TSCA Nomenclature– Friend and Foe

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Thomas C. Berger

- Thomas (Tom) Berger assists clients in bringing forth new products and maintaining the ability to market them cost-effectively using an interdisciplinary approach that combines law and science, emphasizing emerging technologies in the industrial chemicals area.

- Tom helps clients navigate the Toxic Substances Control Act (TSCA) premanufacture notification (PMN) review process and negotiates the terms and conditions of TSCA section 5(e) orders and significant new use rules (SNUR). He also counsels clients on US Environmental Protection Agency (EPA) enforcement matters and assists companies in preparing for Agency inspections, responding to information requests and subpoenas, and defending enforcement actions. Tom is a recognized leader in designing and conducting extensive voluntary TSCA compliance audits (often as part of corporate mergers and acquisitions) and assisting clients in managing liability under EPA's “Audit Policy” and other available penalty mitigation policies.

Matthew B. Harney, Ph.D.

- Matthew (Matt) Harney, Ph.D., specializes in chemical and regulatory issues. He works closely with attorneys to help clients focused on the commercialization of new chemicals and product compliance under the U.S. Toxic Substances Control Act (TSCA), EU Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), the Canadian Environmental Protection Act 1999 (CEPA), and other chemical control systems around the world.
- Matt conducts several large-scale TSCA compliance audits for clients, frequently covering thousands of product formulations, leading to the identification, disclosure, and correction of dozens of compliance issues, saving clients millions of dollars in liability. He has also prepared dozens of premanufacture notices (PMNs) and has worked with the U.S. Environmental Protection Agency (EPA) on many cases to ensure that any regulation of a substance is as least burdensome as possible, allowing clients to bring new products to market without overly restrictive conditions.

Nomenclature Specificity, Importance

- Under TSCA, a substance's name (and CASRN) is critical to everything
  - Forms entire basis for TSCA status of substance
    - Inventory status, SNUR applicability, §4, 6, 8 rules, etc.
  - Envision if you will a parallel, equally important set of rules
- At least for a "Class 1" substance, "The chemical name should contain all of the information known about the details of the structure and should permit the drawing of an unambiguous chemical structural diagram."
  - Where exact identity is not known or may be variable, one must describe substance as completely as possible
- General name / Inventory listing does not cover less precise substance and *vice versa*
  - TSCA Inventory listings are not categories!

CAS-IES

- CAS Inventory Expert Service (IES)
  - Derive unique, fully systematic name using rigorous, comprehensive nomenclature rules
  - Ensures a single chemical description for each unique substance
- "Author Emphasis"
  - Manufacturer/importer responsible for ensuring chemical name accurately identifies substance
  - Provides limited latitude in naming substances

TSCA Inventory, Compilation

- Section 8(b) requires EPA to "compile, keep current and publish a list of each chemical substance which is manufactured or processed in the United States"
  - "Inventory" first issued in 1979 ("initial Inventory"), amended and reissued several times, now on EPA website and updated every year or so
    - Currently contains ~87,000 substances
- Initial Inventory compiled from reports submitted by industry for substances in commerce from 1/1/1975 to 6/30/1979
  - Depending on substance, certain forms, e.g., a "C form," used
    - "C forms" used for substances with no known CASRN and not on "Candidate List," or to assert chemical identity CBI
- Completed reporting forms contained little more than submitter identity, whether manufactured *vs.* imported, and information on chemical identity

Inventory Correction Policy

- On July 29, 1980, EPA issued procedures for correcting Inventory reporting errors
  - Corrections must fall into one of three categories and be adequately documented
- Corrections described in fourth subsection of first category were most common
  - First category included:
    - Corrections of typographical or transcriptional errors
    - Refinement of identity of reported substance, e.g., specifying location of substituent originally described as unspecified or unknown
    - Identification of previously unidentified substance produced with material already reported (e.g., isomer)
    - Discovery that substance different from reported, e.g., determining that substance reported as "A" is "C," or that substance reported as "D" is mixture of "E" and "F"
- <u>If/when correction request granted, corrected substance retroactively added to Inventory</u>

