An Overview of MSDS Requirements and Compliances:

China, Korea and Japan

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by

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Topics

- GHS implementation status of China, Korea, and Japan
- MSDS requirements: mandatory or advisory?
  - MSDS sections: country specific regulations
- MSDS exemptions
- MSDS compliance challenges
  - from legal perspective
  - from industry practice
  - many “fuzzy” area
- Conclusion

GHS Implementation Status

GHS comparison

	China	Japan	Korea
Effective from	May 1, 2010 (a year of grace period from this date)	Dec. 1, 2006	Subs: July 1, 2010 (MOL); July 1, 2011 (MOE) Mixtures: July 1, 2013
Excluded Cat.	26 GB - Aspiration hazard - Specific target organ toxicity (single exposure) Cat 3?	JIS Z 7252:2009 - Acute Tox. Cat. 5 - Skin Cor/irritation Cat. 3 - Aspiration Tox Cat.2	-Flamm. liq Cat. 4 -Acute Tox Cat. 5 -Skin Cor/Irritation Cat. 3 -Aqua Tox (Acute) Cat 2,3 *-Serious eye damage 2A, 2B → combined Cat. 2* *-Respiratory sensitization Cat 1A, 1B → combined 1* *-Skin sensitization Cat 1A, 1B → combined Cat. 1*
GHS Classification List	No	Yes – NITE list (NITE, METI, JAISH)	Yes – MOE (mandatory); KOSHA (Ref); NEMA (Ref)

GHS classification lists

- Japan
  - NITE (National Institute of Technology and Evaluation) – advisory (widely used by industry); 2,231 substances classified
  - JAISH (Japan Advanced Information Center of Safety and Health) – substances of hazardous and harmful substances designated by EU or other countries → integrated into NITE
- Korea
  - MOE classification – mandatory from July 1, 2011; total 800 substances
  - KOSHA – advisory; approx. 11,300 subs
  - NEMA – advisory; approx. 1,000 subs (DG)
  - China – Coming up? (expected 2012 summer)
  - List of dangerous chemicals [危险化学品名录] (about 3,500 substances)
  - Very toxic chemical list [剧毒化学品目录] (335 substances)
  - And more

China/GHS

- Chemical Safety Data Sheets (CSDS) and Precautionary Labels are required by
  - Regulations for safe Handling of Chemicals in the Workplace (Decree No 423 of Ministry of Labor of Dec 20, 1996, and effective 1997, Jan.1)
- Chemical Safety Data Sheets (CSDS) are also required by
  - Registration of Hazardous Chemicals, Management Regulation on the Registration of Hazardous Chemicals (Decree No. 35 of SETC, State Economic and Trade Commission)
  - Regulations on the Control over Safety of Dangerous Chemicals (Decree No. 344 of the State Council of the People's Republic of China)
  - Decree No. 344 is replaced by Decree No. 591 on the Safe Management of Chemicals published on March 2, 2011 and entering in force on December 11, 2011
  - The Decree No 591 gives legal force to the two standards GB 13690-2009 Classification and Hazard Communication of Chemicals and 15258-2009 Precautionary Label for Chemicals.

China/GHS (cont'd)

Classification:

- *26 GB (GB 20576- GB 20602)
  - Effective from Jan 2008 (1 year of transitional period from the effective date)
  - These standards translate the UN Purple Book's (1st version) 26 hazard categories.
- *GB 13690-2009 (Classification and Hazard Communication of Chemicals).
  - Effective from May 1, 2010 and provides the guidance for classification.
  - Based on the 2nd revision of the UN Purple Book
  - The 2009 version does not include a list of GHS classifications (1992 version did)
- GB/T 24774-2009 (Classification and hazard pictograms for chemicals - General specification)
  - Published Dec 15, 2009 & Effective from July 1, 2010

SDSs:

- GB /T 16483-2008 (Safety data sheet for chemical products content and order of sections)
  - Issued: June 6, 2008; Implemented: Feb. 1, 2009
  - Appendix A: "Guidance of SDS Preparation" is normative

Labels:

- GB/T 22234-2008 (Labeling of chemicals based on GHS)
  - Effective from Feb. 1, 2009 and Equivalent to the Japanese JIS Z 7251:2006
- *GB 15258-2009 (Precautionary Label for Chemicals)
  - Published Dec 2009 & Effective from May 1, 2010 (1 year of transitional period from the effective date)

