GRADIENT

OBJECTIVE

Provide takeaways that will help chemical hazard assessors combine multiple sources of data to derive scientifically defensible hazard conclusions and minimize uncertainty in these conclusions.

BACKGROUND

Gone are the days of "no data, no hazard." Customers, regulators, and consumers are demanding more transparency with respect to product ingredients and their hazards. Environmental Health and Safety (EHS) professionals and product stewards serve on the front lines to inform customers about chemical hazards and reassure them that there are no "secret" hazards. This poster will highlight common sources of toxicity data for Globally Harmonized System of Classification and Labelling (GHS) hazard classification, including supplier; company-owned; European Chemicals Agency (ECHA) Classification and Labelling (C&L); ECHA Harmonized Classification, Labelling, and Packaging (CLP); and peer-reviewed, published literature data. Using a sample set of approximately 1,800 GHS hazard assessments, we will discuss the adequacy (and inadequacy) of each type of data source, as well as the use and reliability of read-across data for GHS hazard assessment.

OVERVIEW

Why Do I Care About Getting the Hazards Right?

- 1. Industry moving away from "no data, no hazard"
- 2. Accurately convey product hazards to workers and the public (*i.e.*, minimize liability)
- 3. Meet regulatory requirements
- 4. Impacts Confidential Business Information
- 5. Meet internal or external hazard benchmarks
- 6. Leverage information for a proactive product stewardship program

Reasons Why Hazards Differ for the Same Chemical

- . Different access to/reliance on available data sources
- 2. Different supplier data
- 3. Use of similar compounds (*i.e.*, read-across)
- 4. Non-negotiable hazards (*e.g.*, ECHA CLP)
- 5. Impurities in products
- 6. Different weight-of-evidence approach (*e.g.*, most conservative vs. best supported)

Table 1 Common Hazard Data Sources

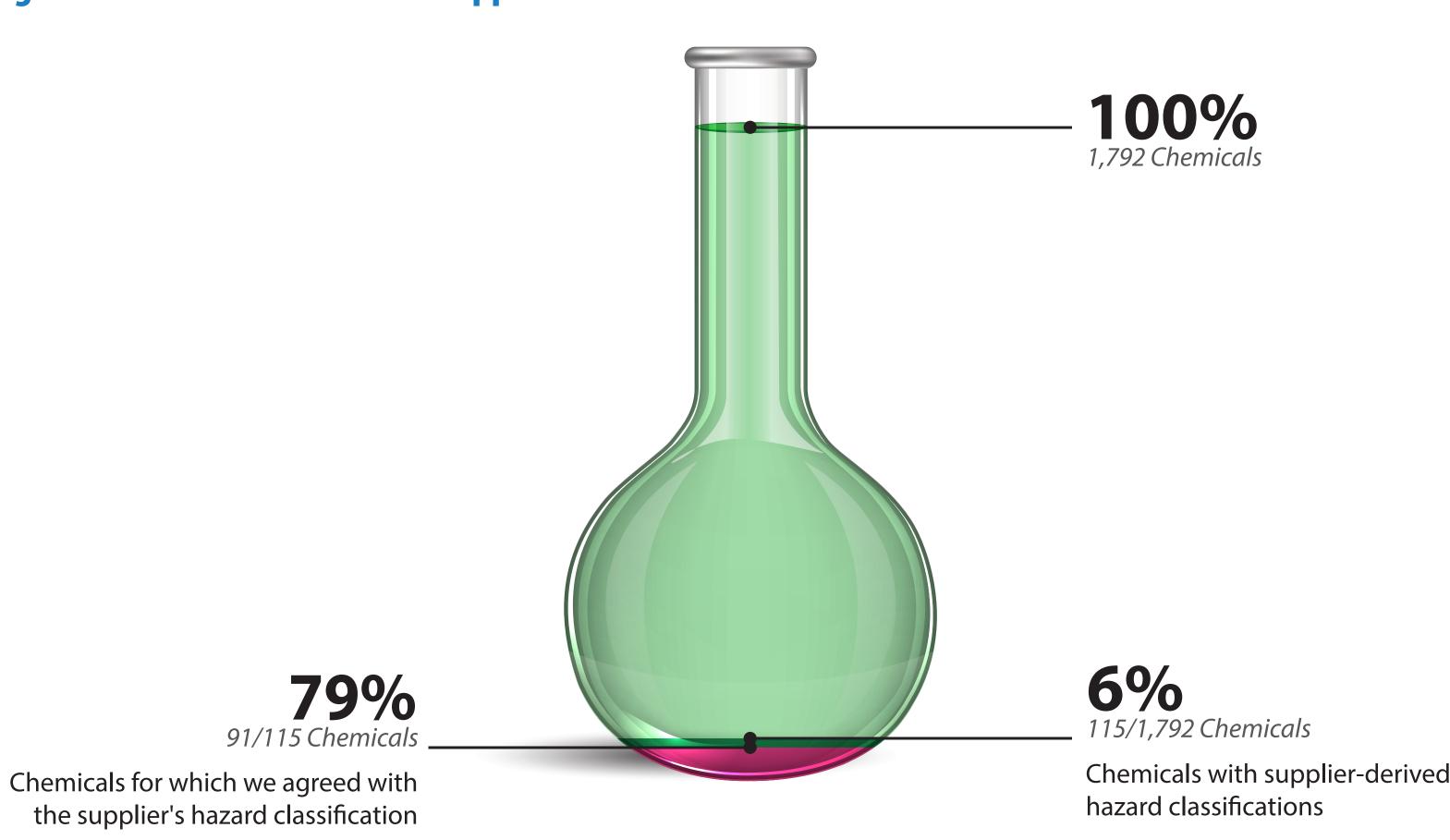
Source Types	Source Names
Internal	Company- or supplier-specific information
Paid Subscription	ToxPlanet
Industry Toxicity Submissions	ECHA Registered Substances Database; IUCLID; ECHA C&L Inventory
Regulatory Agency	ECHA Harmonized CLP; NZ CCID; AUS HCIS
Advisory/Peer-reviewed Publication	HERA on Ingredients of Household Cleaning Products; CIR; HSDB; NTP; TOXLINE

