilutable product classes (semisynthetics and synthetics), generally do not contain water in the product concentrate.¹ As a result, any change in product chemistry (including the possible reaction of water with other chemical components in the product concentrate) that might occur upon dilution would not occur if the soluble oil product concentrate were to be directly aspirated. Thus, in order to assure that laboratory animals are exposed to fluids representing conditions as close to possible to those of machinists, ILMA recommends that any soluble oil product be first diluted one part fluid concentrate to 20 parts deionized water before exposure.

Because other water-dilutable product classes already contain sufficient water to assure that any hydrolysis reactions would occur, ILMA believes that further dilution of such product classes is not necessary before exposure.

As we discussed at our meeting, research over the last 15 years strongly suggests that certain contaminants may play a major role in observed acute respiratory health effects. ILMA, therefore, believes that NTP should also consider exposing laboratory animals to dilutions of metalworking fluid products that are contaminated and compare those results to those of fresh dilutions. Such an inquiry would better simulate conditions in a metalworking shop.

¹ Byers, J. ed., *Metalworking Fluids*, at 165-189 in Marcel Dekker, New York, NY, 1994.

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Product Formulations

The product formulas are trade secrets. None of the companies are therefore able to disclose product formulations *per se* through ILMA to NTP. During our meeting it appeared that NTP recognized this practical constraint. We would imagine also that NTP has an interest in independently determining the composition of the fluids.

Despite these limitations, ILMA is committed to balancing its offer of assistance to NTP with the need to protect this sensitive information from public disclosure. To this end, and because these products are complex and reverse engineering is difficult, we determined that providing a list of the chemical *categories* contained in each of the fluids might be a workable compromise. The matrix on Attachment 1 provides this information. The manufacturers of these fluids submitted these data voluntarily to ILMA with the understanding that this information would be handled on a confidential basis.

Attachment 1 is, in its entirety, exempt from disclosure under any Freedom of Information Act (FOIA) request. More specifically, Attachment 1 qualifies under the U.S. Department of Health and Human Services (HHS) FOIA regulation exemption for both trade secrets and confidential commercial or financial information, 45 CFR § 5.65.² ILMA respectfully requests that Attachment 1 be managed accordingly by NTP.

² First, listing specific constituents of a manufactured product fits squarely within the regulatory definition of a trade secret:

A trade secret is a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

45 CFR § 5.65.1. These materials' status as "trade secrets" provides an independent basis for precluding disclosure in response to a FOIA request.

The materials' status as "commercial or financial information" provides a second, independent basis for precluding disclosure under a FOIA request. Under HHS regulations, "commercial information" must be withheld from a FOIA request to the extent that it was obtained "from a person" and that the commercial information is otherwise "privileged and confidential."

Component ingredients to a manufactured product satisfy the regulatory definition of commercial information: information that relates to "business, commerce, trade . . . [or] profits." 45 CFR § 5.65.2.1. ILMA is a private trade association, and thus these materials are submitted "from a person." *Id.* Finally, the information contained in these materials was compiled at the direction of counsel and thus satisfy the "privileged and confidential" requirement. *Id.*

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NTP's Selection Criteria Document

As we understand the process, the National Institute for Occupational Safety and Health (NIOSH) identified the top ten marketers of metalworking fluids and selected, somewhat arbitrarily, five to six fluids from the top five marketers. The selected fluids were to represent a cross section of each marketer's line. From an initial list of 29 fluids, NTP determined that only 18 were commercially available to them.

NTP, through a contractor, chemically characterized the 18 available MWFs. NIOSH, using that information, along with available marketing materials, material safety data sheets, independent chemical analyses and the contractor's recommendations, narrowed the list to nine products for further evaluation by NTP. NIOSH, using an admittedly arbitrary process, selected three products from each of the three manufacturers whose products were commercially available. The products were sometimes chosen because they were representative of a category but also were sometimes chosen because they were complex or unusual.

Given this process, the fluids selected, while not in fact "top sellers" within their respective companies, do contain chemistries typical of more widely-used products. On the other hand, as each fluid is unique, ILMA believes testing results must be limited to that individual formulation. Indeed, as evidenced in Attachment 1, each of the soluble oil formulations contain chlorinated EP agents. Investigation results regarding the soluble oil fluids selected by NTP should not be applicable to non-additized soluble oils, which are more common in the industry.

ILMA thanks NTP for sharing information regarding its metalworking fluid selection process and looks forward to further information exchanges and discussion as testing and evaluation continues. ILMA would be pleased, for example, to review NTP's chemical analyses in an effort to help put the results into context. Indeed, to the extent the analytical results generated by NTP are inconsistent with what ILMA member companies know to be true, an opportunity to provide additional information to NTP may be in everyone's best interest.

Sincerely yours,

[Signature Redacted]

Celeste M. Powers, CAE
Executive Director

cc: SHERA Committee w/o Attachment 1 (via email)
Jeffrey L. Leiter, Esq.
Adam B. Cramer, Esq.