

How Wide is the Pond

Understanding Differences Between EU GHS
(CLP) and US Hazcom 2012

Overview

- Identify key differences in scope between EU and US adoptions of the GHS
- Review differences in GHS hazard classes/categories adopted
- Explore important differences in substance and mixture classification based on regulatory differences
- Discuss “official” classification variances
- Discuss label differences
- Your input and participation

GHS Goal

“A globally harmonized hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000”

The goal is to promote the safe use of chemicals and protect human health and the environment.

2015: Where are we?

- GHS has been adopted in many countries and regions
- While the GHS harmonized most hazard classification, some issues were left to competent authorities.
- The building block approach allows countries to adopt what works for their systems
- Chemicals covered varies (consumer, industrial, transport)
- Result: great progress/less harmony than hoped

Hazcom 2012 vs CLP

- US Hazcom 2012 covers only workplace chemicals (OSHA's jurisdiction is limited to workplace)
 - Has additional labeling exemptions for products labeled under other regulations (consumer products, drugs, etc.)
- EU CLP covers all chemicals placed on the market unless exempt
- Some exemptions are similar
 - Drugs, cosmetics, food, etc. in final form intended for final user

Hazcom 2012 vs CLP

- US Hazcom 2012 covers hazard classification, SDS and label requirements and workplace hazard communication.
- US Consumer Product Safety Commission covers consumer product labeling and packaging.
- EU CLP covers only classification, labeling and packaging (including child resistant packaging and tactile warnings)
- SDS requirements are in the REACH regulation
- Workplace hazard communication is a MS activity

Physical Hazard Classes

- US and EU adopted all physical hazard classes and categories except:
 - OSHA did not adopt Aerosol Category 3 (must consider all aerosols as gas under pressure)
 - EU did not adopt Flammable Liquid category 4
 - US added pyrophoric gases and combustible dust
 - EU retained 6 specific hazards with EUH phrases

Health Hazards

- EU and US did not adopt Acute Toxicity Category 5, Skin Irritation Category 3 or Aspiration Category 2
- EU did not adopt Eye Irritation Category 2B
- US added simple asphyxiant
- EU retained 6 specific hazards with EUH phrases

Mixture Classification Differences

- Sensitization concentration limits

- US

Ingredient Classification	Solid/Liquid	Gas	All States
Respiratory 1/1A	≥0.1%	≥0.1%	
Respiratory 1B	≥1.0%	≥0.2%	
Skin 1/1A			≥0.1%
Skin 1B			≥1.0%

- EU

Ingredient Classification	Solid/Liquid	Gas	All States
Respiratory 1A	≥0.1%	≥0.1%	
Respiratory 1/1B	≥1.0%	≥0.2%	
Skin 1A			≥0.1%
Skin 1/1B			≥1.0%

EU also adds elicitation at 1/10 classification concentration (protect sensitized people) – SDS required on request – (EUH210 on label)

Mixture Classification Differences

- Carcinogens
 - US concentration limit for category 2 is 0.1%
 - Labeling optional below 1%
 - EU concentration limit for category 2 is 1%
 - SDS must be available on request if 0.1 - <1% (EUH210 on label)

Mixture Classification Differences

- Reproductive Toxicity
 - US concentration limit for categories 1A, 1B, 2 and effects on lactation is 0.1%
 - EU concentration limit for categories 1A, 1B, 2 and effects on lactation is 0.3%
 - EU concentration limit for category 2 is 3%
 - SDS must be available on request if ≥ 0.1 (EUH210 on label)

Mixture Classification Differences

- Specific Target Organ Toxicity (Single and Repeated Exposure)
 - US concentration limit for categories 1 and 2 is 1%
 - EU concentration limits

Ingredient Class	Category 1	Category 2
Category 1	$\geq 10\%$	1 - $< 10\%$
Category 2		$\geq 10\%$

- SDS must be available on request if $\geq 1\%$ (EUH210 on label)

Environmental Classification

- EU adopted:
 - Aquatic Acute Category 1
 - Aquatic Chronic Category 1-4
- US (OSHA) did not adopt environmental classifications (but are permitted)
- US EPA may adopt for regulated pesticides, biocides, etc.

