What Have Our Regulatory Friends Been Up To?

• U.S. & Canada
  • TSCA Reset Rule
  • Chlorinated Paraffins
  • Phosphorus
  • Triazine & CMIT/MIT
  • Boric Acid
  • Prop 65
  • GHS

• Europe
  • REACh
  • BPR
  • CLP & Ecolabel

• Asia Pacific
TSCA Inventory Notification (Active-Inactive) Rule (i.e. TSCA Reset) https://www.epa.gov/tsca-inventory

• Requires EPA to designate chemicals on the TSCA inventory as either “active” or “inactive” in U.S. commerce

• EPA finalized a rule requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over the 10 years ending June 21, 2016

• Reporting period for manufacturers and importers ended February 7, 2018; the reporting period for processors ended October 5, 2018; submitters use NOA Form A through October 5, 2018 (Retrospective Reporting) and NOA Form B starting in November, 2018 (Future Reporting)

• The Inventory has been updated with all reported substances; inactive chemicals (not reported) will be officially “inactive” in February 2019
TSCA Inventory Notification (Active-Inactive) Rule (i.e. TSCA Reset) https://www.epa.gov/tsca-inventory

- Over 13,200 active substances are exempted and searchable by CAS # (non-confidential substances) or ACCesion # (confidential substances); PMN #s are also searchable

- The exemption list includes chemicals reported under the 2012 and 2016 Chemical Data Reporting (CDR) rule; a brief CAS # search showed common raw materials like triethanolamine and oleic, isononanoic and neodecanoic acids

- Substances excluded from reporting include those not on the TSCA inventory, mixtures and registered pesticides

- Reporting the planned use of a designated inactive substance on NOA Form B is required before re-introducing the material into commerce
Chlorinated Paraffins

- EPA published an update on August 17, 2018 regarding significant new use rules (SNURs) for the following chloroalkane derivatives when used as “additives in lubricants including metalworking fluids”:
  - $C_{22-30}$ (vLCCPs, CAS # 288260-42-4)
  - $C_{20-28}$ (vLCCPs, CAS # 2097144-43-7)
  - $C_{26}$ and $C_{28}$ (vLCCPs, CAS # 2097144-46-0 and 2097144-47-1)
  - $C_{20-24}$ (vLCCPs, CAS # 2097144-45-9)
  - $C_{18-20}$ (LCCPs, CAS # 106262-85-3)
  - $C_{18}$ (LCCPs, CAS # 2097144-48-2)
  - $C_{14-17}$ (MCCPs, CAS # 85535-85-9)
  - $C_{14-16}$ (MCCPs, CAS # 1372804-76-6)
  - $C_{14}$ (MCCPs, CAS # 198840-65-2)
Chlorinated Paraffins

• The Rule was due to be finalized September 18, but comments by 13 organizations/individuals have delayed it (MWF is not a “new use”)
  • Existing CP substances remain on the inventory and several are on the “active exempt” list
  • SNUR is in effect on C_{12-13} chloroalkanes

• EPA believes these substances are potentially persistent, bioaccumulative, and toxic (PBT) in part based on their physical/chemical properties and test data on structurally similar medium chain chlorinated paraffins (MCCP)

• The PMN submitter requesting modification of the order agreed to perform chronic aquatic and terrestrial toxicity and biodegradation testing as part of its appeal; test data are due to EPA by May, 2022

• Use of these substances in lubricants is allowed subject to TSCA 5(e) orders requiring the use of appropriate exposure controls; this could change in 2022 when EPA’s consent order allowing production ends
Phosphorus

• Phosphorus compounds can enter waterways through stormwater runoff and wastewater discharges, promoting growth of algae and cyanobacteria; non-point sources are estimated to contribute up to 89% of total phosphorus entering the western Great Lakes basin
  • Algae cause eutrophication (oxygen depletion) which harms aquatic organisms
  • Cyanobacteria produce microcystis (a liver toxin)