Notes: AUS HCIS = Australia Hazardous Chemical Information System; CIR = Cosmetic Ingredient Review; HERA = Human and Environmental*Risk Assessment;* HSDB = Hazardous *Substances Data Bank;* IUCLID = International Uniform Chemical Information Database; <math>NTP = NationalToxicology Program; NZ CCID = New Zealand Chemical Classification and Information Database; TOXLINE = Toxicological Literature Online.

Hidden Hazards: What's in Your Chemical Portfolio?

HAZARD ANALYSIS SUMMARY (1,792 CHEMICALS)

Figure 1 Hazard Data Source: Supplier



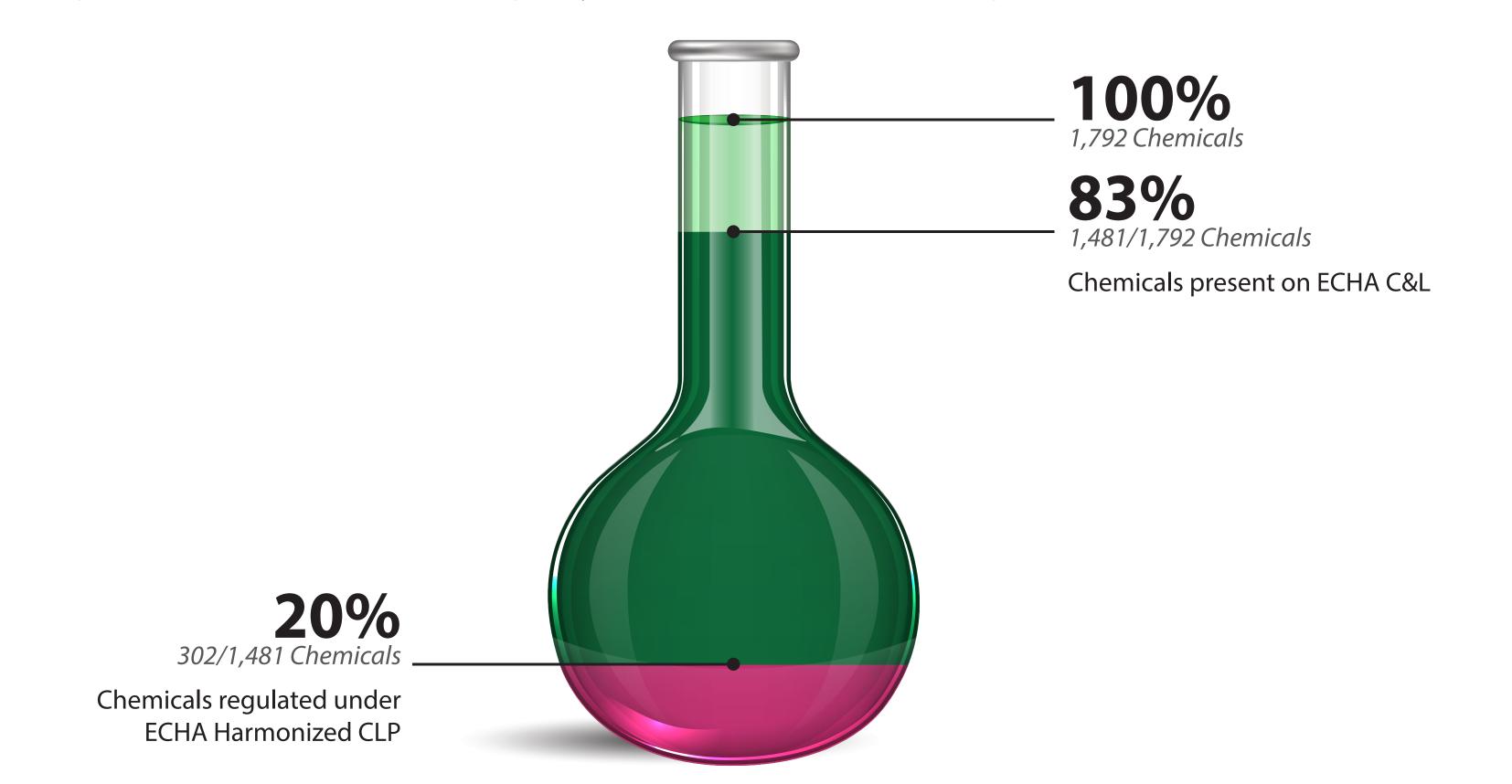
Takeaways: • Supplier data are rarely available.

• When supplier data were available, we generally agreed with the suppliers' hazard classifications.

Advantages	Disadvantages
Requires no professional judgment	Trust that supplier has performed a thorough hazard assessment*

Note: * = Your hazard assessment is only as good as the weakest link in your supply chain.

Figure 2 Hazard Data Source: Agency Hazard Determinations (*e.g.*, ECHA C&L and CLP)

