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# Technical and Logistical Challenges in Implementing the Globally (Un)Harmonized System (GHS) of Classification and Labelling of Chemicals

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## ABSTRACT

In 2003, the United Nations (UN) published the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), a set of "harmonized criteria" for identifying chemical hazards and requirements for labeling and safety data sheets (SDSs). To date, 72 countries have incorporated or are in the process of incorporating GHS into their regulatory frameworks. Because of its widespread implementation, identifying hazards accurately and consistently is becoming increasingly important for regulators and companies at all points in the supply chain. Although one of the GHS's primary objectives is to "harmonize" hazard communication, it has been inconsistently adopted, often resulting in different hazard classifications for one chemical or product. Key factors that can lead to such divergent classifications include reliance on supplier information of variable quality, consideration of country-specific classifications and requirements, differential access to data and information sources, and use of read-across substances to determine the toxicity of data-poor compounds. Moreover, several elements of the GHS rely on professional judgment, requiring toxicology and chemistry expertise to reach weight-of-evidence conclusions. Differences in hazard assignments for the same chemical can cause confusion throughout the supply chain and may invite the scrutiny of competitors, downstream suppliers, and regulators. Developing a successful strategy for conducting and documenting scientifically sound hazard assessments can promote worker safety, meet mandatory regulatory requirements (such as those outlined in the 2016 Occupational Safety and Health Administration Hazard Communication [OSHA HazCom] guidance), optimize the protection of confidential business information (CBI), and serve as the foundation of a proactive product stewardship program.

## INTRODUCTION

The OSHA HazCom Rule and Supplemental Guidance specify requirements and approach for compliant hazard classification:

| | |
|---|---|
| OSHA (2012) | 1910.1200(d)(1): "Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section…"<br>1910.1200(d)(2): "Chemical manufacturers, importers or employers classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning the potential hazards." |
| OSHA (2016) | "Chemical manufacturers and importers are required to perform hazard classifications on the chemicals they produce or import."<br>Anyone that "manufactures, processes, formulates, blends, mixes, repackages, or otherwise changes the composition of a hazardous chemical."<br>Need to "conduct complete and effective literature research and data retrieval… effectively interpret the literature and data…"<br>A lack of qualified workers does not exempt a manufacturer or importer from compliance. |

*Note: OSHA. 2012. "Hazard Communication (Final rule)." Fed. Reg. 77(58):17574-17896.29 CFR Parts 1910, 1915, and 1926, March 26.*
*OSHA. 2016. "Hazard Communication: Hazard Classification Guidance for Manufacturers, Importers, and Employers." OSHA 3844-02 2016. 424p. Accessed at https://www.osha.gov/Publications/OSHA3844.pdf.*

## Reasons Why Chemical Hazard Classification for the Same Chemical May Differ

- Different suppliers may provide differing information about a chemical
- Use of read-across assessment (surrogate substances)
- Variable reliance on publically available sources
- Different authoritative hazard assignments for same chemical
  - Inconsistencies in hazard classifications of a chemical among various countries/ regulatory agencies and available data used in the hazard assessment
- Expert judgment

## General Issues Related to Expert Judgment

- Despite fairly prescriptive GHS methodology, expert judgment is still heavily involved.
  - Study quality
  - Strength of response
  - Adverse vs. adaptive effects
  - Human relevance of findings
  - Consistency across similar compounds
- All leads to building and reaching weight of evidence decisions

## Data Sources for Robust Hazard Classification

- Supplier information
- Authoritative hazard assignments
- Authoritative reviews of a chemical
- EU C & L Inventory
- REACH Dossiers
- Regulatory submissions
- Peer-reviewed literature
- Read-across assessment

## Why Is It important to Get Hazard Classifications Right?

- Accurately convey product hazards to workers and the public
- Meet global chemical compliance requirements
- Protect CBI
- Meet internal or downstream hazard benchmark requirements
- Discrepancies in the hazard classifications of a compound will invite scrutiny from competitors, regulators, and upstream marketers
- Leverage information for an active product stewardship program

### Example 1: Use of Read-Across Assessment

**Issue:** Limited CAS-specific data.
**Chemical of Interest:** Benzyl hexadecyl dimethyl ammonium chloride

| | Chemical of Interest | Chemical of Interest + Read-Across* |
|---|---|---|
| Hazard Conclusion | Acute Toxicity 4 Oral (H302); Skin Irritant 2 (H315) | Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); Acute Toxicity 4 Oral (H302); Acute Toxicity 3 Dermal (H311);Acute Toxicity 2 Inhalation (H330); Skin Irritant 1B (H314); Eye Irritant 1 (H318); STOT SE 3 (H335) |
| Rationale | No CAS-specific test data; Limited descriptions of toxicity | Test data in humans and animals; Regulatory classifications (NZ) |
| Reference(s) | RTECS, TSCAT | REACH Dossier; LOLI Database; US EPA HPV; Peer-reviewed literature |

**Benzyl C12-C16-alkyl dimethyl ammonium chlorides*

**Take Home:** If chemical specific data are limited, look for a similar substance to inform the toxicity determination of the chemical of interest.

### Example 2: Reliance on Various Publically Available Sources

**Issue:** Different classifiers may rely on different sources of toxicity information.
**Chemical of Interest:** Furfuryl alcohol

| | Regulatory Only | Regulatory, Advisory, & Peer-Reviewed Literature |
|---|---|---|
| Hazard Conclusion | Acute 4 (oral); Acute 4 (dermal); Acute 3 (inhalation); Eye Irritant 2; Carcinogen 2; STOT Single 3-Respiratory Tract; STOT Repeated 2 | Acute 3 (oral); Acute 3 (dermal); Acute 2 (inhalation); Eye Irritant 2; Skin Irritant 2; Carcinogen 2; STOT Repeated 2; STOT Single 3-Respiratory Tract; Flammable Liquid 4 |
| Rationale | Based on EU harmonized regulatory classifications | Based on test data in humans and animals; regulatory classifications; and the weight of evidence |
| Reference(s) | EU CLP | EU CLP; REACH Dossier; IUCLID; HSDB; NTP; Peer-reviewed literature |

**Take Home:** Conducting more in-depth assessments, utilizing as many sources of information as possible, will help get hazards right the first time.

### Example 3: Supplier Information

**Issue:** Different hazard classifications of the same chemical.
**Chemical of Interest:** Formaldehyde resin

| Number of Notifiers | ECHA C&L Hazard Classifications |
|---|---|
| 92 | Not classified |
| 64 | Acute 4 (oral); Acute 4 (dermal) |
| 60 | Skin Irritant 2; Eye Irritant 2; STOT 3 |
| 55 | Skin Sensitizer 1 |
| 43 | Acute 4 (oral); Skin Sensitizer; Eye Damage; Aquatic Chronic 1 |
| 1 | Acute 4 (oral); Skin Corrosion 1B; Mutagen 2 |

**Take Home:** Understanding the data that support supplier-specific hazard classifications is critical, particularly if hazards can vary (*e.g.*, impurities, other variable factors).

*Note: CLP = Classification, Labelling, and Packaging Regulation; ECHA C&L = European Chemicals Agency Classification and Labelling; HPV = High Production Volume; HSDB = Hazardous Substances Data Bank; IUCLID = International Uniform Chemical Information Database; LOLI = List of Lists; NTP = National Toxicology Program; NZ = New Zealand; RTECS = Registry of Toxic Effects of Chemical Substances; STOT = Specific Target Organ Toxicity; TSCAT = The Toxic Substances Control Act Test Submissions. Purple Text = Added/changed hazards in fuller review compared to review of only regulatory information.*



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