• P-based compounds are used in fertilizers and lubricant additives
  • Dissolved reactive phosphorus is the concern and it is possible not all phosphorus compounds used in lubricants contribute to algal growth
  • Nitrogen compounds can also contribute but are not currently a focus for EPA; industry might have to study their effects in the future (alkanolamines, etc.)
Phosphorus

- Algal blooms in western Lake Erie near Toledo have occurred three times since 2011 (most recently in 2017)
- The City of Toledo shut down its water supply for three days in 2014 due to microcystis contamination
  - Ohio governor John Kasich issued an executive order on July 11, 2018 prohibiting agricultural and industrial sources from increasing phosphorus loadings into eight distressed waterways emptying into the Maumee River Basin
- EPA’s action plan for Lake Erie (2018-2023) includes:
  - Reduce total P entering the western and central basins of Lake Erie from the U.S. and Canada by 40% (vs. 2008) mainly from sources in Ohio, Michigan and Indiana
  - Maintain cyanobacteria biomass at levels that do not pose a threat to human or ecosystem health in western Lake Erie
  - Agricultural (non-point) sources are the focus but total P discharges allowed by NPDES permits for prioritized wastewater (point) sources will be reduced
Algal Blooms in Western Lake Erie

Phosphorus Concentrations in the Great Lakes

Total Phosphorus

Spring 2013 (Lakes Ontario and Superior)
Spring 2014 (Lake Erie, Michigan, Huron and Georgian Bay)

Total Phosphorus Concentrations (µg/L) based on lake-wide cruises conducted by Environment and Climate Change Canada and the United States Environmental Protection Agency.
Triazine & CMIT/MIT

• There is nothing new from EPA (or Health Canada) regarding a proposal to limit triazine to 500 ppm active ingredient in diluted MWFs*
  • The primary (only?) North American triazine producer is waiting for EPA’s decision; their current label recommendation remains unchanged since 2014 (1,500 ppm as supplied/1178 ppm a.i.)
  • Some triazine marketers have added a 500 ppm maximum (a.i.) statement on their labels but also include higher dosage recommendations (which EPA obviously approved!)

• A Canadian proposal limiting CMIT/MIT to 8 ppm at dilution is pending review of dermal data by the Pest Management Regulatory Agency (due December 2018)

* EPA Reregistration Eligibility Decision (RED), 2008
Boron Compounds

• Nothing new to report on boric acid or boron-containing additives for lubricants in the U.S. or Canada; no limits currently exist

• REACh (in the EU) requires labeling of products containing more than 5.5% boric acid as potentially toxic for reproduction and boric acid is on the candidate list of Substances of Very High Concern (SVHC)
Proposition 65

• Prop 65 applies to chemicals the State of California believes cause cancer, birth defects or other reproductive harm

• Warnings are required 12 months after listing:
  • For example 2-mercaptobenzothiazole was listed on 11/10/17 so warnings are required by 11/10/18

• Amendments of August 30, 2018 concern clear and reasonable warnings for products containing listed chemicals including:
  • Statement that product may result in exposure to listed chemicals
  • Listing the exact name of product or identifying information (UPC, etc.)
  • Posting of all warning materials (labels, warning language for products sold on the internet, etc.)
GHS

• EPA is updating the Hazard Communication Standard (HCS) to maintain alignment with GHS which could require updates to hazard classifications, label elements and SDSs; the final rule is expected in February, 2019

• Canada’s Workplace Hazardous Materials Information System (WHMIS) is also being updated and is expected to align with HCS due to a regulatory cooperation agreement signed by the U.S. and Canada in June, 2018

• U.S. and Canada are allowing concentration ranges on SDSs to avoid disclosing trade secret compositions, but classification must reflect the actual composition

• All manufacturers, importers and distributors must by December 1, 2018 comply with Canada’s WHMIS requirements finalized in 2015
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REACCH

• 32,515 registrations for 10,708 substances in the lowest volume band have been submitted (1-100 metric tons)
  • Deadline was May 31; only 1% of submissions were rejected (incomplete)
  • Pending registrations should be completed by May, 2019
  • Enforcement by ECHA and the EU Customs Union will begin in 2019

