



INDEPENDENT LUBRICANT MANUFACTURERS ASSOCIATION

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June 13, 2014

Ms. Monet Vela

Office of Environmental Health Hazard Assessment

California Environmental Protection Agency

1001 I Street

P.O. Box 4010

Sacramento, CA 95812-4010

Re: Proposition 65 Warning Regulation

Dear Ms. Vela:

The Independent Lubricant Manufacturers Association ("ILMA") submits the following comments on the Office of Environmental Health Hazard Assessment's ("OEHHA") plans to amend Article 6, Clear and Reasonable Warnings (Title 27, California Code of Regulations, at section §25601 et seq.).

I. Introduction of ILMA

ILMA is a national trade association of 317 member companies. As a group, ILMA's Manufacturing Members blend, compound, and sell over 30 percent of the automotive lubricants, including passenger car motor oils ("PCMOs") and heavy-duty motor oils ("HDMOs") for trucks, and over 75 percent of the metalworking fluids utilized in the country. Independent lubricant manufacturers by definition are neither owned nor controlled by companies that explore for or refine crude oil to produce lubricant base stocks. Base stocks are purchased from refiners and re-refiners, who are also competitors in the sale of finished lubricant products, including PCMOs. Independent lubricant manufacturers succeed by manufacturing high-quality, often specialized, lubricants. Their success in this competitive market also is directly attributable to their tradition of providing excellent, individualized service to their customers.

ILMA members' lubricant products primarily are mixtures manufactured by compounding and blending other components, largely additives for performance and other purposes purchased from upstream chemical suppliers, with the lubricant base stocks. As a result, some ILMA members' products may contain very, very small amounts of listed chemicals which are below the levels that can be analyzed yet *may* be in components purchased from upstream suppliers. Unless complicated and expensive calculations to determine whether lubricants may be below the "safe harbor" No Significant Risk Levels ("NSRLs") for carcinogens or for Maximum Allowable Dose Levels ("MADLs") for chemicals which cause reproductive harm are performed, upstream suppliers – and by necessity – downstream blenders, including ILMA members, generally indicate that their products may contain listed chemicals.

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As OEHHA is well aware, chemical manufacturers, including ILMA members, are also subject to the new requirements of the Globally Harmonized System for the Classification of Chemicals (“GHS”) as promulgated by the U.S. Occupational Safety & Health Administration (“OSHA”) on March 26, 2012 as amendments to the Hazard Communication Standard (“HCS”)(29 C.F.R. Part 1910.1200), and for which substantially changed classification rules for mixtures and new requirements for labeling of products and preparation of Safety Data Sheets (“SDS”) become required on and after June 1, 2015.

ILMA members provide industrial lubricants, including metalworking fluids, to many California manufacturers. They also market lubricants, including PCMOs and HDMOs, through several distribution modes to California retail consumers. While supportive of OEHHA’s efforts to provide regulatory specifics for “clear and reasonable warnings,” ILMA believes that the changes as proposed to the warning language will confuse both industrial customers and retail consumers as detailed below.

II. Proposed Changes to Title 27, Section 25601, et seq. – General Comments

ILMA is generally supportive of OEHHA’s efforts to establish requirements for “clear and reasonable warnings.” However, there are serious issues with many of the sections of the proposed regulations, including:

- §25604, Lead Agency Website: while well intentioned, the requirements placed on manufacturers and distributors regarding the information to be provided to the “Lead Agency” will not necessarily appreciably improve consumer safety and is excessively burdensome;
- §25605, Chemicals, Substances or Mixtures that must be Disclosed in Warnings. It is not clear to ILMA that disclosure of the names of any of the chemicals listed in this section will improve consumers or workers’ understanding of the risks associated with exposure since they may be at such low levels;
- §25607.1, Consumer Products Exposure Warnings - Methods of Transmission..., and §25607.2, ...Content. Possible labeling and its impact on retail consumers may cause more confusion than education;
- §25607.12, Occupational Exposure Warnings – Methods of Transmission and §25607.13...Content. The requirements of these sections presented in the March 7, 2014 Pre-Regulatory Draft have serious conflicts with the requirements of the GHS amendments to the HCS as promulgated by OSHA on March 26, 2012, for occupational exposures in an industrial setting. Moreover, as the example below illustrates, the differences between OSHA regulations and the draft OEHHA regulations with respect to, for example, formaldehyde, illustrates that there will be more confusion with respect to worker training and employer requirements than anticipated;
- §25607.15, Environmental Exposure Warnings – Methods of Transmission and §25607.16, Environmental Exposure Warnings – Content. It is unclear how manufacturers, including ILMA members, can anticipate a foreseeable exposure to a product containing a listed chemical with an environmental medium, including air or water contamination.