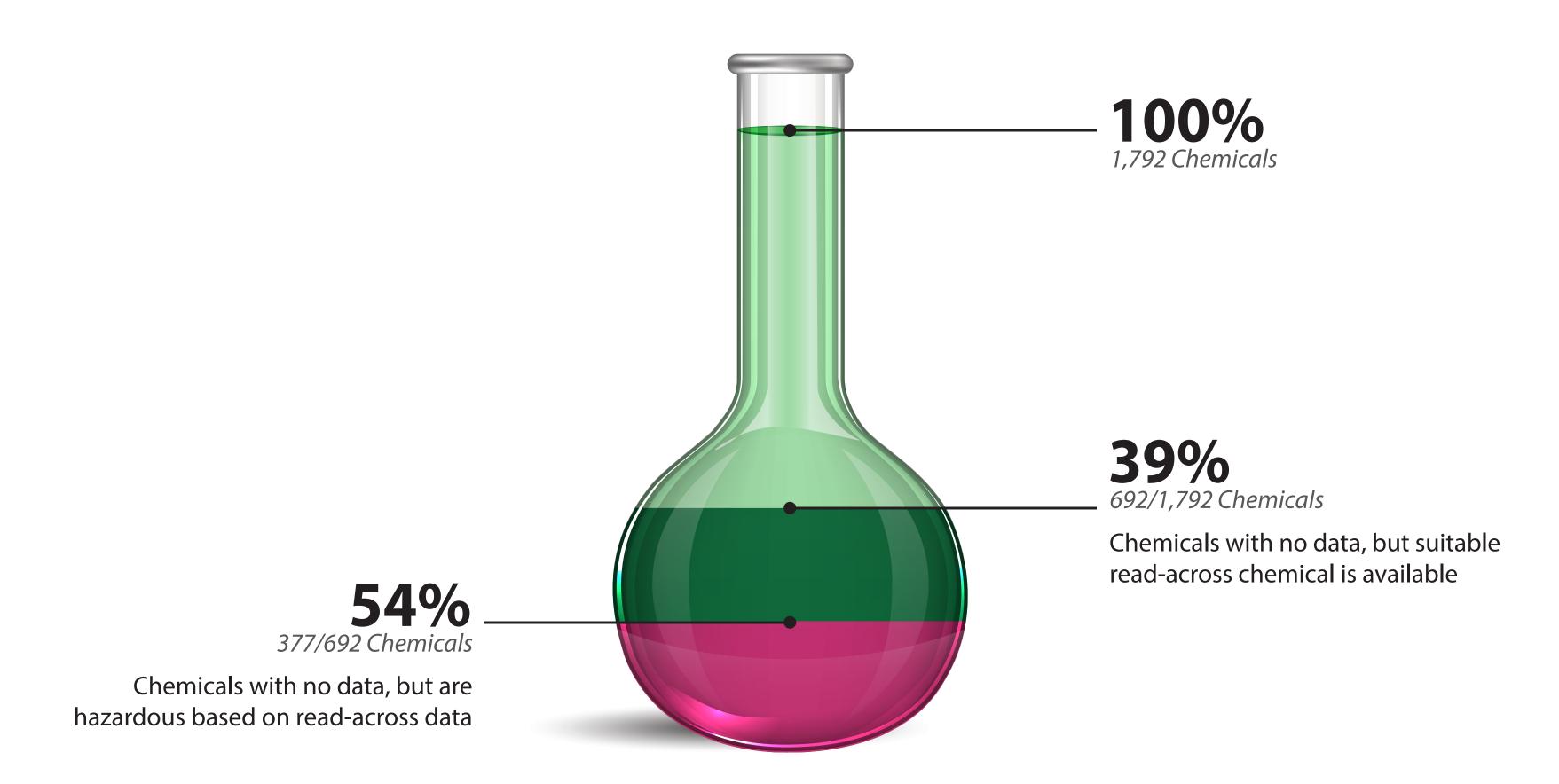


Takeaways: • Data for many chemicals are available *via* the ECHA C&L or Harmonized CLP.

• We generally disagreed with the ECHA C&L or Harmonized CLP hazards for chemicals, based on previous experience.

Advantages	Disadvantages
Readily available information	Discrepancies among agencies; over-/underclassify chemicals based on available data
Requires limited professional judgment	If no agency hazard assessments are available, chemical may not have been evaluated OR may not be hazardous
Hazard assessments are agency-approved	Agency hazard assessments may be outdated

