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Aligning Safety Data Sheet (SDS) Chemical Disclosure Requirements Across a Global Portfolio

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OBJECTIVE

- Propose an integrated approach to harmonizing chemical disclosures across a multi-jurisdictional portfolio.
- Highlight the benefits of making disclosure determinations on a product-by-product, rather than jurisdiction-by-jurisdiction, basis.
- Present options for complying with disclosure requirements while protecting confidential business information (CBI).

BACKGROUND

As the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is adopted by an increasing number of countries and incorporated into regional chemical disclosure regulations, both the hazard classification process and safety data sheet (SDS) format have become more standardized. This has alleviated the hazard assessment burden on chemical retail and manufacturing companies that operate in multiple countries. However, the chemical disclosure requirements for Section 3 (Composition/Information on Ingredients) of the SDS are still largely at the discretion of individual jurisdictions, or "competent authorities," with local CBI regulations taking priority over any stipulations made in GHS guidance (UN, 2015, p. 38).

For multi-national companies, simultaneous compliance with multiple disclosure requirements can pose a challenge, especially if jurisdictional portfolios are not integrated. When assessing SDS needs, it is logical to implement updates and revisions on a jurisdiction-by-jurisdiction basis, but this approach may result in discordant chemical disclosures. Even if SDS updates are implemented at different times, having a centralized process for disclosure determinations will ensure that a company's global chemical portfolio is aligned, compliant across all regions, and sufficiently safeguarded against unintended release of CBI.

PROCESS

Jurisdictional Chemical Disclosure Requirements

Jurisdictional chemical disclosure requirements are generally established as part of a country's effort to align chemical hazard classifications with GHS. There are specific cut-offs for each hazard category, based on the type of hazard. Not all countries have clearly articulated disclosure rules, and those that do tend to differ slightly with regard to cut-off values and how much information is required to be disclosed. The jurisdictions reviewed for this comparison include Brazil, China, the US, the European Union (EU), Australia, Malaysia, and New Zealand. The most common cut-off values are 0.1% and 1.0% (corresponding to the percentage of the chemical contained in the product being sold/manufactured), depending on the nature of the hazard **(Figure 1)**.

Figure 1 Cut-off Values for Hazard-based Chemical Disclosures

0.1%

For most carcinogenicity, mutagenicity, and reproductive hazard categories, as well as sensitizers, a chemical is required to be disclosed if it constitutes ≥0.1% of a product

1.0%

Skin/eye corrosion/irritation categories generally require that a chemical be disclosed if it makes up ≥1.0% of a product.

0.1% or 1.0%

Depending on jurisdictional rules, acute toxicity classifications may require that chemical be disclosed if it constitutes ≥0.1% (*e.g.*, EU) or ≥1.0% (*e.g.*, Australia) of a product.

Aquatic toxicity and physical hazard cut-offs are less consistent across jurisdictions.

Other human health hazard classifications may be subject to higher cut-off values, such as Aspiration Toxicity 1, which requires that a chemical be disclosed if it is ≥10% of the product formulation in the US, EU, Australia, and Malaysia.