ILMA's specific comments follow:

- **§25604, Lead Agency Website**

While well intended, the requirement in §25604(d) for OEHHA to develop an interactive web site to provide information to the public, will lead to frustration and confusion on the part of the public as they attempt to use the website, making it less useful than OEHHA believes. Further, the requirement for businesses, including ILMA members, to notify OEHHA with all of the information specified in draft section §25604 for each product they manufacture or may market in California, or which might arrive in California through other means of distribution, will be extraordinarily burdensome. For example, suppose an ILMA member manufactures a PCMO which contains, as many formulations might, trace amounts (0.1 parts per trillion up to 0.1 part per million) of listed (in section §25605) chemicals cadmium, arsenic, benzene and toluene. For each such product, here is what the draft statute requires be provided to OEHHA:

- a. Name and contact information for the person providing the warning;
- b. Name and contact information for the manufacturer of the PCMOs the warning is intended to cover;
- c. The names of the specific products and barcodes, if any, of the PCMOs which contain the trace chemicals;
- d. Names of the chemicals for which the warning is given: in this example, cadmium, arsenic, benzene and toluene;
- e. That the warning given is for cancer and developmental and reproductive toxicity;
- f. That the anticipated routes of exposure include dermal, ingestion and possibly inhalation;
- g. If known, any available information concerning the anticipated level of human exposure to the listed chemical
- h. If any, information concerning actions a person can take to minimize or eliminate exposure to the listed chemicals.

Together, ILMA member companies and other manufacturers in NAICS code 324191, Petroleum Lubricating Oil & Grease Manufacturers, manufacture hundreds of thousands of products.¹ While it is not clear how many of them are sold or distributed in California, given the relative size of the State's economy, a substantial portion of those products are likely sold and used within California. As a result, not even counting the many, many other types of products which might contain listed chemicals and which therefore would also be listed on OEHHA's website, the chance of consumers, well intentioned as they might, to find the specific product for which they are looking, is likely slim.

ILMA believes that, as burdensome to the industry as the labeling requirements are, the necessity of also needing to provide information to OEHHA to both initially populate the website and then to maintain it means a more confused, not less confused, consumer and added burdens to manufacturers, including ILMA members.

¹ Federal Register, Vol. 77, No. 58, March 26, 2012, page 17620

- **§25605, Chemicals, Substances or Mixtures that must be Disclosed in Warnings**

Of the dozen chemicals listed in section §25605, manufacturers of lubricating oils and greases, including ILMA members, will likely find that a substantial number of listed chemicals *may be present* in the products they manufacture, not because they are deliberately added, but as a result of trace, in fact almost undetectable, amounts of the listed chemicals, contained as contaminants in upstream chemicals they purchase. For example, ILMA has determined through review of additive SDS and other available information that, of the listed chemicals, the following *might* be found in trace amounts (shown are listed chemicals estimated to be possibly in lubricant products, based on maximum levels of contaminants in upstream chemicals, along with maximum estimated concentrations in lubricant formulations. Note: not all lubricant formulations will contain all contaminants and many may contain no listed chemicals as contaminants.):

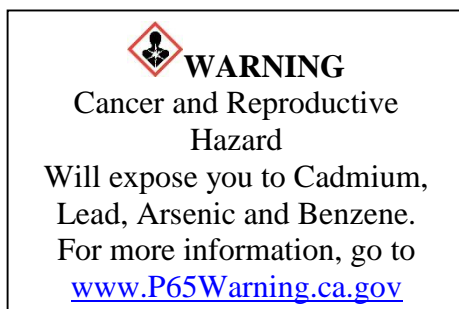
- Arsenic, < 0.1 parts per billion (ppb)
- Benzene, < 0.1 parts per billion (ppb)
- Cadmium, < 0.1 parts per billion (ppb)
- 1,4-Dioxane, < 1 part per billion (ppb)
- Formaldehyde, < 100 parts per billion (ppb)
- Lead, < 0.1 parts per billion (ppb)
- Toluene, < 100 parts per billion (ppb)

These are exceedingly small amounts yet, as exposure scenario calculations as required by other sections of the regulations to determine safe harbor exposures have not been completed, chemical manufacturers, including ILMA members, will be obligated by the new regulations to notify OEHHA per section §25604 and add warning language to labels according to sections §25607.1 and §25607.2 or §25607.12 or §25607.13, depending on the type of product.

