The New Chemicals Program Under Section 5 of TSCA

Topic: "Incomplete Notices"
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EPA's Process for Screening Notices for Completeness

Prescreening

Screening after Day 1

Disposition

Prescreening

- Occurs before Day 1, as soon as notice is received
- Quick review for errors, omissions, inconsistencies or ambiguities
- Focuses mostly on information on chemical identity of reported substance
- ~27% of notices are declared incomplete at the Prescreen stage
- Time limitations preclude comprehensive screening at this stage

Screening After Day 1

Comprehensive screening performed as part of formal review process

Catches specific errors not found at Prescreening stage

~ 5% of the notices are deemed incomplete at this stage

Disposition

- Notices declared incomplete during Prescreen will be mailed back to submitters along with check list of problems identified
- After Prescreen, submitters will only receive a letter with an accompanying check list
- EPA will not further review such notices
- Corrected notices must be resubmitted in their entirety and a new case number will be assigned
- IMD will address incomplete notice user fees

Common Errors in Notices

- Wrong chemical name
- Inconsistencies
- Incorrect/insufficient structural diagrams
- Page 5 not filled out for polymers or oligomers
- Missing identification for Class 2 chemical precursor(s) or polymer monomer(s)

Common Errors (con't)

- Incomplete manufacturing information
- Method 1 not used for consolidated PMNs
- Support letter not provided for a reactant or PMN substance not fully identified
- Incorrect molecular formula
- Insufficient or deceptive generic chemical name
- Failure to make all needed corrections

Wrong Chemical Name

- Incorrect CA (9th CI) name consistent with EPA's TSCA Inventory nomenclature policy
 - Synonyms
 - Common names
 - Trade names
 - IUPAC names
- Not all CA names are acceptable
 - Hydrates
 - Many SRU polymer names
 - Graft/block polymer names will not be used

Inconsistencies

- EPA unable to determine which part of submitted information is correct
- May involve two or more types of chemical identity-related information
 - Chemical name
 - CAS number
 - Molecular formula
 - Structural diagram
 - *Identity of immediate precursor(s) or monomer(s)*
 - Manufacturing process information

Inconsistencies (con't)

- Inconsistencies will cause notices (even those using Method 1) to be deemed incomplete
- Do not provide to CAS (or anyone else, e.g., a consultant) any information different than that which will be submitted to EPA present the same information in the same manner
- Errors may involve use of the "two percent rule" for polymers

Incorrect/Insufficient Structural Diagram(s)

- Incomplete/incorrect Class 1 substance structure
 Incorrect representative/partial structure
 diagram for Class 2 substance or polymer does
 not contain all details reasonably ascertainable
- Allowed abbreviations:

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Me(methyl)Bu(butyl)Et(ethyl)i-Bu(iso-butyl)Pr(propyl)s-Bu(sec-butyl)i-Pr(iso-propyl)t-Bu(tert-butyl)Ph (phenyl)
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Failure to Fill Out Page 5 for Polymers or Oligomers

- Page 5 is <u>required</u> to be filled out for all substances containing or based on
 - a polymer, or
 - oligomer of variable molecular weight
- "Typical composition" values or ranges for reactants must be > 0%

Missing Class 2 Chemical Precursor or Polymer Monomer Identification

- Missing specific chemical name and/or available CAS number for immediate precursor or monomer
- Free-radical initiators or chain-transfer agents used <u>must be listed as reactants</u>
- 9th CI CAS nomenclature <u>not</u> needed for listing immediate precursors or monomers
 - however the chemical name used <u>must</u> be sufficiently specific

Incomplete Manufacturing Information

- Manufacturing process information (i.e., specific name (and/or CAS number) and weight) missing for each starting material
- All non-reactants must be included
 - catalysts
 - solvents
 - other

Method 1 Not Used for Consolidated PMNs

Submitter did not use Method 1 to obtain correct chemical names for all substances reported in consolidated PMNs

Support Letter Not Provided for Reactants or PMN Substances Not Fully Identified

- Applies in cases in which a supplier withholds full identification of a substance
- If a foreign supplier withholds full identity of the PMN substance to be imported, the supplier must provide a "Support Letter" with the correct CA (9th CI) name and all other identity information required for that type of substance
- If a "Support Letter" is needed to identify a reactant, the CA (9thCI) nomenclature requirement for the PMN substance is waived

Remaining Common Errors

- Incorrect Molecular Formula
- Insufficient or Deceptive Generic Name Provided
- Failure to Make All Needed Corrections

Remember that submitted information must be <u>correct</u> as well as <u>complete</u>!!

Error Screening "Check List"

- Will be filled out and attached to an incomplete notice when EPA mails it back to the submitter
- A check mark will indicate the general nature of each error, omission, inconsistency or ambiguity
- EPA chemists may add handwritten notes elaborating on the nature of the identified problem
- The "Check List" is not intended to explain exactly how to "fix" the notice or develop the correct 9th CI CAS name(s)

EPA Recommendations

When using Method 1:

- Fill out pages 4 or 5, 6 and 8 of EPA's PMN form to provide complete chemical identity information to CAS
- Be sure to attach the CAS-developed nomenclature report to the PMN
- Look for corrections on the structure diagram, molecular formula, monomer/reactant identities that CAS (or other source) may have made on your order

EPA Recommendations (con't)

Before submitting a notice to EPA, have a person knowledgeable in chemistry proofread and fully review the notice for typos, accuracy, and consistency

■ Do not ask CAS any questions about EPA's TSCA Inventory nomenclature policy or PMN reporting policies/rules