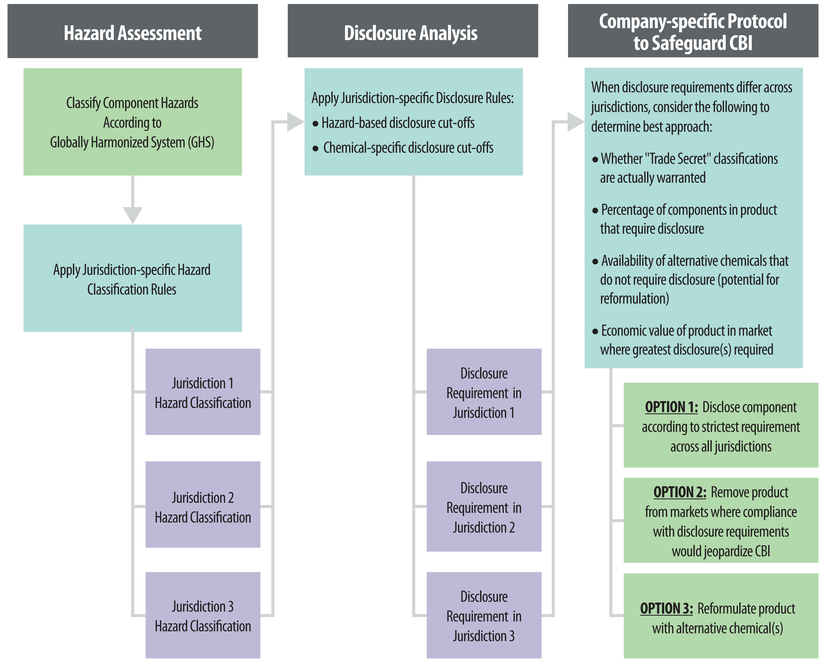
Variations on Disclosure Requirements

- *Component-based disclosure determinations* are made based on the component's hazard classification and the amount of the component in the product.
- *Product-based disclosure determinations* require the calculation of product-level hazard (*via* mixture rules) before determining whether the component contributes to that hazard.
- *Full disclosure* means that a component must be disclosed using its full chemical name and the Chemical Abstract Service (CAS) number.
- *Generic disclosure* means that a component can be disclosed using a generic chemical name/category and that its CAS number does not have to appear on the SDS. Certain jurisdictions, such as Australia, have established guidelines for selecting appropriate generic names.

Benefits of Aligning Disclosures Across Jurisdictions

- Streamlining disclosure determinations so that there is a single, company-wide process – saves time and encourages a centralized approach for managing and tracking chemical disclosures.
- Opportunity to assess the entire product/chemical portfolio to predict future needs for reformulation and make market adjustments when necessary.
- Limit the need to revise and re-issue SDSs to modify disclosures when a product is introduced to a new market with different disclosure requirements.

Figure 2 Process for Aligning Chemical Disclosure Decisions Across Jurisdictions



Considerations for Disclosure

- Why is the component considered CBI/trade secret? Is that classification warranted/justified?
- What percentage of the product's components require disclosure? Could the product recipe be easily replicated if the applicable components were fully disclosed with their CAS numbers?
- What is the economic value of the product in markets where disclosing the greatest amount of information is required?
- Are there newer/less-hazardous chemicals that could serve as suitable alternatives to the chemicals required to be disclosed? Or do replacement components that are not considered trade secret exist?
- Could the product be reformulated to reduce the concentration of the component below the disclosure cut-off?

Table 1 Examples of Chemical Disclosure Determinations

Component	% in Product	Hazard Classification	Disclosure Requirements	Global Portfolio Options
Component 1	0.1%	H300 – Acute Toxicity 1 (Oral)	**EU (45% of sales)** Disclosure with full chemical name and CAS # if concentration ≥0.1%	Option 1: Disclose component with full name and CAS # in all three jurisdictions. Option 2: Pull product from EU and disclose component with generic name (no CAS #) in Australia and US. **Option 3: Reformulate so component is present in product below 0.1%.** Recommendation: Because the concentration of the component is so close to the cut-off, Option 3 is the best option for protecting CBI without having to lose substantial sales from the EU.
			Australia (20% of sales) Disclosure with full chemical name and CAS # if concentration ≥1.0%	
			US (35% of sales) Disclosure with generic name (no CAS #) if concentration ≥0.1%	
Component 2	10%	H314 – Skin Corrosive 1	**EU (40% of sales)** Disclosure with full chemical name and CAS # if concentration ≥1.0%	**Option 1: Disclose component with full name and CAS # in all three jurisdictions.** Options 2: Pull product from EU and Australia and disclose component with generic name (no CAS #) in US. Option 3: Reformulate product using a disclosable alternative or a component that does not require disclosure. Recommendation: Because 80% of product sales are in jurisdictions where the component must be fully disclosed with CAS #, Option 1 is likely the best strategy, unless there is a readily available alternative substance.
			Australia (40% of sales) Disclosure with full chemical name and CAS # if concentration ≥1.0%	
			US (20% of sales) Disclosure with generic name (no CAS #) if concentration ≥1.0%	
Component 3	25%	H304 – Aspiration Toxicity 1	**EU (3% of sales)** Disclosure with full chemical name and CAS # if concentration ≥10%	Option 1: Disclose component with full name and CAS # in all three jurisdictions. **Option 2: Pull product from EU and disclose component with generic name (no CAS #) in Australia and US.** Option 3: Reformulate product using a disclosable alternative or a component that does not require disclosure. Recommendation: Because the EU constitutes such a small percentage of product sales, Option 2 is the best approach for protecting CBI.
			Australia (57% of sales) Disclosure with generic name (no CAS #) if concentration ≥10%	
			US (40% of sales) Disclosure with generic name (no CAS #) if concentration ≥10%	

CONCLUSION

Ideally, a disclosure determination should be made once per component per product. That determination should apply across jurisdictions and should not have to be re-visited each time an existing product is introduced to a new market. Given the complexity of the disclosure landscape, it is difficult to track and organize what has been/needs to be disclosed in which jurisdiction without assessing all markets at the same time and making a single decision for the product. In addition, a component should not be considered CBI/trade secret in one jurisdiction if it has been disclosed elsewhere, because SDSs are publicly available documents and are widely distributed.