

Independent Lubricant Manufacturers Association

2018 Management Forum

Fort Lauderdale, Florida

Metalworking Fluids Committee

April 19, 2018

- Call to Order
- Antitrust Review
- Introductions
- Review and Adopt Minutes

National Association of Manufacturers - Manufacturing Summit 2018

- ▶ Tuesday, June 19, 2018 - Wednesday, June 20, 2018
- ▶ Mandarin Oriental Hotel in Washington, D.C.
- ▶ Great opportunity to convey issues and concerns to elected officials specific to lubricant manufacturers
- ▶ More information on ILMA's website.

Chlorinated Paraffins Update

Andrew Jaques

Executive Director

Chlorinated Paraffins Industry Association

Topics

- ▶ TSCA Update
 - ▶ New CP Substances SNUR
 - ▶ TSCA Inventory Reset Rule
 - ▶ Status of Existing CP Substances
 - ▶ LCSA Implementation
- ▶ California DTSC Safer Consumer Products
- ▶ Canada DSL Activities
- ▶ REACH Activities
- ▶ SCCP Global Status

New CP Substances SNUR

- ▶ 11 new CP substances added to the TSCA inventory in June and July 2017 covering MCCP, LCCP and vLCCP range
- ▶ All new CP substances are under Consent Orders, which will result in corresponding Significant New Use Rules (SNUR)
 - ▶ Metalworking fluid applications permitted for all new CP substances (i.e. not a “new use”)
- ▶ Most recent update from EPA is that the SNUR will be published by the end of April 2018.
 - ▶ This date has slipped several times over the past year. CPIA continues to push EPA to get it published.

New CP SNUR - 2

- ▶ SNURs will make the CO requirements applicable to all U.S. manufacturers, importers, and processors. Ensures that any new manufacturers or importers must meet the same requirements.
- ▶ Most current uses are permitted and will not require a SNUN, provided they are:
 - “a flame retardant and plasticizer in PVC and polymers; a flame retardant, plasticizer and lubricant in adhesives, caulks, sealants, and coatings; an additive in lubricants including metalworking fluids; a flame retardant and plasticizer in rubber; a flame retardant and waterproofer to textiles.”
- ▶ MCCP environmental fate testing program is the main requirement.

EPA MCCP Testing Program

- ▶ Technically a requirement of all recently approved CPs, regardless of chain-length.
- ▶ Biodegradation
 - ▶ OECD 308 sediment simulation studies on C14, 56% Cl (wt.) and C16, 56% Cl (wt.)
- ▶ Aquatic Toxicity
 - ▶ OECD 225 sediment-water Lumbriculus and OECD 211 chronic daphnia studies on C14, 30% Cl (wt.)
 - ▶ If adverse effects are observed in C14 studies above the triggers, run same tests with C16, 56% Cl (wt.)
- ▶ Bioaccumulation Testing
 - ▶ Only If adverse effects are seen in toxicity studies
 - ▶ OECD 315: Bioaccumulation in Sediment-dwelling Benthic Oligochaetes and OECD 305: Bioaccumulation in Fish in C16, 56% Cl (wt.)

TSCA Inventory Reset Rule

- ▶ EPA required to reset the TSCA inventory under the LCSA.
- ▶ Process will create “active” and “inactive” chemicals in the U.S.
 - ▶ EPA rule attempts to identify those chemicals that were active during the period June 2006 to June 2016.
- ▶ EPA developed a reporting process for manufacturers, importers and processors to alert EPA to the active status of a chemical.
- ▶ EPA identified a number of “exempt” substances that are automatically considered active.
 - ▶ All existing and new CP substances are exempt from reporting and considered active. This was confirmed in April 12, 2018 updated inventory.

Existing CP Substances

- ▶ Several ILMA members have asked about the status of the existing/legacy CP substances on the TSCA inventory.
- ▶ These substances remain on the TSCA inventory and several are on the active exempt list (e.g. CAS 63449-39-8).
 - ▶ Some of these existing CAS numbers are also on the Canadian DSL and the EU Inventory.
- ▶ EPA indicated last year that they may pursue a delisting of these legacy CAS numbers, though there has been no further discussion/action by EPA or CPIA on this.
- ▶ The manufacture/import of these legacy CP CAS numbers may not be advisable given EPA's prior enforcement actions on them.

