

Best Practices in MSDS Authoring & Distribution

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3E Company Background



- Nearly 20 years of industry leadership
- 7,000 customers, 75,000 customer sites, many Fortune 500
 - Including 70% of world's top chemical companies
- Serve global customers
 - U.S.
 - Europe
 - Asia
 - South Africa
- Global locations
 - Carlsbad, CA – Corporate HQ
 - Bethesda, MD – Ariel Regulatory Research & Operations
 - Kingsport, TN – Ariel MSDS Authoring & Related Services
 - Copenhagen, Denmark – Ariel MSDS Authoring & Related Services
 - Massillon, Ohio – HSE Systems' acquired June 2007 (MSDgen authoring platform)
 - Montreal, QC, Canada – MSDS Solutions acquired August 2007 (web-based vendor MSDS management system)

Expert International Staff



- Fully dedicated team of highly qualified employees
- Regulatory attorneys and researchers
- PhDs, chemists, toxicologists, industrial hygienists and chemical engineers
- Software systems and data experts
- MSDS Authors
- 26+ languages spoken

Today's agenda



MSDS Authoring & Distribution – a global perspective

- Global MSDS requirements
 - US, Canada, Europe, Japan, Korean and China to represent the global perspective
- Global Distribution Requirements
 - US, Canada, European distribution rules and guidelines

MSDS's - Purpose



- The material safety data sheet (MSDS) is a means for providing information from the manufacturer to the user.
- The MSDS is the official document for transmission of information related to the possible impact on human health, safety and the environment to workers, emergency responders, transporters and the public.
- Employers must have MSDSs in the workplace for each hazardous chemical that they use.
- Background for
 - Risk assessments - Substitutions
 - Planning of preventive measures

MSDS's - Regulations



US/OSHA:

- Hazard Communication Standard, 29 CFR 1910:1200

Canada:

- Hazardous Products Act (HPA) and
- Controlled Product Regulations (CPA)

EU:

- REACH (Regulation concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals)
- Additional national regulation will apply

Japan:

- Industrial Safety and Health Law (ISHL)
- Pollutant Release and Transfer Registry (PRTR)
- Poisonous and Deleterious Substances Control Law (PDSCL)

Korea:

- Industrial Safety and Health Law
 - The Standard for Preparing and Keeping on File the Material Safety Data Sheets, etc. (Ministry of Labor Notice No. 2008-1)

China:

- The General Rules for the Preparation of Chemical Safety Data Sheet (CSDS), GB16483-2000

MSDS's - Content



Provide information for the safe handling of the chemical

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY
2. HAZARDS IDENTIFICATION
3. COMPOSITION/INFORMATION ON INGREDIENTS
4. FIRST-AID MEASURES
5. FIRE-FIGHTING MEASURES
6. ACCIDENTAL RELEASE MEASURES
7. HANDLING AND STORAGE
8. EXPOSURE CONTROLS/PERSONAL PROTECTION
9. PHYSICAL AND CHEMICAL PROPERTIES
10. STABILITY AND REACTIVITY
11. TOXICOLOGICAL INFORMATION
12. ECOLOGICAL INFORMATION
13. DISPOSAL CONSIDERATIONS
14. TRANSPORT INFORMATION
15. REGULATORY INFORMATION
16. OTHER INFORMATION

Regulations for Hazard Determination



US/OSHA:

- Hazard Communication Standard, 29 CFR 1910:1200

Canada:

- Controlled Product Regulations – WHMIS

EU:

- Directive 67/548/EEC and 99/45/EC
- Regulation (EC) No. 1272/2008 (GHS)

Japan:

- The Industrial Safety and Health Law (GHS)

Korea:

- The Industrial Safety and Health Law, The Standard for Preparing and Keeping on File the Material Safety Data Sheets, etc. (Ministry of Labor Notice No. 2008-1) (GHS)

China:

- GB 13690-92 on the Classification and Labels of Dangerous Substances Commonly Used
- GB12268-2005, List of Dangerous Goods
- GB 6944-2005, Classification and Code of Dangerous Goods

Substance Classification



US (Hazard Communication Standard, 29 CFR 1910:1200):

- Self classification.

