Support Tools and services for GHS/CLP compliance management

20th May 2014

Speaker Bio

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• Specializes in the internationalization and global use of 3E Services. She has many years of collected international Environmental, Health and Safety knowledge, beginning with Communications Officer for the Department for Food and Rural Affairs (DEFRA) in the UK, then in Canada as Product Marketing Manager for MSDS Solutions. She began her tenure with 3E Company in 2007, and is now located in Ireland.

• Holds an Honors degree in Management and Information Systems (MIS)

Agenda

- GHS/CLP Adoption and Resource Impacts
- Support Tools and Services
- Evaluation Criteria

GHS/CLP is Resource Heavy

- Volume of classification work
- GHS is not "harmonized"
- Conflicting regulatory approach among governmental agencies/ministries
- Transitional – occurring over period of months/years
- Multilingual needs to understand differing adoption regulations and information from suppliers

Country Classification Comparison

	US	EU	Japan	Brazil
Acute toxicity - Oral	Category 3	Category 3	Category 3	Category 3
Acute toxicity - Dermal		Category 3	Category 3	
Skin corrosion/irritation	Category 1B	Category 1B	Category 2	Category 2
Serious eye damage/eye irritation	Category 1		Category 2B	Category 2A
Respiratory sensitizer	Category 1	Category 1	Category 1	Category 1
Skin sensitizer	Category 1	Category 1	Category 1	
Carcinogenicity	Category 1A	Category 2	Category 1A	Category 1A
Germ cell mutagenicity			Category 2	
Toxic to reproduction			Category 1B	
Specific target organ toxicity - single exposure		Category 3 - Respiratory	Category 1 - Nervous & Respiratory	
Specific target organ toxicity - single exposure			Category 2 - Central Nervous	
Specific target organ toxicity - repeated exposure			Category 1 - Central Nervous & Respiratory	
Specific target organ toxicity - repeated exposure			Category 2 - Visual Organs	
Acute hazards to the aquatic environment	Category 1	Category 1	Category 2	Category 1

Country Classification Comparison: Classification Cut-off

		US	EU	Japan	Brazil
Carcinogenicity	1	≥ 0.1 %	≥ 0.1 %	≥ 0.1 %	≥ 0.1 %
	1A	≥ 0.1 %	≥ 0.1 %	≥ 0.1 %	≥ 0.1 %
	1B	≥ 0.1 %	≥ 0.1 %	≥ 0.1 %	≥ 0.1 %
	2	≥ 0.1 %	≥ 1.0 %	≥ 1.0 %	≥ 0.1 %
Reproductive Toxicity	1	≥ 0.1 %	≥ 0.3 %	≥ 0.3 %	≥ 0.1 %
	1A	≥ 0.1 %	≥ 0.3 %	≥ 0.3 %	≥ 0.1 %
	1B	≥ 0.1 %	≥ 0.3 %	≥ 0.3 %	≥ 0.1 %
	2	≥ 0.1 %	≥ 3.0 %	≥ 3.0 %	≥ 0.1 %
	Effects on or via lactation	≥ 0.1 %	≥ 0.3 %	≥ 0.3 %	≥ 0.1 %

GHS/CLP asks a lot of a few people

Few companies have access to regulatory attorneys, PhDs, chemists, toxicologists, industrial hygienists, and chemical engineers!

Classification Support: Reference Tools

Description: GHS/CLP substance classification reference databases

- **Benefits:**
  - Regulatory Body managed
  - Little-to-no further work required for single substances
  - Access to other information (Physical property data, etc.)
  - Baseline for mixtures

- **Sources:**
  - Regulatory bodies (next slide)
  - EHS vendors populate lists into user-friendly applications to aid searching and exporting results

GHS Reference Lists

- **EU CLP** – mandatory; approx. 4,500 subs

- **Japan**
  - NITE (National Institute of Technology and Evaluation) – advisory (widely used by industry); approx. 1,900 subs
  - JAISH (Japan Advanced Information Center of Safety and Health) – substances of hazardous and harmful substances designated by EU or other countries

- **Korea**
  - MOE classification – mandatory from July 1, 2011
  - KOSHA – advisory; approx. 11,300 subs
  - NEMA – advisory; approx. 1,000 subs (DG)