February 2022 Policy Revocation

- Feb. 25, 2022 (87 FR 10,781), EPA (abruptly) revokes 1980 policy
  - EPA:
    - Companies have had ample opportunity to correct
    - Passage of time has made provision of substantiating records difficult
    - Possibility of ineligible correction requests being processed(?)
- Companies only had until Apr. 26, 2022 to submit requests
  - Incomplete submissions “will be rejected”
  - PMN (or LVE) corrections cannot be made (after review period expires)
- After April 26, 2022, must submit PMN rather than remain on the market
- EPA reserved right to initiate corrections at its discretion

Revocation Policy Issues/Ramifications

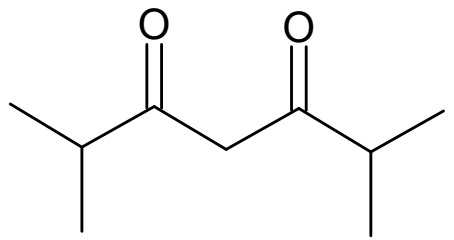
- No notice/comment, reliance
- No apparent consideration of alternatives (e.g., monomer acid, activated phosphor approach)
- Insufficient time to prepare/submit requests
- Exclusion of PMN substances
  - What if PMN substance made from corrected initial Inventory substance?
- Process should be improved (perhaps even streamlined), not abolished
- Why 2022…?
  - Could have been part of reset

Benefits of Nomenclature Ambiguity

- If you manufacture or import a substance, you are “strictly” liable (i.e., liable without regard for knowledge or intent) for its name, and, therefore, its TSCA classification
- However, if nomenclature ambiguity exists:
  - Likely can avoid knowing or willful TSCA violations
  - Likely can process/distribute/use existing stocks
  - Likely can avoid triggering 21-day reporting clock under EPA “Audit Policy”
- Correct/proper name might have “better” TSCA status
  - We have seen this hundreds of times

Classes of Substances

- Class 1 substance:
  - A substance that can be represented by a definite chemical structural diagram
  - *e.g., 3,5-Heptanedione, 2,6-dimethyl-* (18362-64-6)



- Class 2 substance:
  - Complex, difficult to characterize, and variable (a.k.a. “UVCB”)
  - *e.g., Tall-oil pitch* (8016-81-7)

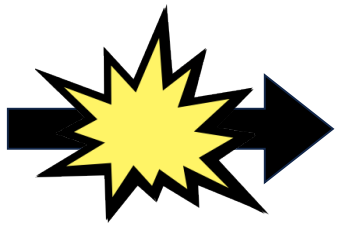
Class 2 Nomenclature

- Some Class 2 substances are named according to their raw materials or manufacturing process
  - *Formaldehyde, reaction products with acetone and ammonia* (68411-65-4)
  - *Canola oil, hydrogenated* (226993-69-7)
- **Limitations:** the substances can **only** be made using the raw materials and processes identified in the chemical name
- **Advantages:** reaction product composition is not defined, can be manipulated by relative amounts of reactants or other reaction conditions

Alkyl-Range Substances (1)

- Many substances are identified with a range of alkyl lengths denoted "C_{x-y}"
  - Example: *Alcohols, C_{12-15}* (63393-82-8)
- **Limitations:**
  - Must contain C_x, C_y, and very alkyl chain length between x and y; or only even-numbered chains **<u>if</u>** both x and y are even numbers
  - Alkyl ranges between raw materials and products must be the same

Amides, C_{8-18}



Amides, C_{8-18}, N,N-bis(hydroxyethyl)

Alkyl-Range Substances (2)

- **Advantages:**
  - Relative amounts of each alkyl chain length can vary; no minimum amount of any particular chain length required to justify its inclusion
  - C_{x-y} range of reaction products can be manipulated by combining raw materials of overlapping ranges

Mixed-Metal Oxides (1)