Canada (Controlled Product Regulations – WHMIS):

- Self classification
- WHMIS Classifications Database

EU:

- Substance Directive 67/548/EEC
 - Annex 1 to Substance Directive provides harmonized/mandatory classifications
 - Self classification required for Annex 1 with Notes (H, J, K, L, N, P, Q, R) and Substances not listed
- **Regulation (EC) 1272/2008:Table 3.1 – List of harmonized classification and labeling of hazardous substances**

Japan (The Industrial Safety and Health Law):

- Self classification (GHS)
- Advisory list with GHS classifications of published by NITE (National Institute of Technology and Evaluation) www.safe.nite.go.jp/ghs/index.html

Korea (Ministry of Labor Notice No. 2008-1):

- Self classification (GHS)
- Ministry of Labor (MoL) has classified 310 substances under GHS. <http://www.kosha.net/index.jsp> - Requires pass word
 - The classification is to be used for reference only.
 - The classification is published by the Korea Occupational Safety and Health Agency

China:

- ◆ GB 13690-92, lists the classification of nearly 1000 substances
- ◆ GB12268-2005, lists app. 2200 substances/generics
- ◆ Self classification (GB 6944-2005)

Cyclohexanone CAS 108-94-1



Using official classifications (not all are mandatory to use):

Korea Ministry of Labour:

Flammable liquids: Hazard category 3
Acute toxicity (oral): Hazard category 4
Acute toxicity (dermal): Hazard category 3
Acute toxicity (inhalation - vapour): Hazard category 3
Skin corrosion/irritation: Hazard category 2
Serious eye damage: Hazard category 1
Target organ systemic toxicity following repeat exposure: Hazard category 1

Current EU classification

R10, Xn;R20 Flammable. Harmful by inhalation.

WHMIS Classification:

B3 - Flammable and combustible material - Combustible liquid
D1B - Poisonous and infectious material - immediate and serious effects – Toxic
D2B - Poisonous and infectious material - Other effects - Toxic

Japan NITE:

Flammable liquids: Hazard category 3
Acute toxicity (oral): Hazard category 4
Acute toxicity (dermal): Hazard category 3
Acute toxicity (inhalation - vapour): Hazard category 3
Skin corrosion/irritation: Hazard category 2
Serious eye damage/eye irritation: Hazard category 2A
Germ cell mutagenicity: Hazard category 2
Carcinogenicity: Hazard category 2
Toxic to reproduction: Hazard category 2
Target organ systemic toxicity following single exposure: Hazard category 1, 2 and 3
Target organ systemic toxicity following repeat exposure: Hazard category 1
Aspiration hazard: Hazard category 2

EU/GHS (converted)

Flammable liquids: Hazard category 3
Acute Tox. 4 (minimum classification)

Classification of Mixtures



If no test data on the mixture:

US:

- >1% (>0.1%) hazardous substances
- If there is evidence that a component is present at less than 1% (< 0.1% for carcinogens) and could be released into the workplace environment in concentrations that would exceed an OSHA PEL or ACGIH TLV, or present a health hazard in those concentrations, the mixture is assumed to present the same hazard

Canada:

- >1% (>0.1%) hazardous substances

EU:

- Directive 1999/45/EC: Calculation rules which add substances with same effect except for certain long term effects
- **Regulation (EC) 1272/2008 (GHS): Specific rules for classifying mixtures**

Japan:

- The Industrial Safety and Health Law: GHS classification rules

Korea:

- The Industrial Safety and Health Law, The Standard for Preparing and Keeping on File the Material Safety Data Sheets, etc. (Ministry of Labor Notice **No. 2008-1**): GHS classification rules

China:

- % cut off not defined by lists
 - for Banned or Severely Restricted Toxic Chemicals: > 0%
 - Other chemicals: acceptable to use US or EU cut off

MSDS: What to disclose?



USA/OSHA

- If the mixture has been tested:
 - Name of the chemicals contributing to the hazard
- If the mixture has not been tested:
 - Name of hazardous chemicals >1% (0.1%)
- Concentration range accepted
- Claim of trade secret is possible

Canada

- Hazardous chemicals by chemical name
- Thresholds are specified (1%/ 0.1%/ specific threshold on Ingredient Disclosure List)
- Ingredients for which no information on toxicity is held must be disclosed from 1%
- Concentration ranges accepted: 0.1-1%, 0.5-1.5%, 1-5%, 3-7%, 5-10%, 7-13%, 10-30%, 15-40%, 30-60%, 40-70%, 60-100%
- Claim of trade secret is possible ("CBI granted")

EU/Europe (REACH)

- EU Hazardous chemicals
- Thresholds are specified (0.02/ 0.1/ 0.2/ 1 % or other)
- Chemical to be identified by name & REACH registration number & EINECS/ELINCS number (cas number is recommended)
- Concentration range is accepted
- Claim of trade secret is possible – but difficult and restricted to certain hazard classes

Japan

- Listed by
 - Industrial Safety and Health Law (ISHL)
 - PRTR and Promotion of Chemical Management Law (PRTR)
 - Poisonous and Deleterious Substances Control Law (PDSCL)
- Chemical to be identified by name
- Concentration range: ISHL: +/- 5%; PRTR: 2 significant digits
- Claim of trade secret is possible