* : Compulsory

China GHS - Confusions

Discrepancy of GB20599-2006 and GB15258 (both are compulsory): Specific target organ single Cat.3

GB 20599

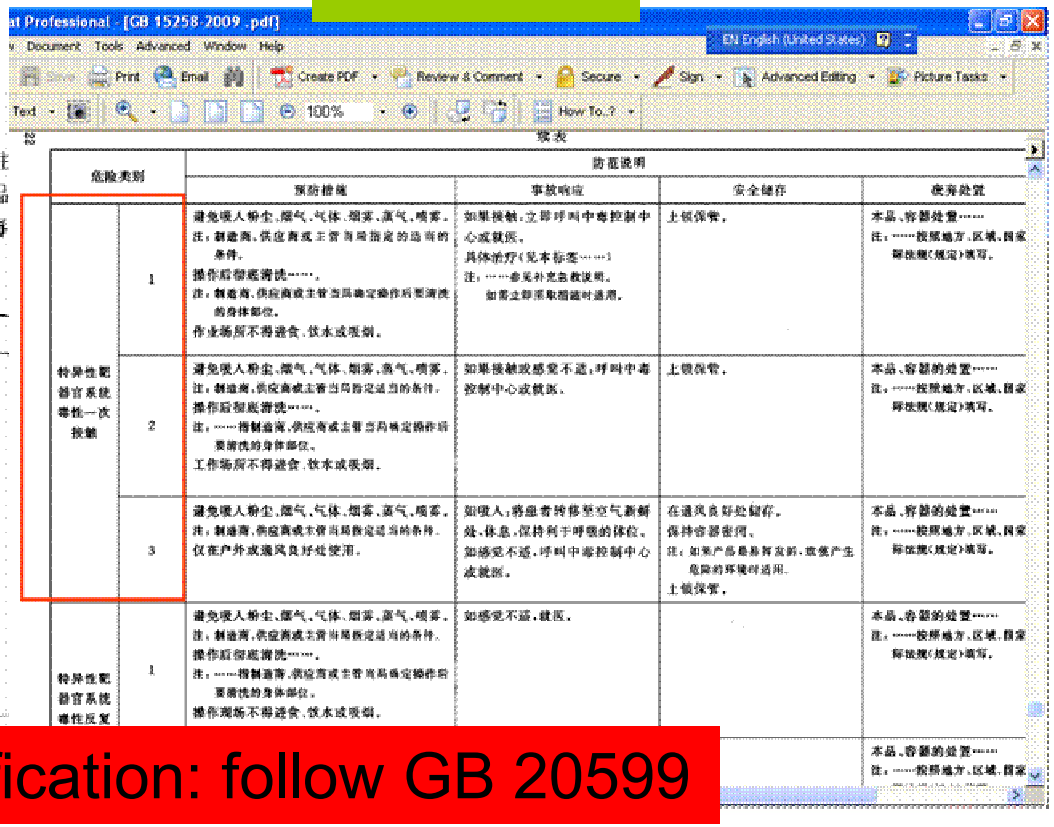
7 类别和标签要素的配置

对于化学品分类和警示标签，危险种类的每个类别都以指定的图形符号、名称和危害性列出。联合国《关于危险货物运输的建议书 规章范本》涉及的危险种类，按联合国《化学品全球协调制度》(GHS)要求下面列出每个类别的指定相应图形标志。特异性靶器官系统毒类别和标签要素的配置见表5。

表5 特异性靶器官系统毒性一次接触分类和标签要素的配置

类别1	类别2
	
危险	警告
致损害(如果没有确切证据指明受损器官，说明受损的全部器官或做一般性说明)(如果确认无其他接触途径引起危害，说明引起危害的接触途径)	可能致损害(如果没有确切证据指明受损器官，说明受损的全部器官或做一般性说明)(如果确认无其他接触途径引起危害，说明引起危害的接触途径)
在联合国《关于危险货物运输的建议书 规章范本》中不要求	