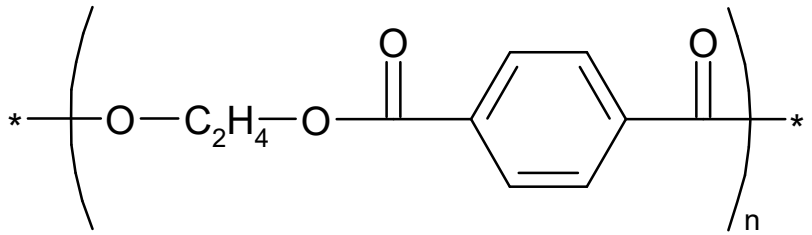
- Representation of mixed metal oxides (MMOs) for TSCA purposes is confusing due to inconsistent guidance
  - **EPA (1977):** MMOs should be reported for Initial TSCA Inventory as mixtures of individual metal oxides
  - **EPA (1995):** MMOs should be represented on TSCA Inventory as mixtures of individual metal oxides
  - **EPA (2022):** it has always been our position that MMOs are specific chemical substances subject to PMN reporting requirements

Mixed-Metal Oxides (2)

- Chemical names for MMOs generally follow the "*Metal A metal b metal c oxide*" format
  - Example: *Iron nickel zinc oxide* (12645-50-0)
- **Limitations:** all of the identified metals must be present in the substance; no metals other than those identified can be present (except as impurities)
- **Advantages:** relative amounts of identified metals can vary to any extent
  - Unless specified in the chemical name, *e.g.*, *Barium strontium titanium oxide (BaSrTi2O6)* (12430-73-8)

Polymer Nomenclature (1)

- Monomer-Based Nomenclature
  - *1,4-Benzenedicarboxylic acid, polymer with 1,2-ethanediol* (9003-68-3)
  - *1,4-Benzenedicarboxylic acid, 1,4-dimethyl ester, polymer with 1,2-ethanediol* (9003-71-8)
- Structural Repeat-Unit (SRU) Nomenclature
  - *Poly(oxy-1,2-ethanediyloxycarbonyl-1,4-phenylenecarbonyl)* (25038-59-9)



polyethylene terephthalate
(PET)

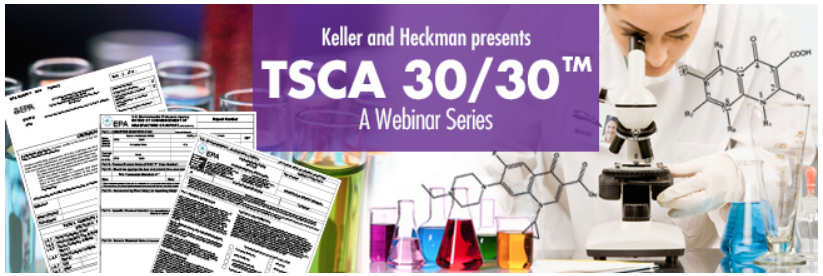
Polymer Nomenclature (2)

- Monomer-Based Nomenclature
  - **Limitation:** polymer must be made from exact monomers specified in the chemical name, even if different monomers could have given same structure
  - **Advantage:** flexibility in relative amounts of monomers, polymer structure, and molecular weight
- Structural Repeat-Unit (SRU) Nomenclature
  - **Limitation:** polymer must match exact structure described in chemical name
  - **Advantage:** flexibility in exact monomers and molecular weight

Polymer "Two-Percent Rule"

- Monomers and other reactants used at ≤ two weight percent may optionally be omitted from a polymer name
- **Advantages:**
  - Monomers/reactants not included in polymer name can be present up to two weight percent
  - Monomers/reactants in polymer name must be included at some level greater than zero, with no minimum amount
- **Limitation:** monomer weight-percent calculations under TSCA can be counterintuitive, may exceed two percent inadvertently

Please join us at 1:00 PM Eastern U.S.
Wednesday, April 19, 2023
www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, May 10, 2023
www.khlaw.com/TSCA-3030

Please join us at 10:00 AM Eastern U.S.
Tuesday, June 21, 2023
www.khlaw.com/REACH-3030

Thank you

Any questions?

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