As illustrated below, ILMA does not believe the public will be better served by chemical-specific warnings than they already are served by the more general Prop 65 warning.

- **§25607.1, Consumer Products Exposure Warnings - Methods of Transmission..., and §25607.2, ...Content.**

Based on the information provided in the draft regulation and based on the information provided above, ILMA believes a label on a container of PCMO or a label of hydraulic oil for an agricultural tractor that a consumer would purchase might need to contain this additional labeling information:



Per the draft regulations, there is not an ability to quantify the maximum concentration, as small as it is likely to be for products manufactured by ILMA members, of possible contaminant


chemicals. Without knowing the maximum concentrations of contaminant chemicals, there is no ability for the consumer to ascertain the risk from any exposure. As a result, it is ILMA's belief that, while upgrading consumers' knowledge about chemicals in products they purchase is a laudable goal, without any way to quantify and advise of the minimal risk associated with using the product which might contain tenths of a part per billion of a listed chemical, the general public is not well served.

- **§25607.12, Occupational Exposure Warnings – Methods of Transmission and §25607.13...Content.**


The requirements of these sections presented in the March 7, 2014 Pre-Regulatory Draft have serious conflicts with the requirements of the GHS amendments to the HCS, as promulgated by OSHA on March 26, 2012, for occupational exposures in industrial settings.

While OEHHA in the draft regulations offers the introductory phrase, "Except where prohibited by federal law," chemical manufacturers, including ILMA members, are left to discern for themselves how to reconcile the differences between these sections of the proposed regulations and OSHA's GHS amendments to the HCS, which, for product classification, labeling and creation of new SDS, come into effect on June 1, 2015.

Here are the differences which are of most concern to ILMA members:

The required use of the health hazard pictogram () in California for listed chemicals at concentrations much, much lower than in the Federal law. For example, if a manufacturer were to include benzene at level of 0.1% or higher in a product, there is no argument that the product would need to be labeled with the health hazard pictogram and its associated signal word (DANGER). As a GHS Category 1A carcinogen and Category 1B mutagen, the associated hazard statement would be "May cause cancer and genetic effects." Included in the group of GHS-defined label elements besides the health hazard pictogram, the signal word and the hazard statement would be these other precautionary statements: "Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection." (Specific type of personal protective equipment to be specified by manufacturer.) While not entirely clear, it appears, in the draft OEHAA regulations, that a product label meeting the requirements of OSHA's GHS standard, would satisfy the requirements of section §25607.12(b).

For purposes of illustration, an ILMA member manufactures a product that contains an upstream component which includes benzene only as a contaminant. Under OSHA's GHS amendments to the HCS, there would be no warning associated with cancer or mutagenicity because the concentration of benzene was much, much lower than specified under the revised HCS. But, say, in our example, that the product included, as a possible contaminant, up to 0.1 ppb benzene, a concentration *ten million times lower* and for which no safe harbor calculations had been made. In the other 49 States (and most of the rest of the world), no cancer warning would be required. Yet, in California, such a product would need to carry a label approximately as follows:


	<p>WARNING</p> <p>Using this product will expose you to Benzene, a chemical known to the State of California to cause cancer or other reproductive harm.</p> <p>For more information, ask your employer or go to www.P65Warning.ca.gov</p>
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OEHHA must appreciate there is a substantial difference in risk associated with the two products with one containing ten million times the concentration of benzene than the other.

ILMA predicts that workers will be very confused about the relative hazards and risks of the two products, and either will underappreciate the risks associated with the product containing 0.1% benzene or be will unnecessarily be overly concerned about the risks associated with the product containing only a trace amount of benzene. The situation is not good either way. Moreover, training programs designed to meet the OSHA's revised HCS standard will be confounded by the new requirements contained in OEHHA's draft regulation.