- **Taiwan** – CLA, advisory; approx. 2,000 subs

- **South Africa** – mandatory; derived from EU CLP list

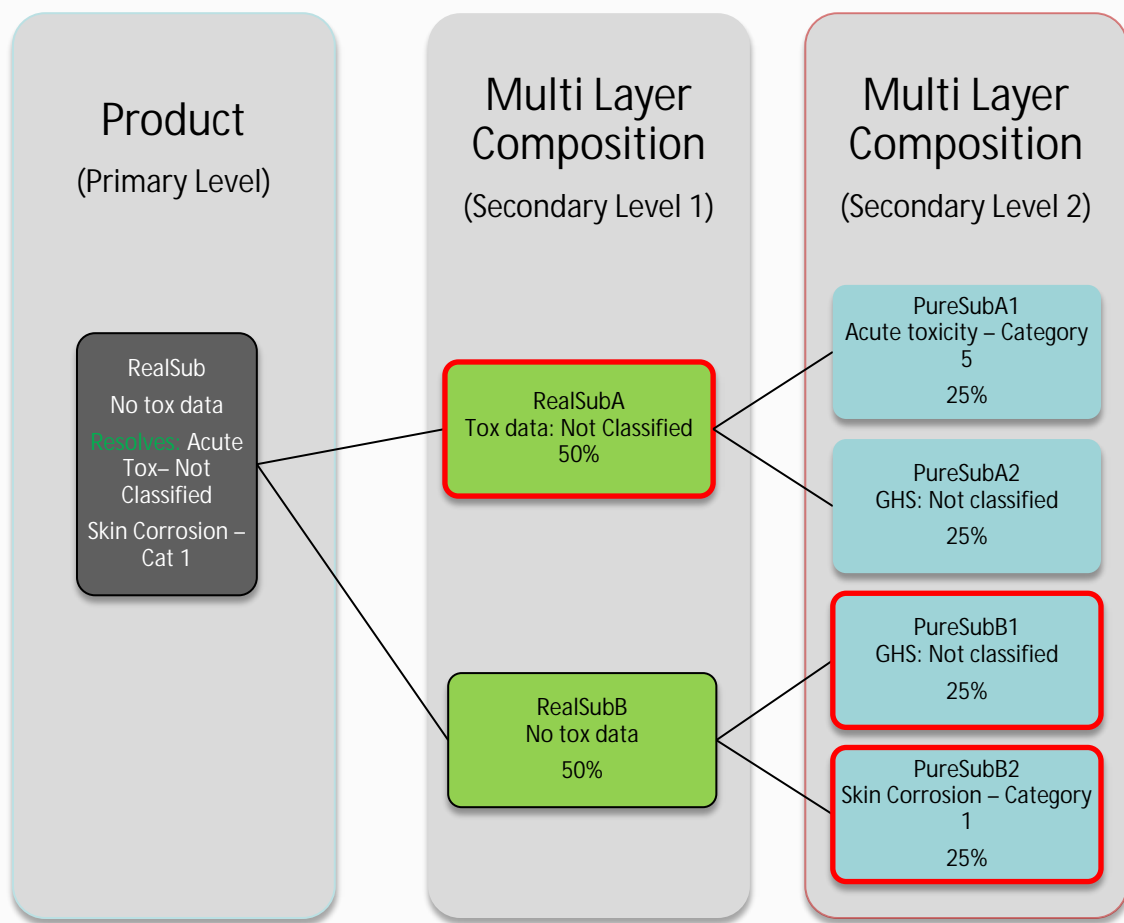# Classification Support: Calculation Tools

Description: Electronic tools with built-in classification algorithms that automate the classification and labeling for substances and/or mixtures.

- **Benefits:**
  - Consistency
  - Time saving, with near immediate results
  - Substance and mixture-level classification assistance based on regulatory substance-level data and available empirical raw material data (e.g. toxicity and eco-toxicity data from databases such as ECHA dissemination site and NLM's HSDB)
  - Accounts for variations in jurisdictions
  - Visibility for the logic used as part of the assessment and determination process
- **Sources:** Vendor rules and software, or vendor rules imported into another vendor's platform, or vendor rules imported into an in-house platform. Very few companies create their own rules and software.

Classification Support: Calculation Tools Rule Logic Examples

- **Bridging Logic:** Sufficient information on comparable mixtures from which classification can be extrapolated
- **Multi-layer Logic:** Use both ingredient and supplier classifications. Product at the primary level comprises of other products (e.g. SAP's REAL_SUBs) at the secondary levels and the rule drills down to the data at these secondary levels to calculate the hazards at the primary level.
- **Exclusion Logic:** Redundant components are CASRN listed hazardous subcomponents which are contained in the parent substance that itself is already listed by a CASRN. These are excluded from classification checks so they do not contribute twice to the classification.

Rule Logic:
Multi-layer Logic, 2 levels

Product
(Primary Level)

RealSub
No tox data
Resolves: Acute Tox– Not Classified
Skin Corrosion – Cat 1

Multi Layer Composition
(Secondary Level 1)

RealSubA
Tox data: Not Classified
50%

RealSubB
No tox data
50%

Multi Layer Composition
(Secondary Level 2)

PureSubA1
Acute toxicity – Category 5
25%

PureSubA2
GHS: Not classified
25%

PureSubB1
GHS: Not classified
25%

PureSubB2
Skin Corrosion – Category 1
25%

Classification Support: Classification Tool Audit Tracking

Provides immediate explanations of how secondary data is determined. Auditable reports for how primary data, rules, and conditions led to the results.

- Transparency
- Audit trail
- Historical tracking when reports are saved

Classification Support: Classification Resources

Description: Outsource classification workload to external expert(s)

- **Benefits:**
  - Removes burden from internal teams
  - Ensures consistency with industry standards
  - Helps streamline resources and workflow
    - Manage overflow during CLP/REACH transition
    - Fill gaps during employee turnover (employees replaced)
    - Fill gaps to handle employee attrition (employees not replaced)
- **Sources:** EHS Vendors, Independent Consultants

External Evaluation Criteria

- One system for all employees for consistency

- Substance and mixture classification support

- Support for wide breadth of regulations – plus enhanced use of evaluation within regulations, such as "Generics" data

- Adapt and alert when regulations change

- Multilingual capabilities

- Well-defined, transparent processes and products – e.g. Exclusion logic

- Scalability – geographically, technologically (infrastructure & IT personnel)

Internal Evaluation Criteria

- **Budget available** – Noting that tools and outsourcing are cost saving resources
- **Volume of classification & Timeline for workload completion –** One-time, consistent expanding into new geographies requiring more monitoring , expansion of finished goods
- **In-house knowledge** – External support while teams adjust to new classification systems, need for tools to avoid teams creating internal databases, tools, or searching the internet endlessly for regulatory information
- **In-house resources** – Protection against unpredictable staffing ebb and flow

Thank you for your attention