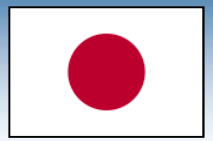
GB 15258



危险类别		防范说明			
		预防措施	事故响应	安全储存	废弃处置
特异性靶器官系统毒性一次接触	1	避免吸入粉尘、烟气、气体、烟雾、蒸气、喷雾。 注：制造商、供应商或主管当局确定适当的条件。 操作后彻底清洗……。 注：制造商、供应商或主管当局确定操作后要清洗的身体部位。 作业场所不得进食、饮水或吸烟。	如果接触：立即呼叫中毒控制中心或就医。 具体治疗(见本标签……)。 注：……参见补充急救说明。 如需立即采取措施时适用。	上锁保管。	本品、容器处置…… 注：……按照地方、区域、国家环境规(规定)填写。
	2	避免吸入粉尘、烟气、气体、烟雾、蒸气、喷雾。 注：制造商、供应商或主管当局确定适当的条件。 操作后彻底清洗……。 注：……指制造商、供应商或主管当局确定操作后要清洗的身体部位。 工作场所不得进食、饮水或吸烟。	如果接触或感觉不适，呼叫中毒控制中心或就医。	上锁保管。	本品、容器的处置…… 注：……按照地方、区域、国家环境规(规定)填写。
	3	避免吸入粉尘、烟气、气体、烟雾、蒸气、喷雾。 注：制造商、供应商或主管当局确定适当的条件。 仅在户外或通风良好处使用。	如吸入，将患者转移至空气新鲜处，休息，保持利于呼吸的体位。 如感觉不适，呼叫中毒控制中心或就医。	在通风良好处储存。 保持容器密闭。 注：如果产品易易挥发的，放储产生危险的环境时适用。 上锁保管。	本品、容器的处置…… 注：……按照地方、区域、国家环境规(规定)填写。
特异性靶器官系统毒性反复	1	避免吸入粉尘、烟气、气体、烟雾、蒸气、喷雾。 注：制造商、供应商或主管当局确定适当的条件。 操作后彻底清洗……。 注：……指制造商、供应商或主管当局确定操作后要清洗的身体部位。 操作现场不得进食、饮水或吸烟。	如感觉不适，就医。		本品、容器的处置…… 注：……按照地方、区域、国家环境规(规定)填写。
					本品、容器的处置…… 注：……按照地方、区域、国家

Clarification: follow GB 20599

Japan/GHS



- SDSs are required by three laws in Japan:
  - the Industrial Safety and Health Law (ISHL by MHLW),
  - the Pollutant Release and Transfer Registry and Promotion of Chemical Management Law (PRTR Law by METI and MOE),
  - the Poisonous and Deleterious Substances Control Law (PDSCL by MHLW)
- Labels are required by
  - the Industrial Safety and Health Law (ISHL by MHLW),
  - the Chemical Substance and Control Law (CSCL by MHLW, METI and MOE),
  - the Poisonous and Deleterious Substances Control Law (PDSCL by MHLW)
  - the Fire Services Law (Dangerous Goods)
- Only the ISHL implements GHS as the classification system but GHS classification is accepted under the other laws.

Japan/GHS (cont'd)

- Japan Industrial Standard (JIS) Z 7250:2010 – Material Safety Data Sheets
  - JIZ Z 7250:2005 Until December 31, 2015 (2000 version could be used till end of 2010)
- Japan Industrial Standard (JIS) Z 7251:2010 – Labeling of Chemicals based on GHS
  - MLHW Notice No. 619: Z 7251 is mandatory from Dec. 1, 2006
- Japan Industrial Standard (JIS) Z 7252:2009 – Classification
  - Provides classification for Health Hazards and Environmental Hazards
  - Excludes the following categories:
    - Acute hazards category 5
    - Skin irritation category 3 (Mild Irritant)
    - Aspiration hazards category 2
- Japan Chemical Industrial Association (JCIA) - GHS Guideline for MSDS and labeling (2nd edition – Oct. 2008) based on JIS Z 7250 and Z 7251 – Reference only

Japan GHS: Confusions…

Multiple GHS classification guidelines…(NITE, JIS, UN, and even EU?)

Industry practice:

- Substance classification – NITE list (including JAISH and METI classification)
- Mixture classification – JIS Z 7252:2009 or UN Purple Book

Some company follows EU CLP. In fact, JIS Z 7252:2009 very similar to EU CLP. Only flammable liquids cat 4 and aquatic toxic (acute) cat 2,3 followed UN.

*JIS Z 7252:2009 excludes physical hazards and takes higher cut-off values of mixtures on

- Respiratory or Skin Sensitizer Carcinogenicity
- Reproductive Toxicity
- Specific Target Organ Toxicity (Single exposure)
- Specific Target Organ Toxicity (Repeated exposure)

Korea/GHS

Ministry of Labor (MOL) (new name: Ministry of Employment and Labor):

- Industrial Safety and Health Law
- Pure substances: July 1, 2010; Mixtures: July 1, 2013
- MOL Notice No. 2009-68 published October 2009 provided new format of MSDS and new category adoption.