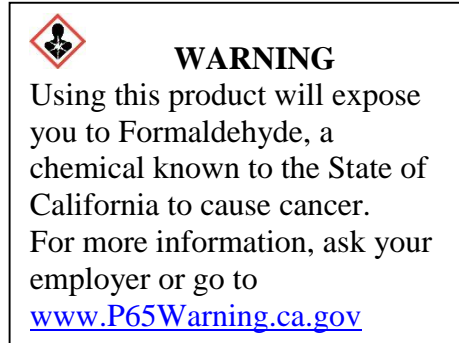
Here is another example: as noted above, ILMA members supply the majority (more than 75%) of what are known in the trade as "metalworking fluids" ("MWFs") – that is, formulated mixtures which are used to cut, grind and machine metal surfaces. In California, there are many shops, large and small, associated with the aerospace industry and these shops use a variety of fluids, both oil- and water-based. Most water-based fluids contain a preservative to prevent slow microbiological degradation of critical fluid components, and the majority of such fluids utilize small amounts of a biocide which releases formaldehyde. OSHA and other organizations, such as American Council of Governmental Industrial Hygienists ("ACGIH[®]"), have set exposure levels to formaldehyde based on understanding of a wide variety of factors (*see* 29 C.F.R. Section 1910.1048). As a part of its regulations, OSHA requires that employers provide training to workers exposed to formaldehyde except where, using objective data, employees are not exposed to formaldehyde at or above 0.1 ppm or 100 ppb. In the 1990s, a study² was conducted and while it was determined that there were no exposures above the OSHA Permissible Exposure Limit, there were some exposures at or above 100 ppb. However, the imprecision of the data suggested that it was not possible to determine whether exposures were in fact above or below 100 ppb. As a result, most employers who use water-based MWFs which contain a formaldehyde-release biocide do not provide training regarding the hazards of formaldehyde.

In California, OEHHA lists a NSRL for formaldehyde (gas) of 40 µg/day. This is an exceedingly low exposure, and while detailed calculations have yet to be performed, it is likely that calculated exposures to formaldehyde as a result of release from a formaldehyde-release biocide incorporated into a water-based MWF, even though they cannot be precisely measured, may exceed the NSRL. So, even though training under OSHA 1910.1048 might not otherwise be required, employers and manufacturers will likely need to provide, under §25607.12 and §25607.13, a warning message similar to:

	<p>WARNING</p> <p>Entering this area will expose you to Formaldehyde, a chemical known to the State of California to cause cancer.</p> <p>For more information, ask your employer or go to www.P65Warning.ca.gov</p>
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² Cohen, Howard A., "A Study of Formaldehyde Exposures From Metalworking Fluid Operations Using Hexahydro-1,3,5-Tris(2-Hydroxyethyl)-s-Triazine," in Symposium Proceedings, The Industrial Metalworking Environment: Assessment & Control, November 13-16, 1995, pp. 178 – 183. American Automobile Manufacturers Association, Dearborn, MI, 1996.

Moreover, manufacturers will separately have to affix labels to products containing such a formaldehyde-release biocide similar to:



Again, ILMA believes workers will be very confused about the hazards of MWFs containing a formaldehyde-release biocide because exposures to formaldehyde, even if somewhat above the NSRL, are well below OSHA's PEL and ACGIH's TLV for formaldehyde (0.3 ppm (ceiling)). In order to properly advise workers, California employers will likely need to provide much more training than contemplated so that workers, while understanding the hazards of formaldehyde, also understand the very low risk associated with such low exposures.

The use of the signal word **WARNING** and its association with the health hazard pictogram lies in stark contrast to the Federal requirements detailed in 29 CFR 1910.1200, Appendix C. In the Federal requirements, the health hazard pictogram is always associated with the signal word, **DANGER**. There will be continuing confusion in California workplace settings on account of these differences in signal words associated with the health hazard pictogram.

- **§25607.15, Environmental Exposure Warnings – Methods of Transmission and §25607.16, Environmental Exposure Warnings – Content.**

It is unclear how manufacturers, including ILMA members, can anticipate an exposure to a product containing a listed chemical with an environmental medium, including air or water contamination. Yet, by the wording of the proposed regulation, it appears manufacturers of chemical products might need to anticipate environmental exposures resulting from inappropriate disposal of either consumer or industrial products.

III. ILMA Recommendations

ILMA believes the draft regulations are seriously flawed as detailed above and that substantial revisions must be made before they can be presented again for public comment.

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We appreciate the opportunity to provide these comments.

Sincerely,

Celeste M. Powers, CAE
Executive Director

Ms. Monet Vela
June 13, 2014
Page 8 of 8

cc: ILMA Board of Directors
ILMA SHERA and Metalworking Fluids Committees
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