

Spring 2015 San Francisco, California

Handling trade secret claims in the USA when authoring a Safety Data Sheet

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When authoring a Safety Data Sheet under Hazcom 2012, it is sometimes difficult to obtain the complete list of hazardous ingredients in a mixture, with CAS numbers and percentages and build an SDS from the ground up. Some suppliers may wish to keep some of the ingredients found in the mixture confidential and claim a trade secret and will thus not provide the CAS number or sometimes even the percentage or percentage range of that ingredient. It is then very challenging to author an accurate and representative SDS without knowing what the product contains.

A solution to this challenge would be to do something similar to what is done in Europe and enter the hazards for each ingredient, as a pure, so at 100% concentration, in section 3 of the SDS, next to that trade secret ingredient's name. This way, authoring an SDS for a mixture containing a trade secret ingredient could be done based on the hazards shown in section 3, when considered at 100%, taking into account that ingredient's precise percentage or a narrow percentage range, in order to calculate the applicable hazards in the final mixture. In addition, for any SDS, whether it contains ingredients claimed as trade secret or not, hazards shown in section 2 could be more easily correlated to the responsible ingredient(s) shown in section 3. This poster will discuss the Trade Secret enforced in the USA, the approach taken in Europe and proposed solutions with examples.



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Globally Harmonized In-Plant Labeling System

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With the implementation of GHS in the US and across the globe there exists an opportunity to dramatically increase worker comprehension and safety for handing hazardous chemicals. For complex formulated products manufacturers, there can be over 1000 different raw materials that are used in the production environment and most all of these materials have hazards that need to be managed. The plant label, while not replacing the labels that arrive on the containers, is a key element of managing these hazards for the plant worker.

The Globally Harmonized In-Plant labeling system overcomes challenges related to opposing hazard scales of the existing systems and incorporates GHS elements into a concise yet robust system that can be applied on a global scale. As part of this system, key elements of GHS pictograms and GHS Classifications along with PPE pictograms have been incorporated into a plant label that aligns with the GHS. We have also developed additional collateral consisting of pocket cards for employees and a poster that provides details of the system. Utilizing this system will provide increased comprehension on the factory floor, allow for easy assessment of the hazards of the chemicals by workers, and present the information to the worker in an easy to use and consistent manner. In addition to meeting the statutory requirements for hazard communication the use of this system will result in a safer work environment and reduced risk for plant workers.



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Regulation Analysis in East Asia

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Chemical Regulation in South Korea

- → K-REACH Entered into Force on 1 Jan 2015
- → The First Batch of Existing Chemical Inventory Subject to Registration will be Released in June 2015.
- → Regulatory Issues Existed in K-REACH
 - 1. LR Election
 - 2. Data Sharing

China regulations updating

- → MEP order 7: Revised Guidance of Registration is Expected to be Released Soon.
- → MEP order 22: Registration of Hazardous Substances will be Required in Some Provinces in China.
- → Catalog of Hazardous Chemicals will be Released Soon.

TCSCA in Taiwan

- → Taiwan Implemented the Revised Edition of Toxic Chemical Substance Control ACT (TCSCA)
- → Taiwan Updated Standard CNS 15030 to Align with the 4th Revision of UN GHS
- → Pre-registration for Existing Substances are Required during 1 September 2015 to 31 March 2016



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DNELs and DMELs - Understanding their role in REACH and their relationship to health-based OELs

Adam Bettmann 3M Company

Derived No Effect Levels (DNELs) and Derived Minimal Effect Levels (DMELs) are defined as "...the level of exposure above which humans should not be exposed." DNELs and DMELs are required to be prepared and be present on the REACH-compliant SDS (section 8.1) for any hazardous substance manufactured in, or imported into, the European Union at a volume of greater than or equal to 10 tons per year. They are typically derived from a No Observed Adverse Effect Level (NOAEL), Lowest Observed Adverse Effect Level (LOAEL), or Bench Mark Modeling (BMDL) from experimental animal studies. The process to derive DNELs and DMELs has been outlined in guidance provided by the European Chemicals Agency (ECHA), and they are ultimately used in the risk characterization process of the Chemical Safety Report (CSR) when registering a hazardous substance for REACH.

This poster is designed to provide a brief overview of when DNEL/DMEL derivation is required, the types of DNELs/DMELs that can be calculated, an example calculation of DNEL derivation, an example of how the data are used in the REACH registration process, and lastly, how DNELs/DMELs set for inhalation in the occupational setting compare to the chemical's health-based Occupational Exposure Limit(s) (OELs).



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The Good the Bad and the What?!@#\$% – SDSs after GHS Adoption – Samples and Thoughts on the What?!@#\$%

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We are all aware that the adoption of GHS by various regulatory bodies across the globe has triggered a landslide of SDS revisions. We are starting to see a wide variety of SDSs that try very hard to meet regulatory criteria and effectively communicate the hazards of a material, but within the bounds of the new regulatory schema and SDS requirements that have been promulgated. While some of the SDSs do quite well satisfying the new requirements and providing consistent and clear hazard communication throughout the new document, there are others that are not quite there yet. In some cases the SDS prior to the change actually provided clearer more consistent communication throughout the document. I would like to specifically explore the what?!@#\$%.

Come along with me and as we examine a few examples and the what?!@#\$%. It is my hope that you have a laugh or scratch your head and furrow your brows with confusion as we try to figure out exactly what the hazards for the material should be. Maybe even when you are finished you won't feel so bad at all about your attempt at a 'GHS' SDS. All sample SDSs are real and available publically on vendor websites. The vendor identification information (material name, manufacturer, stylistic elements of the document, etc.) has been removed from the clippings shown as we all know writing an SDS is a difficult process and it would not be fair or professional to call any one vendor or even SDS author out. We all make mistakes and are fighting battles on various fronts to get these SDSs updated.



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DIY Visual GHS Compliance Using Tools You Have Around the House (or Office)

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See how easy it is to use regular Office (or similar) software to create visually intuitive and easy to maintain GHS compliance support documents. Import from virtually any source documents or other software system, in some cases the resulting documents are self-maintaining, and easy for a non-specialist to tell at a glance what areas need action and what areas are in good shape.



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Inconsistencies in consumer and occupational labeling requirements following U.S. adoption of GHS

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In 2012, the Occupational Safety and Health Administration (OSHA) updated its Hazard Communication Standard to incorporate requirements of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), with requirements for manufacturers intended to go into effect in June of 2015. However, other U.S. regulations for chemical labeling such as the Federal Hazardous Substances Act (FHSA) have not been updated to incorporate GHS. While OSHA permits the use of FHSA labeling for products that are used in consumer as well as occupational applications, some manufacturers may wish to include elements of both OSHA and FHSA labeling systems, hoping to further the GHS system's goals of uniformity and consistency. This is challenging, however, given the varying and, in some instances, conflicting aspects of the two labeling systems. This poster presents examples of these challenges, along with related human factors considerations and examples of available guidance.