

2016 ILMA Management Forum

Metalworking Fluids Committee

April 14, 2016

2:30PM-4:30PM

Chemical Salts Update

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Inc.

ILMA 2015 Chemical Salt Testing Results

- In April, 2015, ILMA Board of Directors approved testing five chemical salts for dermal and eye irritation and acute toxicity testing.
 - Subsequently, per international protocols, OECD 437 “bovine corneal opacity and permeability” (BCOP) testing was added prior to any eye irritation tests being conducted
- Salts tested:
 - The TEA and DGA salts
 - AMP salt of tall oil fatty acids
 - The TEA and MEA salts of a short chain acid, isononanoic acid

| Salt | CAS Number | Estimated Substance Classification, Eye (BCOP) | Estimated Substance Classification, Skin Irritation | Estimated Acute Toxicity Classification |
|----------------------------|---------------|--|---|---|
| TEA + dibasic acids | 107871-2-94-3 | Not classified, not an eye irritant | Uncategorized, not a dermal irritant | GHS Acute Tox 5 or unclassified (OSHA) |
| DGA + dibasic acids | 292849-36-6 | Not classified, not an eye irritant | GHS Cat 3 mild dermal irritant or unclassified (OSHA) | GHS Acute Tox 5 or unclassified (OSHA) |
| AMP + tall oil fatty acids | 67701-21-7 | Mild eye irritant, GHS Eye Cat 2B | GHS Category 1C skin corrosive | GHS Acute Tox 5 or unclassified (OSHA) |
| TEA + isononanoic acid | 67801-51-8 | Moderate eye irritant, GHS Eye Cat 2A | Uncategorized, not a dermal irritant | GHS Acute Tox 5 or unclassified (OSHA) |
| MEA + isononanoic acid | 67801-50-7 | Severe eye irritant, GHS Eye Cat 1 | GHS Cat 3 mild dermal irritant or unclassified (OSHA) | GHS Acute Tox 5 or unclassified (OSHA) |

ILMA 2015 Chemical Salt Testing Results

Classification implications/listings in Section 3:

- If you formulate/had formulated with:
 - either the TEA or DGA salt, based on the testing results, neither salt nor CAS number would need to be listed. No classification implications.
 - and identify as a reaction product in Section 3, either the AMP salt of tall oil fatty acid or the MEA salt of isononanoic acid, and it is present at $\geq 3\%$, then a finished product (unless tested for eye and skin irritation) must be classified as Cat 1 corrosive (skin, AMP-tall oil) or Cat 1 corrosive eye (MEA-isononanoic). Other additivity rules apply.
 - and identify as a reaction product in Section 3 the TEA salt of isononanoic acid, and it is present at $\geq 10\%$, then a finished product must be classified as Cat 2 eye. Other additivity rules apply.
 - Many TEA producers/distributors do not classify TEA
- Possible solution: test *your finished* products for eye and skin irritation

Chemical Salts

- A possible substitute: an imported dibasic acid mixture
- Section 3 SDS composition:
 - Sebacic acid, CAS 111-20-6, 8 – 11%
 - Undecanedioic acid, CAS 1852-04-6, 47 – 52%
 - Dodecanedioic acid, CAS 693-23-2, 39 – 42%
 - Brassylic acid, CAS 505-52-2, < 2%
 - Tetradecanedioic acid, CAS 821-38-5, < 2%

Decanedioic, Undecanedioic, Dodecanedioic Acid/Alkanolamine CAS Numbers/Registrations

- Decanedioic acid, compd. with 2-(2-aminoethoxy)ethanol, 292601-82-2
 - TSCA, NDSL (Canada)
- Decanedioic acid, compd. with 2,2',2''-nitrilotris[ethanol], 70103-35-4
 - ECHA (EINECS, REACH pre-registered); China, Australia, New Zealand, Philippines
- Undecanedioic acid, compd. with 2,2',2''-nitrilotriethanol (1:2), 85030-07-5
 - ECHA (EINECS; REACH pre-registered); Philippines (PICCS))
- Dodecanedioic acid, compd. with 2,2',2''-nitrilotriethanol (1:2), 85030-08-6
 - ECHA (EINECS , REACH pre-registered); China, Philippines
- Dodecanedioic acid, compd. with 2-(2-aminoethoxy)ethanol, 292601-80-0
 - TSCA, NDSL (Canada)