Korea

- Hazardous chemicals (1%/0.1% for CMRs and respiratory sensitizers)
- Name of chemical component and cas number
- Concentration range is accepted (+_ 5%)
- Claim of trade secret is possible

China:

- All hazardous
- Thresholds are specified (0.1 % for CMR-substances, 1.0 % for others)
- Chemical to be identified by name
- Concentration range is accepted
- Claim of trade secret is possible

Additional data requirements



- Other regulatory requirements (in addition to hazard classification)
 - Registration number (Section 1)
 - Inventory number for substances in the product (Section 3)
 - Storage classification (Section 7)
 - Occupational Exposure Limits (Section 8)
 - Standards for PPE (Section 8)
 - Waste classification (Section 13)
 - Transport classification and information IMDG/IATA/DOT/ADR/TDG/ADG/etc (Section 14)
 - Labeling information (Section 15)
 - “Right to know” lists (Section 15)
 - Restrictions in use (Section 15)

 - Additional classifications (Section 15 or 16)
- Other type of data
 - Supplier address and email address (EU) (Section 1)
 - DerivedNoEffectLevels and PredictedNoEffectConcentrations (EU) (Section 8)
 - Tox data for substances and/or mixture (Section 11)
 - Ecotox data for substances and mixture (Section 12)
- Languages/translation
 - Each country require MSDSs in its national language(s)

When to update?



- US/OSHA: Update for significant new information within 3 months
- Canada: Every 3 years or when new information / significant changes
- EU/Europe: When new regulation comes into force and when new information / significant changes
- Japan: When deemed necessary to change the information
- Korea: Significant new information must be included in the MSDS within 3 months
- China: Every five years and whenever new dangerous characteristics evolve

How can a vendor partner like 3E assist your company with global compliance?



- Developing Company Standards that balance regulatory requirements and company needs
- Training/checklists
- Regulatory information for reference (lists and national text regulation)
- Regulatory data for your authoring software systems
- MSDS authoring software
 - With rules assisting you with the different classification system and other regulatory information
- Classifications:
 - Identification of relevant data (tox/ecotox/physchem)
 - Review of data
 - Classification of substances and mixtures
- Labels:
 - UN/GHS
 - Japan
 - Korea
 - EU/GHS & Australia/GHS based on draft regulation
- MSDSs:
 - National compliant MSDSs
 - UN GHS MSDS

MSDS Best Practices - Authoring



- **Starts “under the hood” with expert underpinning in right disciplines (chemistry, biological sciences, toxicology, IT, law, etc.)**
- **Regulatory knowledge across many geographies**
- **Proper understanding of requirements for document content**
- **Tools and skills to perform correct hazard determination for “pure” substances and mixtures (often complex)**
- **Knowledge regarding proper composition disclosure---sensitive issues for some clients**
- ***Regulatory data bases that are flexible to meet client needs***
- **Partnering with the right company. The 3E difference.**

(M)SDS Distribution

Keys to a successful global
(M)SDS Distribution Program

(M)SDS Distribution



- What are your responsibilities for (M)SDS Distribution
 - Frequency
 - Delivery Methods
 - Customer Access
- Cost Effective Methods for Distribution
- Benefits of a centralized global distribution program

(M)SDS Distribution - US



- Responsibility:
 - Manufacturer or Importer of product into the US
- Distribution Requirements:
 - MSDS required for customer's first purchase
 - Manufacturer must provide MSDS to customer upon request
- Revised MSDS:
 - Within 3 months of a significant change
 - Updated MSDS are required to be sent with customer's next shipment

(M)SDS Distribution - US



- Electronic distribution of MSDS is permitted by OSHA with the following caveats:
 - The manufacturer must ensure that the downstream user has agreed to this type of information access. (Evidence is required)^{1,2}
 - The manufacturer cannot require the purchase of equipment or technology to obtain the MSDS ¹
 - The manufacturer must ensure that some positive and verifiable form of notification (email etc.) is provided with all of the information necessary to access the MSDS ¹
 - The manufacturer must ensure that positive and verifiable notification is provided to ensure the at he downstream user is aware when MSDS are updated due to significant changes in the health hazard data or means to protect against the hazards of the product
 - A back-up system may be required (in the event of system failure)³

{1} 12/30/97 - OSHA Letter of Interpretation "MANUFACTURER AND EMPLOYER RESPONSIBILITIES WHEN PROVIDING MSDSs ELECTRONICALLY"

{2} 4/21/99 - OSHA Letter of Interpretation "CHEMICAL SUPPLIERS MUST ENSURE DOWNSTREAM FLOW OF HAZARD INFORMATION (MSDSS)