• Companies sourcing raw materials from the EU or exporting formulated products there should:
  • Confirm registrations with suppliers or search the European Chemicals Agency (ECHA) website under “Information on Chemicals“ at www.echa.europa.eu
  • Confirm their usage is covered on supplier SDSs; if not ask the supplier to update the registration and SDS
REACH

• ECHA has been requested by early 2019 to:
  • Prepare a restriction proposal for the use of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses
  • Gather existing information to assess potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses
  • Demonstrate whether and what action on formaldehyde and formaldehyde releasers is necessary on a Union-wide basis
Biocidal Products Regulation (BPR)

- Effective December 2018 the following biocides for MWFs will require Category 1B carcinogen labels:
  - N,N'-methylenebismorpholine (MBM)
  - 3,3′-methylene-bis[5-methylloxazolidine] (MBO)
  - α,α′,α″-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol (HPT)
- Similar labeling could be required for triazine and other formaldehyde condensates in 2022
Classification, Labeling & Packaging Regulation (CLP)

- EU regulation based on the UN’s Globally Harmonized System (GHS)
- Requires formulators supplying products to the EU to:
  - Classify, label and package in accordance with Titles II, III and IV respectively
  - Re-evaluate classifications and labeling if/when updated technical information is available which could change them
- Substances of Very High Concern (SVHC) Authorization:
  - Boric acid has been on the list since 2015 (reproductive toxicant)
  - Disodium octaborate was added in June 2018 (reproductive toxicant)
Ecolabel for Lubricants

• Current regulation states: "the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction"

• A proposed revision was finalized in July 2018 and a vote in Parliament is scheduled for November 2018
  • Includes information on potential lubricant impact on the environment and human health
  • Additional hazard statements are proposed including "Acute Tox Cat. 4"; Ecolabel not allowed if Cat. 4 substance present above 0.5% in the finished lubricant
  • Packaging must contain at least 25% recycled material
  • Eliminates requirement for minimum quantity of biobased ingredients unless promoted as "Bio"
## Additional Hazard Statements Proposed (partial list)

<table>
<thead>
<tr>
<th>Hazard statement according to the CLP Regulation</th>
<th>Limit Value [%] for substances(^{18}) in the final product(^{19} \ast)</th>
<th>Limit Value [%] for impurities in the substance(^{20})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lact.</td>
<td>H362</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 1</td>
<td>H300 (oral)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 1</td>
<td>H310 (dermal)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 1</td>
<td>H330 (inhal.)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 2</td>
<td>H300 (oral)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 2</td>
<td>H310 (dermal)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 2</td>
<td>H330 (inhal.)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 3</td>
<td>H301 (oral)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 3</td>
<td>H311 (dermal)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 3</td>
<td>H331 (inhal.)</td>
<td>0</td>
</tr>
<tr>
<td>Acute Tox. 4</td>
<td>H302 (oral)</td>
<td>0.5 x Classification limit for Acute Tox. 4</td>
</tr>
<tr>
<td>Acute Tox. 4</td>
<td>H312 (dermal)</td>
<td>0.5 x Classification limit for Acute Tox. 4</td>
</tr>
<tr>
<td>Acute Tox. 4</td>
<td>H332 (inhal.)</td>
<td>0.5 x Classification limit for Acute Tox. 4</td>
</tr>
</tbody>
</table>
Ecolabel for Lubricants

• Lubricant Substance Classification (LuSC) is a list of substances and brands assessed with regard to Ecolabel requirements; the list is published at ec.europa.eu/environment/ecolabel
  • Formulating with ingredients on LuSC simplifies the application process
  • Roughly 34 of 155 substances and brands on the LuSC would be limited to 0.01% in the final lubricant
  • Ingredients which are mixtures have not been fully assessed due to lack of data from the manufacturers
### LuSC: Examples of Non-Branded Substances

