Can More Be Less?

Assessing Data Available from the C&L Inventory and REACH Websites

SOCIETY FOR CHEMICAL HAZARD COMMUNICATION

CHARLESTON, SC MARCH 25, 2014

Today's Discussion

- Using the C & L Inventory database
- What is "reliable" data? Can we assess quality easily?
- Reviewing the REACH datasets
- Implications to GHS classifications

Using the C&L Inventory Database

- First: What is the C & L Inventory?
  - Classification and labeling information
    - Notified under REACH Regulation, and
    - Notified under CLP Regulation, and
    - Annex VI of CLP (legally binding harmonized classifications)
  - Tool for hazard communication
  - Reveals the differences in the classification and labelling of the same substance applied by different suppliers
  - http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

Using the C&L Inventory Database

- Second: Who are the notifiers?
  - Classifications in REACH registration dossiers are automatically placed in the database and marked with a green check mark
  - Any manufacturer or importer who places on the market a substance that meets the hazard criteria in the CLP shall notify the Agency (ECHA).
    - Substances placed on the market on or after 1 Dec. 2010 within 1 month
    - Includes substances in mixtures

Using the C&L Inventory Database

- Third: What is NOT in the public database?
  - Contact details of notifier or registrant
  - No information on impurities or additives
  - Substances claimed confidential by the submitter/notifier

Using the C&L Inventory Database

Information submitted to ECHA	Information available in database
Identity of the notifier	X
Identity of the substance, including impurities or other information	EINECS name, EC#, CAS#
Classification of the substance	(as determined by the submitter)
Indication of reason for empty class	Lack of data or does not meet criteria
Specific concentration limits or M-factors	(recommendations by submitter)
Label elements	

Using the C&L Inventory Database

- Fourth: Who verifies the classifications submitted?
  - No one. The information published in the C&L Inventory is not reviewed or verified by ECHA or any other authority.
  - ECHA does not guarantee the correctness of the information.
  - ECHA cannot make a change to any element in the database without a prior notice.

Using the C&L Inventory Database

- Fifth. Why are there differing classifications for the “same” substance?
  - Some may be due to technical errors made during the notification process
    - Not assigning all labeling elements correctly
    - Slight differences in classification such as route of entry or no route indicated
  - Different interpretations of scientific studies used for classification
  - Different access to data
  - Different identified properties and/or impurities **J**

Using the C&L Inventory Database

- Sixth. Will the different classifications for “single” substances be “harmonized”?
  - That is the intent of the inventory
  - It is essentially the responsibility of the registrant(s) and notifier(s) to make every effort to come to an agreed entry
  - Not much movement or incentive to take this on, so it may be a very long time
    - There are more than 6 million notifications for more than 110,000 substances

Using the C&L Inventory Database

- Seventh: Can I download the results of a search?
  - No. Viewing is the only option.
- Eighth: Can I use the search results from the C&L Inventory database?
  - Reproduction or further distribution of search results may be subject to copyright protections.

Using the C&L Inventory Database

- Ninth: How can this information be useful?
  - Check results against your own classification. You may want to see what the majority of notifiers have concluded (majority may not always be right).
  - Confirm mandatory harmonized classification and labeling elements from Annex VI.
    - If there is a hazard class not included for which you have information or data, obliged to add to your classification but can't change the hazards presented.
  - Might use toxicity category to assign an ATE value or in the absence of a category, look to see if due to "lack of data" or "conclusive but does not meet criteria"

Using the C&L Inventory Database

- Tenth: What should I be aware of as I review the information in the database?
  - Every substance on the market on 1 Dec 2010 had to be notified within 30 days
  - Not all notifiers were/are skilled in the "art" of GHS
  - Impurities and additives may account for different classifications but no information provided
  - Aggregation of notifiers is done by computer
  - CLP criteria has been updated to GHS 4th edition in the interim since first notifications
  - More may be less....

What is Reliable Data?

- Toxicologists have developed some best practices for evaluating data quality and reliability.
  - Standards of quality often driven by programs like REACH, TSCA, pharmaceutical and pesticide programs.
  - Established test protocols, and good laboratory practices (GLP)
- Datasets for “existing” chemicals may have been developed over decades by a wide range of methods
  - EPA-HPV, OECD-HPV and REACH have adopted Klimish scoring system

What is Reliable Data?

- Klimish established system for evaluation of data quality for hazard and risk assessments
  - Reliability – evaluating inherent quality of a test report/publication
  - Relevance – extent to which data/tests are appropriate for a particular hazard
  - Adequacy – usefulness of the data

What is Reliable Data?