Ministry of Environment (MOE):

- Ministerial Decree of Toxic Chemical Control Law
- Classification and labeling of new chemicals under the revised TCCL is mandatory since July 1, 2008.
- Existing chemicals : Single toxic chemical (July 1, 2011); Mixtures (July 1, 2013)

Ministry of Public Administration and Security (MoPAS):

- NEMA (National Emergency Management Agency) Notice No. 2008-18 on November 13, 2008
- Fully adopt GHS classification and labeling requirements for the explosives and dangerous goods under the Dangerous Substances Safety Management Act (DSSMA)
- Effective from the date of notice publication (November 13, 2008)

Korea/GHS (cont'd)

- Lists of GHS classifications:
  - MOE classification – mandatory from July 1, 2011
    (About 800 substances as of Oct 19, 2011)
  - KOSHA – advisory; approx. 11,300 subs
  - NEMA – advisory; approx. 1,000 subs (DG)

- GHS categories not adopted by MOL and MOE
  - Flammable liquid category 4
  - Acute hazards category 5
  - Skin irritation category 3 (Mild Irritant)
  - Acute aquatic toxicity category 2 and 3

National cut offs allowed

	UN Purple book 3rd edition optional cut offs
Skin Sensitizer CAT 1:	≧ 0.1%; ≧ 1.0% Declaration in SDS > 0.1%
Respiratory Sensitizer:	Solid/Liquid - ≧ 0.1%; ≧ 1.0% Gas - ≧ 0.1%; ≧ 0.2% Declaration in SDS > 0.1%
Carcinogen Category 2:	≧ 0.1%; ≧ 1.0%. Declaration in SDS > 0.1%
Reproductive Toxicant Category 1:	≧ 0.1%; ≧ 0.3%
Reproductive Toxicant Category 2:	≧ 0.1%; ≧ 3.0% Declaration in SDS >0.1%
Effects via lactation	≧ 0.1%; ≧ 0.3%
STOT (single exposure) Category 1 and 2:	≧ 1.0%; ≧ 10% Declaration in SDS >1% Between 1 and 10% of CAT 1: optional to require mixture to be classified as Cat 2
STOT (repeated exposure) Category 1 and 2:	≧ 1.0%; ≧ 10% Declaration in SDS >0.1% Between 1 and 10% of CAT 1: optional to require mixture to be classified as Cat 2

GHS Compliant MSDS

GHS compliant MSDS Status

- China GB /T 16483-2008: follows UN Purple Book 2nd edition
- Japan JIS Z 7250:2010 aligns with UN Purple Book 3rd edition by including hazard to Ozone Layer in Section 2 and 12.
- Korea MOL No. 2009-68 aligns with UN Purple Book 2nd edition

GHS compliant MSDS layout

1. Substance identity and company contact information
2. Hazards identification
3. Chemical composition and data on components
4. First aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls and 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

MSDS language requirements

- China – must be in Simplified Chinese (GB/T 16483-2008 “The SDS should be written in the language acceptable to the users.”)
- Japan – must be in Japanese (JIS Z 7250:2010 “MSDS should be in a language that the recipient will easily understand.”)
- Korea – must be in Korean (MOL 2009-68 Korean translation is not necessary if it’s for purely R&D)

→ Chemical names, foreign entities may be in English.

MSDS exceptions?

- China

  - No specific exemptions

  - Basically “all hazardous chemical substances and mixtures” are required MSDS including any product that includes dangerous chemicals listed in GB 13690-1992 *Classification and Labels of Dangerous Chemical Substances Commonly Used* and more!

MSDS exceptions: Korea (1)

- Chemicals that are listed as “Substances Excepted from Preparing and Maintaining its Material Safety Data Sheet” in Enforcement Decree of the Industrial Safety and Health Act Article 32 (2).

  1. Radioactive substances regulated by **Nuclear Energy Act**
  2. Medical, pharmaceutical, and cosmetic products regulated by **Pharmaceutical Law**
  3. Cosmetics regulated by **Cosmetics Law**
  4. Narcotics and drugs that are regulated by **Narcotics and Drugs Management Law**
  5. Agricultural Chemicals that are regulated by **Agricultural Chemicals Management Law**
  6. Materials that are regulated by **Feed Management Law**

MSDS exceptions: Korea (2)

7. Materials that are regulated by **Fertilizer Management Law**
8. Food and food additives regulated by **Food Sanitation Act**
9. Chemicals that are regulated by **Laws regarding firearms, swords and explosives control**
10. Waste materials that are regulated by **Waste Management Law**
11. Materials excluding regulated substances above 1 or 10 that are not used for industrial purpose, but for general public consumption
12. Other materials that are designated by Ministry of Labor as low risk from toxicity or explosion.