Issues/Questions

- Should MWF Committee recommend that ILMA test TEA and DGA/decanedioic acid, TEA/undecanedioic acid and TEA and DGA/dodecanedioic acid salts for eye and skin irritation and acute toxicity?
- What about registration status of TEA and DGA/decanedioic acid and TEA and DGA/dodecanedioic acid salts in other jurisdictions currently now not registered, i.e., TSCA, Canada DSL, EU (REACH), China, Korea?
- Would creation of an F-TAP be advisable?
 - to develop needed acute toxicity testing info?
 - to submit registration dossiers to TSCA, Health Canada, ECHA, China, Korea (all through “Only Representative”)?
 - Potentially expensive
 - Still need ILMA Manufacturing Member or Members to file Notices of Commencement to place on inventories.
- If there is interest, a conference call can be arranged to discuss issues further.

Phosphorus Issue in the Great Lakes Region

John Burke

Houghton International

Chlorinated Paraffins Update

Recent Activities

- ILMA continued to work with the Coalition of other impacted trade associations including: the American Chemistry Council, the Chlorinated Paraffins Industry Association, the American Wire Producers Association, the Industrial Fasteners Institute, the Center for the Polyurethane Industry, the Auto Alliance, the Global Automakers, the Vinyl Institute, the Aerospace Industry Association, the Adhesives and Sealants Council, and the Motor and Equipment Manufacturers Association.

EPA Publishes Federal Register Notice

- As a result of joint efforts, EPA published a Federal Register Notice on December 23rd that contained the risk assessments and requested “new, available data” on MCCPs and LCCPs.
- While ILMA was appreciative that EPA published its FR Notice, the Association has been steadfast that the opportunity to comment on the risk assessments is in no way an appropriate or adequate substitute for independent scientific peer review of the Agency’s conclusions.

ILMA Comments

- ILMA submitted comments that focused primarily on the MWF formulator sections of EPA's risk assessment.
- It highlighted ILMA's 2015 survey results and urged the Agency to utilize the information already provided to EPA to develop more accurate, real-world risk scenarios.
- Further, it highlighted that the Agency's own rules under the Clean Water Act preclude discharges of oil and grease at the level EPA assumes for downstream users of MWFs.
- The comments also argued that the Agency should review MCCPs and LCCPs as existing chemicals as outlined in EPA's 2012 TSCA Work Plan.
- The comments can be viewed on ILMA's website.

Coalition Comments

- In addition to ILMA's individual comments, the Association was a signatory to another set of "Coalition comments" that addressed concerns with EPA's overall regulatory approach, offered alternative paths forward, and questioned EPA's conclusions that MCCPs and LCCPs are persistent, bioaccumulative, and toxic (PBT).
- Additionally, the comments echoed the need for independent scientific peer review and that MCCPs and LCCPs should be reviewed as existing substances.

Other Comments Submitted

- EPA received several other comments from other stakeholders. Overall, the Agency received a total of 27 comments.
- Other notable submissions, in addition to comments filed from the Coalition's members, came from the Department of Defense, Boeing, Dow Chemical, 3M, the Auto Alliance, Global Automakers, and the Aerospace Industries Association.
- All comments submitted can be viewed at [regulations.gov](https://www.regulations.gov)

Comments Were Submitted, Now What?

- Unfortunately, no guarantee how EPA will proceed since virtually this entire process is unprecedented.
- ILMA requested in the written comments an outline of next steps once the comment period closed.
- Additionally, CPIA and ILMA had a conversation with the Small Business Administration just before the Management Forum and updated the Office of Advocacy.

Congressional Letter Response

- The Members of Congress finally received a response from EPA regarding the letter that was sent in July 2015 just before the Management Forum.
- It is fairly generic and sticks primarily to EPA's talking points that MCCPs and LCCPs are new chemicals and are being reviewed as such.
- It did indicate that the Agency "anticipates making a final decision on the PMNs after consideration of new data."