{3} 2/20/97 - OSHA Letter of Interpretation "MANUFACTURERERS' USE OF THE INTERNET FOR DISTRIBUTION OF MSDSs TO DOWNSTREAM USERS

(M)SDS Distribution - Canada



- Responsibility:
 - "Supplier" is defined as a person who is a manufacturer, processor or packager of a controlled product or a person who, in the course of business, imports or sells controlled products.
- Canadian Requirements:
 - MSDS required for customer's first purchase
 - Manufacturer must provide MSDS to customer upon request
- Revised MSDS:
 - Must be updated regardless of a significant change every 3 years
 - Updated MSDS are required to be sent with customer's next shipment

(M)SDS Distribution - Canada



Electronic Distribution Approval:

- According to the Hazardous Product Act, the use of the Internet to transmit an MSDS would be acceptable if the supplier is able to demonstrate the following:
 - Purchaser has downloaded the complete and correct MSDS, i.e., one that contains all of the required information
 - Downloading is done at the time of the sale of the controlled product
 - Downloaded file must be readable
 - Satisfaction, on the part of the supplier, may be provided through written confirmation, provided to the supplier from the purchaser, specifying that the above conditions have been met

(M)SDS Distribution - EU



- Responsibility:
 - Those who are responsible for putting the product/substance into the marketplace
- EU Requirements:
 - MSDS required for customer's first purchase
 - Manufacturer must provide MSDS to industrial users upon request
- Revised MSDS:
 - SDS must be revised when there is a significant regulation change
 - Updated MSDS are required to be sent to all customers who have purchased the product in the previous 12 months

(M)SDS Distribution - EU



- Electronic Distribution Approval
 - Manufacturer/Distributor/Importer may provide SDS electronically as long as they can prove that their customer has the means for which to access the SDS

(M)SDS Distribution – Asia Pacific



- Responsibility:
 - Those who are responsible for putting the product/substance into the marketplace
- EU Requirements:
 - MSDS required for customer's first purchase
 - Manufacturer must provide MSDS to industrial users upon request
- Revised MSDS:
 - SDS must be revised when there is a significant regulation change
 - Updated MSDS are required to be sent to all customers who have purchased the product in the previous 12 months

(M)SDS Distribution – Asia Pacific



- Electronic Distribution Approval
 - Manufacturer/Distributor/Importer may provide SDS electronically as long as they can prove that their customer has the means for which to access the SDS

MSDS Distribution: Importers/Resellers



- Issues for Importers/Distributors
 - Need a method to maintain MSDS and track manufacturer MSDS revisions
 - Need to track regulatory changes to determine if there are significant change that may require a change to the MSDS

Distribution Techniques



Method	Advantages	Disadvantages
In the box	No additional postage costs	High printing and processing costs as MSDS goes with every shipment
“Snail” Mail	Easy to manage	High Postage & Printing Costs , no guarantee the MSDS gets to the correct contact
Fax	Easy to manage	High costs for global distribution
Email	Low Cost	Based on country requirements, may require customer permission
Website	Low Cost	Requires permission from customer to avoid pushing the MSDS

How do you implement a compliant, yet cost effective (M)SDS Distribution Program?

How to optimize your (M)SDS Distribution Program?



- Analyze Current MSDS Distribution Methods
 - Volume per distribution method
 - Internal costs per distribution method
- Review Customer Records for relevant data
 - Fax Numbers
 - email addresses
 - EHS contact management
- Determine the number of customer phone inquiries for MSDSs per year

How to optimize your (M)SDS Distribution Program?



- Develop a plan to move customers to low cost distribution methods
 - Mail to Fax
 - Fax to email
 - Email to web
 - Phone to web
- Determine System Requirements
 - Utilize internal applications (Sales, Authoring, Custom Developed)
 - Research third-party providers
 - Recommended for fragmented companies with multiple internal systems
- For electronic distribution, develop campaigns to get customer sign-off
- Perform Cost/Benefit Analysis
- Implement

Benefits



- Cost Reductions based on the implementation of electronic distribution methods
 - Reduce inbound (internal/external) MSDS requests by offering MSDS via website
 - Limit printing and postage costs by converting customers to email or web distribution methods
- Improved record keeping and compliance
- Improved customer satisfaction
- Preserves Corporate Brand
- Helps your customer ensure a safe work environment

How can a vendor partner like 3E assist your company with MSDS Distribution?



- **Web Hosting Services**
 - Development of a web environment for your customers to access MSDS
- **Push Distribution Services**
 - Process Daily Sales Files
 - Determine appropriate method
 - Deliver MSDS to your customers
- **Distributors**
 - MSDS Management services to check with your manufacturers to ensure the MSDS is the most current



Thank you for your attention!