→ All substances and mixtures that contain

- Nonhazardous chemicals that do not fall under any hazard category criteria
- Concentration with below 1% of physical hazards
- Complete products in **solids** where workers would not be exposed to the product and its chemical substances. The exception does apply to products that contain carcinogenic substances.

Japan MSDS legislations

- PRTR
  - Class I (including Specific Class I) and II
  - Concentration cut-off (≥ 1% or ≥ 0.1%)
  - Content must be indicated to two significant figures (e.g. 1.6%)
- ISHL
  - Industrial chemicals – Table 9 in Enforcement Rule
  - Content % with range (10% max)
- PDSCL
  - Required for all specified chemicals, specified and poisonous substances
  - Prescribed concentration cut-off
  - Exact content % must be provided on MSDS

MSDS exceptions: Japan

- Low concentration - 1% below (for PRTR Specific Class I chemicals, 0.1% below)
- Solid articles such as metals, pipes (except powered ones)
- Products in a completely sealed condition (i.e. batteries)
- Consumer products (i.e. household cleansers, pesticides, etc)
- Recycled products (i.e. metal cans, metal scraps)

http://www.meti.go.jp/policy/chemical_management/law/msds/2.html

National level of MSDS Requirements

- Even though the SDS is GHS based there are still differences. Examples:
  - Sec 1: Emergency contact
  - Sec 3 (listing of ingredients)
    - What to list (CAS number, other IDs)
    - Use of ranges
    - Use of CBI
  - Sec 9: Physical and Chemical properties
  - Sec 14: Transportation
  - Sec 15: Regulatory information/right to know

Section 1: Emergency contact

China	Japan	Korea
• Must be 24/7 available	• Preferable to describe the emergency telephone number.	• "real" Emergency contact" is strongly recommend, but not legally mandatory

Must be LOCAL number?

-The MSDS regulations do not specify it as a must but local number is highly desirable.

- But labeling may have more stringent regulation.

i.e) China GB 15258 – 2009 "On the precautionary label of any imported chemical, there shall be at least one 24-hour emergency phone number, which is located in China, for chemical accidents."

In real-time scenario: MSDS and Labeling emergency contact information are in sync.

Section 1: Korea unique case

- MOL No. 2009-68: What has changed?

– Change from “3. manufacturer/supplier/distributor contact information” to “3. manufacturer/importer/distributor contact information”

– more specific guidance – “regardless manufacturer, importer, or distributor, contact information of a party who supplies a product and provide MSDS required.”

Section 2: Japan unique case

- GHS classification results

  It is desirable to list all hazard categories with statements below:

  -“Not applicable” (分類対象外) – when the hazard category is not applicable i.e.) product is liquid, hazard category with solids

  -“Not classified” (区分外, 非該当) – when classification does not meet the GHS criteria

  -“Classification not possible” (分類できない) – due to the insufficient data

  -“Not implemented” (未実施) – when GHS classification is not implemented.

Section 3: CBI claim (China)

- Currently there is no clear guideline for CBI claim

  1) GB/T 17519.2 -2003 – need an approval to claim CBI but hazardous chemicals can't be applied.

  2) GB/T 16483-2008 – "non-confidential information related to the composition"

Therefore, for now…

1. May use certain name (such as generic name) to represent the specific substance name; or
2. Use the specific substance name, but provide the range of concentrations

→ GB/T 17519.2 is expected a revision to provide detail definitions.

Section 3: CBI (Korea)

- Very clear definitions!!
- CBI can be claimed to:

  - Chemical name
  - CAS number or identification number
  - Amount of each typical composition

However, below must be disclosed:

- **Prohibited Hazardous Chemicals** regulated under Industrial Safety and Health Act Article 37
- **Permission Requiring Hazardous Chemicals** regulated under Industrial Safety and Health Act Article 38
- **Controlled Hazardous Substances** regulated under “Rules on Industrial Safety Standard” Article 166
- **Toxic chemicals** under Toxic Chemical Control Law

Section 3: CBI (Japan)

- MANDATORY to declare the classification, ingredient, concentration (or concentration range) if following:

1) if the mixture contains 0.1% or more of respiratory sensitizers or skin sensitizers.