Next Steps

- ILMA intends to work both independently and with the Coalition to push EPA to treat MCCPs and LCCPs as existing chemicals, to review the substances under its 2012 Work Plan, and to subject the Agency's conclusions to independent scientific peer review.

ILMA 2016 Management Forum Metalworking Fluids Committee

Mid-Chain Chlorinated Paraffin
Lactation Issue Update

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

vLCCP February 2016 SNUR

For ILMA Management Forum Meeting

Tom Kelley
Dover Chemical

vLCCP SNUR Overview

- Approval of 3 new vLCCP (C21+ chloroalkanes; <1% C<21) PMNs resulted in a tiered environmental fate testing program.
- This testing program was part of a TSCA Section 5 consent order (CO) that Trinity Manufacturing (Qualice LLC) signed with EPA in March 2013.
- The SNUR rule makes the requirements of the CO applicable to all manufacturers or importers of these substances.
- SNUR do not impose use restrictions.

vLCCP SNUR Substances

- **Alkanes, C21-34-branched and linear, chloro.**
CAS No. 1417900-96-9
- **Alkanes, C22-30-branched and linear, chloro.**
CAS No. 1401947-24-0
- **Alkanes, C24-28, chloro.**
CAS No. 1402738-52-6

vLCCP Testing Program

- 4 Phases, several phases have multiple parts.
- Testing has triggered deadlines based on volume or time from first manufacture.
 - The full testing program will take many years to complete.
- Testing requirements are for manufacturers or importers not for processors or users.
- vLCCP manufactures have already completed Phase 1 and are in the process of addressing Phase 2a and subsequent phases.

vLCCP Testing Program: Preliminary Phases

- Phase 1: Analysis for chain length and weight % Cl for all products under these substances.
 - Due before 1.2 million kg or 9 months since first manufacture/import.
- Phase 2a: Inherent biodegradation study – highly modified SCAS (OECD 302A) or Zahn Wellens (OECD 302B) on C_{21} , C_{26} , C_{product} average at 3 chlorination levels.
 - Due before 14.1 million kg or 4 yrs, 4 mos

vLCCP Testing Program: Future Phases

- Phase 2b: Bioaccumulation in sediment-dwelling benthic oligochaetes (OECD 315) and aerobic and anaerobic soil metabolism studies (OECD 307) on C_{21} , C_{26} , $C_{\text{product average}}$ at 3 chlorination levels.
 - Due before 59.1 million kg or 12 yrs, 8 mos.
- Phase 3: Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) or *Lumbriculus* Toxicity Test Using Spiked Sediment (OECD 225) on any parent substances in Phase 2b testing that are absorbed by the benthic oligochaetes
 - Due before 78.4 million kg or 15 yrs, 5 mos

vLCCP Testing Program: Future Phases (continued)

- Phase 3: Bioaccumulation in sediment-dwelling benthic oligochaetes (OECD 315) “for any of the degradation products in Phase 2a or 2b that are identified to potentially present an unreasonable risk or to further degrade to generate a substance of potential concern.”
 - Due before 78.4 million kg or 15 yrs, 5 mos
- Phase 4: Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) or *Lumbriculus* Toxicity Test Using Spiked Sediment (OECD 225) on any of the degradation substances in Phase 3 testing that are absorbed by the benthic oligochaetes.
 - Due before 86.1 million kg or 16 yrs, 5 mos

Conclusions

- vLCCP testing efforts are underway to address SNUR requirements.
 - Testing program is to address data gaps identified by EPA on vLCCP's and will take many years to complete.
- Testing requirements are for vLCCP manufacturers and importer, not users.
- SNUR does not impose use restrictions on vLCCP substances.