Other Classification Issues

- CLP Annex VI contains harmonized classifications for substances
- Harmonized classifications “shall” be used for the hazard classes/categories addressed
- Additional hazards shall be self-classified
- OSHA has no list of classification (other than OSHA regulated chemicals) but permits reliance on IARC and NTP for carcinogen classification
- OSHA requires the identification of IARC and NTP carcinogens on SDS
- All other substances self-classified

Registered/Notified Classifications

- Registrants often provide self-classifications for substances in Annex VI based on dossier data
- Often used outside the EU as preferable
- Notified classifications vary and are not supported by data
- Relevance of notified classifications not established

Concentration Limits

- US follows the listed concentration limits for mixtures but requires classification at lower concentrations if chemical is a hazard and allows higher limits but only if supported by data.
- EU often sets higher and lower mandatory concentration limits in Annex VI – not always supported by data.

Labeling

- US and EU adopted the basic GHS label
 - Product identifier
 - Signal Word
 - Hazard Statements
 - Pictograms
 - Precautionary Statements
 - Name, address and phone number of manufacturer / supplier

Label Differences

- Product Identifier
 - US – any name or other designation same as on the SDS (mixture ingredients not required)
 - EU
 - Substance – name and identification number
 - Mixture
 - trade name or designation
 - Identity of substances in mixture that contribute to classification (other than for eye/skin irritation and environmental) – generally not more than 4

Label Differences

- Pictograms
 - US modifies precedence
 - If skull and crossbones – no exclamation mark for acute toxicity
 - EU
 - If skull and crossbones – no exclamation mark for any hazard

Label Differences

- US requires all hazard and precautionary statements designated in tables except when inappropriate
 - Can be combined to reduce label text and improve readability
- EU requires all hazard statements designated in table or Annex VI
 - Wording as in Annex III
 - No more than 6 precautionary phrases (unless necessary) – guidance on selection provided

Label Differences

- Label format
 - US requires the pictograms, signal word and hazard statements be together, no label, font or pictogram size specified.
 - EU requires the pictograms, signal word, hazard and precautionary statements be together. Minimum label and pictogram size.
 - Hazard and precautionary statements must be grouped by language

SDS

- US follows the GHS format for SDS
- EU REACH format far more detailed
- US Ingredient Disclosure
 - All health hazards above concentration limits (or a hazard below) or have exposure limits
- EU Ingredient Disclosure
 - All health or environmental hazards above cut-off values (0.1 or 1%), or above specific concentration limits, or above M values, or have exposure limits

Can a single SDS and Label work?

- Substances
 - In many cases: Yes
 - EU Harmonized Classifications may not be valid in the US
- Mixtures
 - In many cases: No
 - Mixture default and harmonized concentrations limits may be too different

Discussion Groups

- 40 minutes allocated for discussion in small groups.
- Each group should select someone to report back to the group briefly on their discussion and solutions.
- Reports to the group will be limited to 5 minutes.

Discussion Topics

1. Does the lack of true harmonization under the GHS lead to confusion in the workplace? How can that be addressed? Worker training? Using only locally compliant products? How will you know?
2. Does the lack of true harmonization result in trade barriers? Increased cost? Lower safety? How can that be addressed?
3. How can countries be encouraged to better harmonize their adoption of the GHS? Is political action needed or work with trade groups?
4. What can you do when 2 SDS for the same product are different? Which do you trust? What strategies can you use to find the truth?
5. Does reliance on agreed classification lower protection for workers? How can we assure that new information is quickly available but is scientifically reliable?
6. Is you could change something about the GHS, what would it be? How would that make the workplace safer?
7. Is the transition from your previous system making workers more or less safe? How can you ease or simplify the transition?



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