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Carcinogenic, Mutagenic, and Reprotoxic (CMR) Chemical Classification

Society for Chemical Hazard Communication

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Paola Chrysostomou
Senior Scientist
Center for Chemical Regulation & Food Safety

Agenda

- Define CMR
- Regulatory standards
- BlueGreen Alliance / Clearya analysis
- Best practices for CMR classification
- Q&A

Carcinogens, Mutagens, and Reprotoxic (CMR) Chemicals

- CMR chemicals are associated with causing or promoting cancer, genetic mutations, and/or damage to the reproductive processes
- Regulatory standards for classifying CMRs vary between jurisdictions and lack global enforceability for hazard communication resulting in inaccuracies and inconsistencies in SDS, putting workers and consumers at risk

Regulatory Standards for Hazard Communication

Regulatory standard	Enforceability
UN Globally Harmonized System (GHS)	Voluntary international system, not legally binding until standards adopted by a country's regulatory body
U.S. Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS)	Enforceable in US
EU Classification, Labeling, and Packaging (CLP)	Enforceable in EU member states
Health Canada Workplace Hazardous Materials Information system (WHMIS)	Enforceable in Canada
Safe Work Australia Work Health and Safety (WHS)	Enforceable in Australia

Putting the BlueGreen Alliance / Clearya Assessment into Context

BlueGreen/ Clearya Position

- During the previous administration, EPA accepted the American Chemistry Council (ACC) position that OSHA provides all the federal rules needed to fully protect workers from chemical exposures, weakening risk evaluations conducted by EPA under TSCA.

Actuality

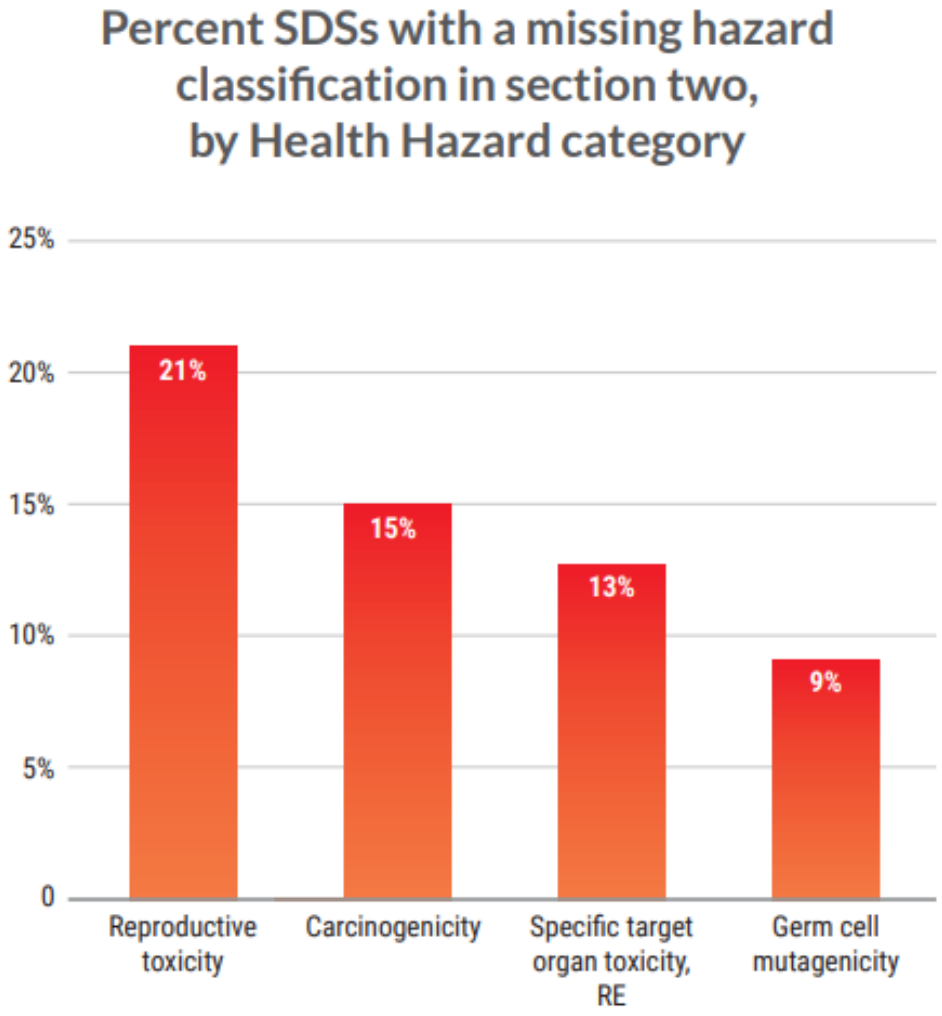
- Even before the 2016 Lautenberg amendment, TSCA evaluated worker safety and risk.
- TSCA often requires changes to SDS and labels based on their assessment.

2021 TSCA and OSHA Memorandum of Understanding
While EPA, not OSHA, bears the responsibility for making the new chemical risk determination, EPA seeks OSHA input on workplace exposures through regular communication.

Obstructing the Right to Know: BlueGreen Alliance/Clearya Analysis of the Chemical Industry's Health Hazard Warnings on Safety Data Sheets

BlueGreen Alliance/Clearya Analysis of SDSs

- Screened 655 SDS of 34 CMR chemicals to evaluate the accuracy of health hazard warnings from various chemical producers
- Found 30% of the SDSs included inaccurate chemical hazard warnings



BlueGreen / Clearya Position

- Employers who purchase chemical products and the workers who handle those products do not have the information they need to protect themselves. The essential safety information in SDSs is, in many cases, simply inaccurate and insufficient.

BlueGreen Position	Assessment
1,3-Butadiene - 75% failed to report reproductive toxicity	ECHA Harmonized classification does not include reproductive hazard; classified for cancer and mutagenicity
Diethylhexyl phthalate – 57% failed to report carcinogenicity	ECHA harmonized classification as reproductive hazard

Putting the BlueGreen Assessment into Context

- Some hazard classifications identified in this BlueGreen Alliance/ Clearya assessment are not “known” hazards.
  - There is no authoritative source for the CMR classification in the North America
  - Self-classification: justify your conclusion and understand your sources
  - OSHA HAZCOM Appendix F
    - Non-mandatory guidance on hazard classification for carcinogenicity

Best practices for documenting CMR

- Consideration of strength of evidence of carcinogenicity, mutagenicity, or reproductive toxicity, and all other relevant information to form a weight of evidence determination
- Consideration of the worst case individual ingredient toxicity for classification of mixtures
- CMR classification applies a risk-based approach vs. hazard-based approach for acute hazards
- Follow UN GHS decision logic when evaluating data on CMR hazard
- Factors to consider when assessing level of concern:
  - Routes of exposure, toxicokinetics, relevance of effect in humans, mode of action, known vs. suspected toxicity

Key learnings to improve SDS accuracy for CMRs

- Enforcement from regulatory authoritative bodies, stakeholders to notify chemical companies of legal obligation to provide accurate and complete information on health hazards
- Consult competent authorities/ experts to comprehensively evaluate the available CMR hazard data
- Reliance solely on supplier SDS can lead to promulgation of an error
- Understand and be able to defend the source of your classification data

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Questions?

Paola Chrysostomou

Senior Scientist
Center for Chemical Regulation & Food Safety
Washington DC
pchrysostomou@exponent.com