South Coast Air Quality Management District –
Proposed Rule 1430.1 – Control of Emissions
from Grinding Operations at Forging Facilities

Mike Pearce

Dodge Oil

SCAQMD Update

- General
 - Board of Governors now has Republican majority
 - Long term Executive Officer fired
 - New Executive Officer just hired
 - Long term effects unknown
- Rule 1144 (VOC)
 - No changes anticipated in foreseeable future

SCAQMD Update

- Proposed Rule 1410.1-Forging and Grinding
 - Control heavy metal particulate emissions from grinding and forging
 - Possibly also look at “toxics” from lubes
 - Eventually look at emissions from other grinding operations
 - First Working Group last October
 - Second meeting not yet scheduled
 - “Have been doing field visits”
 - Several other forgers are under scrutiny
 - “Not sure what impact, if any, new Executive Officer will have on process”

National Toxicology
Program's Study of the
Metalworking Fluid –
TRIM[®] VX

Background

- NTP peer review panels are technical scientific advisory bodies established on an “as needed” basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues.
- Initially NIOSH compiled and reviewed a list of 29 candidate fluids and then four fluids were selected for 90-day “subchronic” studies. Two fluids, CIMSTAR[®] 3800 and TRIM[®] VX, were selected for two-year studies.

NTP's Conclusions

- NTP completed its two-year study of TRIM[®] VX and published its draft technical report in late November 2015 that yielded the following draft conclusions:
 - Under the conditions of these 2-year inhalation studies, there was *equivocal evidence of carcinogenic activity** of TRIM VX in male Wistar Han rats based on the combined occurrences of alveolar/bronchiolar adenoma or carcinoma of the lung.
 - There was *equivocal evidence of carcinogenic activity* of TRIM VX in female Wistar Han rats based on the occurrences of alveolar/bronchiolar adenoma of the lung.
 - There was *clear evidence of carcinogenic activity* of TRIM VX in male B6C3F1/N mice based on the increased combined incidences of alveolar/bronchiolar adenoma or carcinoma of the lung.
 - There was *clear evidence of carcinogenic activity* of TRIM VX in female B6C3F1/N mice based on the increased combined incidences of alveolar/bronchiolar adenoma or carcinoma (primarily carcinoma) of the lung.

Peer Review Panel Meeting

- NTP convened its peer review panel on February 16th in North Carolina to review the draft technical report and conclusions.
- ILMA and Master submitted written comments to NTP in advance of the meeting and presented oral comments during the panel meeting as well.
 - Dr. John Howell and Dr. Wally Dalbey presented on ILMA's behalf and Dr. Steve Florio and Dr. Pat Beattie presented on Master's behalf.

ILMA's Comments

- ILMA's initial oral and written comments focused on several issues with NTP's study including:
 - That the batch of TRIM[®] VX tested was significantly beyond its recommended shelf life
 - The likely fungi and bacterial growth
 - The discrepancy in the measured component parts
 - Good Laboratory Practices and Storage Concerns

Master's Comments

- Master Chemical fully supports ILMA's written and oral comments, as well as post peer review follow-up comments
- Comments focused on product-specific issues:
 - Product intended to be diluted & used at 5-20%
 - Limited market niche product & has been discontinued
 - Lack of transparency within NTP process – data not provided upon request prior to or after the peer review
 - Concerns with NTP Good Lab Practices not being followed (temperature/storage & used beyond expiration date)
 - Significant differences in as-measured components compared to the product as produced

Peer Review Panel Vote

- ILMA, Master, and members of the peer review panel raised significant substantive issues with the manner in which the study was conducted and the resulting conclusions; however, the panel ultimately voted to adopt NTP's recommended conclusions.
- Thankfully, the panel instructed NTP's scientists to include limiting language that the fluid is unique and is NOT representative of MWFs as a class.

ILMA Follow-Up

- Subsequent to the panel meeting, ILMA submitted two more sets of written comments.
- The first addressed concerns with a poster abstract the lead scientists from NTP intended to present during the Society of Toxicology Meeting in March 2015.
- The second reiterated comments previously made by ILMA and highlighted oral statements from the peer review panel that questioned several aspects of the NTP's study and its conclusions.

ILMA Follow-Up

- ILMA intends to monitor the status of the NTP's final technical report that should be finalized within the next few months.
- It is the Association's hope that the final report will incorporate all of the instructions from the peer review panel and the recommendations from ILMA and Master.