2) if the mixture contains 0.1% or more of carcinogens category 2

3) if the mixture contains 0.1% or more of germ cell mutagens category 1 or 2 as well as effects in lactation.

4) if the mixture contains 1% or more of specific target organ (single and repeated exposure) category 2

- Substances not listed in PRTR, PDSCL, and ISHL, CBI may be claimed.

- Generic names can be used, but no guidelines

Section 9: Physical/chemical properties

- China

  - No viscosity

- Korea

  - 17 properties (from Appearance to Viscosity) are identical to the ones of UN Purple book.

  - Korea added Molecular Weight as No. 18 property

- Japan JIS Z 7250:2010

  - “Viscosity” added

Section 14: Transportation

- China

  - No #6 “special precautions for users” sub-header

- Korea

  - Does not require No. 7 information of Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

- Japan

  - MARPOL and IBC code for bulk marine transport are added.

Note: if a product is different from Section 1, follow a name listed in IBC code chapter 17 or 18, or IMO MEPC.2/Circular (latest version).

Section 15: Regulatory Information

China	Japan	Korea
• No specific laws to be listed	• Regulations to be listed: - ISHL - PRTR -PDSCL -CSCL (Chemical Substance Control Law) -Fire Service Law - High Pressure Gas Safety Law -Explosive Control Law -Ship Safety Law -Aviation Law -Marine Pollution Prevention Law	• Five distinctive regulations must be listed: 1.ISHA (Industrial Safety and Health Act) 2.TCCA (Toxic Chemical Control Act) 3.DGSMA (Dangerous Goods Safety Management Act) 4.Waste Control Law 5.Other domestic/foreign laws

Section 15: Japan unique case

- PRTR

  Cabinet Order No (政令番号). is required.

Ministerial Order (METI No. 27) [指定化学物質等の性状及び取扱いに関する情報の提供の方法等を定める省令] Art. 3

09.03.12版

政令改正後の第一種指定化学物質リスト

＊1:CAS番号はあくまでも参考として掲載しています。異性体が存在する場合等、対象物質か否かの判断は物質名及び別名で行って下さい。また、該当するCAS番号が複数存在する場合は、記載していない場合もあります。
＊2:別名欄に()で記載している名称は一般的に使用されている名称であり、政令で規定している名称ではありません。
※:現行政令で既に指定されている物質で統合,分割等を行い、名称が変更されたものです。

改正後の号番号	CAS番号（参考＊1）	物質名	別名（＊2）	特定第一種	元素等に換算する化学物質	現行の種-号番号
1	-	亜鉛の水溶性化合物			亜鉛(Zn)に換算	1-001
2	79-06-1	アクリルアミド				1-002
3	140-88-5	アクリル酸エチル				1-004

MSDS Compliance - Challenges

To what extent your MSDS is considered as "compliant"?

- Legal requirements
- Industry practice/client company's preference

Even if your MSDS is complaint to the respective authority's jurisdiction, it may be rejected if it does not meet your client's requirement

i.e.) Sec 2, Sec 15 – some companies want detailed information and list ALL applicable regulations whereas some want brief information.

Section 15 – Korea case

- What specific chemical lists under each regulation?

ISHA (Industrial Safety and Health Act)

- Harmful Substances Prohibited from Manufacturing
- Harmful Substances Requiring Permission for Manufacture or Use
- Controlled Hazardous Substances
- Harmful Substances Requiring Special Medical Examination
- Workplace Environmental Monitoring Harmful Materials
- Occupational Exposure Limit

TCCA (Toxic Chemical Control Act)

- Toxic Chemicals
- Observational Chemicals
- Banned/Restricted Toxic Chemicals
- Accidental Release Prevention Substances

DGSFA (Dangerous Goods Safety Management Act)

- Dangerous Material List: substance searchable in http://nema.go.kr/hazmat/main/main.jsp

Conclusion

- GHS – not straightforward!

  - Implementation is vary on classification (pure substance or mixture), MSDS, labeling

  - Transitional period

  - Mandatory vs. Recommended
- National level of MSDS guideline, standards, and regulations are critical

  - Some countries show lack of clarity

  - Some countries show lack of consistency between ministries and legislations
- Full understanding of both of legal requirements and industrial practice for MSDS compliance

Thank you for your attention

Questions/discussions ?

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