- Reliability scores
  - 1= reliable without restriction
  - 2= reliable with restrictions
  - 3= not reliable
  - 4= not assignable
- A short justification is included with the score
- Scoring does not exclude all unreliable data since it may be used as supporting other results

Reviewing the REACH Datasets

- First: What does the REACH registration information represent?
  - As part of registration, companies must compile all available data and information on the substance, evaluate it and provide a classification and label.
    - 2010 registration deadline was for companies manufacturing/importing ≥1000 tons/year
    - 2013 registration deadline was for companies manufacturing/importing ≥100 tons/year
    - 2018 registration deadline is for companies manufacturing/importing ≥1 tons/year
  - http://echa.europa.eu/information-on-chemicals/registered-substances

Reviewing the REACH Datasets

- Second: Who are the notifiers?
  - Manufacturers and importers in the EU
  - Foreign suppliers can be represented by an EU "Only Representative" who "complies" on their behalf
  - Notifiers of a single substance are grouped together to compile and submit data jointly. These groups are called SIEFs
  - A company can opt out of a SIEF so you may see a registered chemical that is both a "Joint Submission" and an "Individual Submission"
  - The notifying companies are identified in the publically available REACH registration data

Reviewing the REACH Datasets

- Third: Who verifies the information shown in the dataset?
  - No one. Neither ECHA nor any other authority verifies the information before its dissemination
  - Companies in preparing the registration were obliged to evaluate the data they compiled
  - Viewers of the data can see the Klimish score assigned to particular data and the “reason” for the score

Reviewing the REACH Datasets

- Fourth: Is the substance identity along with any applicable impurities provided?
  - Yes.
  - This may result in multiple identities and therefore multiple classifications for the substance **J**
- Fifth: What if the substance already had a harmonized classification?
  - Some provided the harmonized classification even if the assemble data did not coincide
  - Some provided the harmonized classification and a “self-classification”

- Classification and Labelling
  - GHS
    - Low boiling point naphtha (Annex VI)
    - CLP 1. Low boiling point naphtha, (flashpoint < 23°C initial boiling point ≤ 35°C, benzene ≥ 0.1%, n-hexane ≥ 3%, OR toluene ≥ 3%, OR toluene ≥ 3% and n-hexane ≥ 3%)
    - CLP 2. Low boiling point naphtha, (flashpoint < 23°C initial boiling point ≤ 35°C, benzene < 0.1%, n-hexane ≥ 3% OR toluene ≥ 3%, OR toluene ≥ 3% and n-hexane ≥ 3%)
    - CLP 3. Low boiling point naphtha, (flashpoint < 23°C initial boiling point ≤ 35°C, benzene ≥ 0.1%, toluene < 3% and n-hexane < 3%)
    - CLP 4. Low boiling point naphtha, (flashpoint < 23°C initial boiling point ≤ 35°C, benzene < 0.1%, toluene <3% and n-hexane < 3%)
    - CLP 5. Low boiling point naphtha, (flashpoint < 23°C and initial boiling point > 35°C, benzene ≥

	known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
Effects via lactation	conclusive but not sufficient for classification

Germ cell mutagenicity

Germ cell mutagenicity	conclusive but not sufficient for classification

Carcinogenicity

Carcinogenicity	conclusive but not sufficient for classification

Specific target organ toxicity - single

Specific target organ toxicity - single	STOT Single Exp. 3 H336: May cause drowsiness or dizziness. Affected organs: Central nervous system Route of exposure: Inhalation

Specific target organ toxicity - repeated

Specific target organ toxicity - repeated	conclusive but not sufficient for classification

Environmental hazards

Hazardous to the aquatic environment (acute/short-term)	conclusive but not sufficient for classification
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 2 H411: Toxic to aquatic life with long lasting effects.
hazardous to the ozone layer	conclusive but not sufficient for classification

Labelling

Signal word	Danger

Hazard pictogram

Reviewing the REACH Datasets

- Sixth: Can I download the results presented?
  - No. Viewing is the only option.
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Reviewing the REACH Datasets

- Eighth: How can this information be useful?
  - In most cases, multiple studies are presented ranking them in as key studies, supporting studies (weight of evidence) as well as including "alternate" results.
  - Assigns Klimish scores and reason for scoring which may be useful when compared to your "information"
    - Think about an LD50 your SDS has used indefinitely that comes up as unreliable…
    - Think about your classification as a skin irritant when the studies compiled and reported show dermal studies with no irritation…
    - Think about inhalation study results which you may have (LC50 result) for which you don't know if mist or vapor…
  - May provide greater confidence in your own classification
  - More may be less….

Implications to GHS Classifications

- We have a wealth of information that has flooded our potential resources for toxicity and ecotoxicity data
- We can't use this information without potential copyright infringement
- We need to thoroughly understand the sources of the information and reasons for the wide range of comparative results

Implications to GHS Classifications

- We need to take the time to dig deeper on every substance to know whether the absence of a particular hazard class is due to lack of data or the data indicates it does not meet the criteria
- Updates will occur on these (C&L Inventory and REACH) so they need to be reviewed frequently and assessed as to how you can (rightfully) use the information