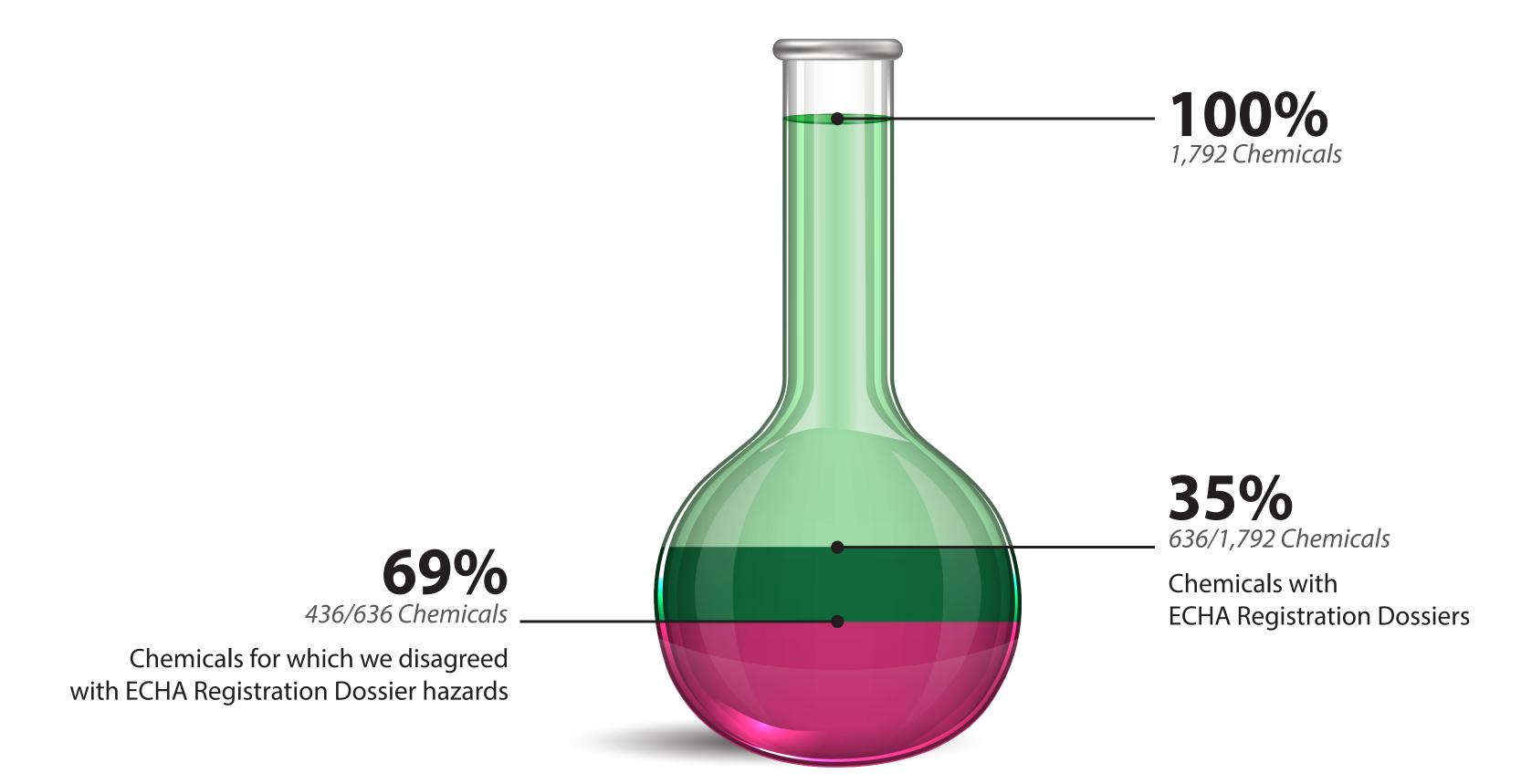
Figure 3 Hazard Data Source: Read-Across



- **Takeaways:** No data were available for a minority (two-fifths) of chemicals in this portfolio, but data-rich read-across chemicals were available.
 - We would have missed the hazards of one-fifth of the portfolio had we not used read-across data.

Advantages	Disadvantages
Able to determine a chemicals' likely hazards using read-across	Requires highly qualified chemists and toxicologists to perform
No testing (animal or <i>in vitro</i>) required	Requires substantial professional judgment

Figure 4 Hazard Data Source: ECHA Registration Dossiers



Takeaways: • ECHA Registration Dossiers are available for only a minority (two-fifths) of the chemicals in the portfolio.

• We generally disagreed with the hazards assigned by ECHA registration dossiers.

Advantages	Disadvantages
Readily available information	Most ECHA Registration Dossiers are NOT approved by ECHA; only 10% have been completely reviewed by ECHA
Requires limited professional judgment	Hazard conclusions in the ECHA Registration Dossiers may be unfounded

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CONCLUSIONS

- Supplier data is rarely available.
- No data doesn't always mean no hazard. Read-across can help identify hazards for many chemicals for which no data are available.
- ECHA Registration Dossiers are great sources of toxicological information; however, their hazard conclusions are generally not well supported.
- Multiple sources of data must be used to evaluate chemical hazards to reassure customers that there are no "secret" hazards.
- Getting the hazards "right" depends on a company's approach to determining the hazards of the chemicals in its portfolio.
- Could require a high level of toxicology and chemistry expertise.
- Full-scale hazard assessments (*i.e.*, considering all available data sources) would result in the most complete and "accurate" hazard determinations. However, highly skilled toxicologists and chemists are needed to perform such assessments.

Full-scale Assessment

Agency Determinations

Supplier Information

Increasing completeness and confidence More professional judgment and resources

Occupational Safety and Health Administration Hazard Communication (OSHA Haz Com) 2012: 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.