LCSA/TSCA Implementation

- ▶ TSCA fee regulation proposed rule out for comment until April 27, 2018.
- ▶ Proposed fees primarily impact manufacturers and importers, though some of the proposed fees are in the millions \$ (Section 6 risk evaluations) and may impact the entire value-chain.
- ▶ Organizations with substances on the TSCA Work Plan may want to consider commenting on the Section 6 fee structure given the increased likelihood of being selected for risk evaluation.
 - ▶ EPA hopes to have the final fee rule in place before the end of 2018.
- ▶ Initial prioritization list (priority existing substances for risk evaluation) still under development.
 - ▶ None of the new CP substances are expected to be on this list given the activities under Section 5.

California Safer Consumer Products

- ▶ “Chlorinated paraffins”, chain length unspecified, were included on California’s Department of Toxic Substances Control (DTSC) draft 2018-2020 Priority Product Work Plan for the Safer Consumer Products program
- ▶ CPs were identified as a possible candidate chemical for building products
- ▶ CPIA and ACC-CPI commented
- ▶ No anticipated impact on MWFs

Canadian DSL

- ▶ Some of new CP substances now on the TSCA Inventory are already on the Canadian Domestic Substances List (DSL), though many are not.
- ▶ Those substances not on the DSL will require the submission of a New Substance Notification (NSN) to Environment and Climate Change Canada (ECCC).
 - ▶ This process is similar to the PMN process and must be done by individual Canadian manufacturers/importers.
- ▶ CPIA has been working with ECCC to streamline this NSN process by providing a summary of the available phys-chem, environmental and toxicology data on CPs.
 - ▶ ECCC provided positive feedback on the CPIA LCCP/vLCCP assessment.
 - ▶ CPIA members are moving forward with the NSN process for various new CP substances.

Europe - REACH

- ▶ MCCP and LCCP are actively registered under REACH by numerous companies.
 - ▶ MCCP: CAS 85535-85-9; EC 287-477-0
 - ▶ LCCP: CAS 63449-39-8; EC 264-150-0
- ▶ MCCP currently undergoing substance evaluation with additional testing on environmental fate.
- ▶ LCCP not currently under review.

SCCP Global Status

- ▶ SCCP: C10-13 Alkanes, chloro
- ▶ No longer manufactured in U.S./Europe and use effectively prohibited in U.S., Canada and EU
 - ▶ U.S. regulation is a SNUR on C12-13 as C10-13 is not specifically listed on TSCA inventory
- ▶ Added to Stockholm Convention list (identification of POPs)
- ▶ China MEP just added SCCP Prioritized List of Substances to be Subject to Control
- ▶ Asian manufacturing status is unclear, though some Asian products do not specify carbon-chain lengths and may contain constituents in the C10-13 range

Thank You!

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Health Canada - PMRA

CIT/MIT Update &
European Biocide Update

Richard Rotherham
Troy Corporation

- Nothing has changed
- Currently, all registrants are in the process of submitting revised labeling to PMRA for approval - including restoring MWF use levels to original levels

- Based on ACC Isothiazolinone Task Force discussions with PMRA, it is expected that PMRA will approve the revised labeling within 6 months
- This will negate implementation of lower use levels (currently required by December 2018).

UEIL - January HSE Meeting Update

Ron Powell
MorOil Technologies

UK Metalworking Fluid Guidance Document

Richard Rotherham
Troy Corporation

Proposition 65

- ▶ **TRIM VX®**
- ▶ **Monsanto**
- ▶ **New Clear & Reasonable Warnings**

Prop 65 -TRIM VX®

- ▶ Based on prior NTP review, California's OEHHA proposed to list MWF - TRIM VX® on Prop 65 using “authoritative bodies” listing mechanism
- ▶ ILMA submitted extensive comments arguing that NTP study was flawed for a number of reasons (e.g., inappropriately stored sample, etc.) and therefore did not meet standard for listing
 - ▶ Can review full comments on ILMA's website
- ▶ In alternative, comments seek to ensure that OEHHA was clear that MWFs are unique formulations and that no read across was possible
- ▶ No final decision as of April 18

Prop 65 - Monsanto Developments

- ▶ On going litigation for Roundup® - contains glyphosate
 - ▶ Challenging Prop 65 listing for glyphosate based upon IARC's conclusions
- ▶ Court decision to grant Monsanto's request for a preliminary injunction, temporarily preventing implementation of the Prop 65 listing for glyphosate
- ▶ Judge determined that Monsanto was likely to prevail on its First Amendment, free-speech claim that the required Prop 65 listing was akin to "government-compelled speech" and that Monsanto was likely to prevail on the merits of its claim.
- ▶ The federal court decision at odds with a California state court decision issued in January 2017 that upheld the Prop 65 listing.
- ▶ Need final decision on the merits, but could have wide-ranging ramifications for industry depending upon the scope of the final decision

Prop 65 - Clear & Reasonable Warnings

Jeff Leiter

ILMA 2018 Management Forum MWF Committee

MWF Studies on Autoworkers

John K. Howell, Ph.D., GHS Resources Inc.