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS no</th>
<th>EINECS no</th>
<th>Biodegradability</th>
<th>Aquatic toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatty acids, coco, Me esters</td>
<td>61788-59-8</td>
<td>262-988-1</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Cellulose Pulp</td>
<td>65996-61-4</td>
<td>265-995-8</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Glycerides, C16-18 and C18-unsatd. This substance is identified by SDA Substance Name: C16-C18 and C18 unsaturated triacyl glyceride and SDA Reporting Number: 11-001-00</td>
<td>67701-30-8</td>
<td>266-948-4</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Glycerides C10-18</td>
<td>85665-33-4</td>
<td>288-123-8</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Palmitic acid, pure C16H32O2</td>
<td>57-10-3</td>
<td>200-312-9</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Stearic acid, pure C18H36O2</td>
<td>57-11-4</td>
<td>200-313-4</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Oleic acid, pure C18H34O2</td>
<td>112-80-1</td>
<td>204-007-1</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Lauric acid, pure C12H24O2</td>
<td>143-07-7</td>
<td>205-582-1</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Potassium oleate C18H34O2K</td>
<td>143-18-0</td>
<td>205-590-5</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Sodium stearate, pure C18H36O2.Na</td>
<td>822-16-2</td>
<td>212-490-5</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Limestone A noncombustible solid characteristic of sedimentary rock. It consists primarily of calcium carbonate</td>
<td>1317-65-3</td>
<td>215-279-6</td>
<td>Not biodegradable, Not bioaccumulative (C)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Sunflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, and oleic. (Helianthus annuus, Compositae)</td>
<td>8001-21-6</td>
<td>232-273-9</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
<tr>
<td>Soybean oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic (Soja hispida, Leguminosae)</td>
<td>8001-22-7</td>
<td>232-274-4</td>
<td>Ultimately (A)</td>
<td>Not toxic (D)</td>
</tr>
</tbody>
</table>
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- REACH-like regulations are in force in China, Korea, Japan and Thailand
  - Korea requires all substances on its inventory (KECI) produced or imported above 1 MT/year to be preregistered by June 30, 2019 (*no registration = no market*)
  - Korea BPR becomes effective in September 2019 with similar requirements to the European BPR; it is not certain if EU dossiers will be acceptable in Korea
  - China’s “Blue Sky” initiative resulted in temporary production stoppage of the precursor to benzisothiazolinone (BIT); supply disruptions could ease in Q1, 2019

- Regulatory information is difficult to find without a local presence or a fee-based intermediary like Chemical Inspection & Regulation Service:
  - **CIRS China:** 11F Building 1, Dongguan Hi-Tech Park, 288 Qiuyi Road, Binjiang District, Hangzhou 310052, China
    Tel: +86-571 8720 6555 | Fax: +86-571 8720 6533
    Email: service@circs-reach.com
Helpful Resources*

• **Chemical Watch** [www.chemicalwatch.com](http://www.chemicalwatch.com): Fee-based access to global regulation news including industrial chemicals and biocides

• **European Chemicals Agency (ECHA):** Covers REACh, CLP, Biocidal Products Regulation (BPR) and Prior Informed Consent regulation (PIC) [www.echa.europa.eu](http://www.echa.europa.eu)

• **OSHA Hazard Communication:** GHS requirements for SDSs and labeling [http://www.osha.gov/dsg/hazcom/](http://www.osha.gov/dsg/hazcom/)

• **U.S. Biocide Regulations (FIFRA):** [https://www.epa.gov/pesticides/antimicrobial-pesticides](https://www.epa.gov/pesticides/antimicrobial-pesticides)

• **EPA Biocide Label Approvals:** [http://npirspublic.ceris.purdue.edu](http://npirspublic.ceris.purdue.edu)

• **Canadian Regulations Governing Chemicals:** Inventory updates and links to antimicrobial information and many others [https://www.canada.ca/en/health-canada/services/chemical-substances/canada-approach-chemicals](https://www.canada.ca/en/health-canada/services/chemical-substances/canada-approach-chemicals)


* If link doesn’t work, copy and paste address into browser
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