Papers Reviewed - 2018 Management Forum

- ▶ Park, Robert M., “Risk assessment for cancer and metalworking fluid outcomes,” *Am J Ind Med.* 61, 198-203 (2018)
- ▶ Colin, R., et al., “Bladder cancer and occupational exposure to metalworking fluid mist: a counter-matched case-control study in French steel-producing factories,” *Occ Env Med.* 75, 328-336 (2018)

Papers Reviewed - 2018 Management Forum

- ▶ Ryan, Kristen R, et al., “Comparative pulmonary toxicity of metalworking fluids in rats and mice,” *Toxicology & Industrial Health*, 33, 385-405 (2017)

Park, Risk assessment for cancer and metalworking fluid outcomes

- ▶ Method: using published data from all of the GM-UAW studies, Park calculated an exposure response for each cancer site. Aggregate excess cancer risk was estimated by applying a lifetable calculation.
- ▶ Cancer sites producing the most attributable risk: Larynx, esophagus, brain, female breast, uterine cervix

Park, Risk assessment for cancer and metalworking fluid outcomes

- ▶ With constant workplace exposure of 0.1 mg/m³ over 45 years of a working life, risk of attributable cancer was 3.7% or, excluding less certain female cancers, 3.1%
- ▶ Park notes that excess cancer risk was calculated to occur at exposures ¼ of **NIOSH Recommended Exposure Level**. “Because ingredients in certain MWF remain from earlier formulations, it is likely that some MWF carcinogenicity remains today.”

Colin, et al., Bladder cancer and occupational exposure to metalworking fluid mist: a counter-matched case-control study

- ▶ To assess relationship between MWF exposure and bladder cancer, a nested case-control study setup for a cohort of workers from six plants (2006 - 2012).
- ▶ Three controls were selected for each bladder cancer case (total cases, 84; total controls, 251); all were interviewed.
- ▶ Methods: conditional multiple logistics regression analyses were used to calculate Odds Ratio (OR) and 95% Confidence Intervals (CI) taking occupational and non-occupational exposures into account 25 years before diagnosis.

Colin, et al., Bladder cancer and occupational exposure to metalworking fluid mist: a counter-matched case-control study

▶ Results:

- ▶ ORs increased significantly with duration of exposure to straight MWFs (OR=1.13 (1.02-1.25)) and increased with frequency-weighted duration of exposure to straight MWFs (OR=1.44 (0.97-2.14)).

Colin, et al., Bladder cancer and occupational exposure to metalworking fluid mist: a counter-matched case-control study

▶ Results:

- ▶ ORs increased with soluble MWFs but not significantly. No significant association was found with older exposures to MWFs or with exposure to synthetic MWFs.
- ▶ The authors note: “The increased risk of bladder cancer observed among workers exposed to straight MWFs and to a lesser extent to soluble MWFs may be explained by the presence of carcinogens (such as PAH) in mineral oils component of straight and soluble oils.”

Ryan, Kristen R, et al., Comparative pulmonary toxicity of MWFs in rats and mice

- ▶ Hypothesis: unrecognized health hazards exist in currently marketed MWF formulations that are presumed to be safe based on hazard assessments of individual ingredients.
- ▶ *In vivo* 13-week inhalation studies were designed to characterize and compare the potential toxicity of four MWFs: Trim VX, Cimstar 3800, Trim SC210, and Syntilo 1023.

Ryan, Kristen R, et al., Comparative pulmonary toxicity of MWFs in rats and mice

- ▶ Rats and mice were exposed to MWFs via whole-body inhalation at concentrations of 0, 25, 50, 100, 200, or 400 mg/m³ for 13 weeks; although high concentrations were used, survival was not affected

Ryan, Kristen R, et al., Comparative pulmonary toxicity of MWFs in rats and mice

- ▶ Results: toxicity primarily within the respiratory tract of male and female rats and mice.
- ▶ Minor variances in toxicity attributed to differences among species as well as in the chemical components of each MWF.
- ▶ Pulmonary fibrosis was present only in rats and mice exposed to Trim VX.

Ryan, Kristen R, et al., Comparative pulmonary toxicity of MWFs in rats and mice

- ▶ Data confirm that newer MWFs have the potential to cause respiratory toxicity in workers who are repeatedly exposed via inhalation.
- ▶ The authors note, “It should be noted that these four MWFs cannot be considered as representative of other MWFs within their respective classes because of the significant variability in MWF formulations.”

TEA - Department of Homeland Security Update

Jeff Leiter