

# **The Implementation of GHS and MSDS/Labeling in Japan**

**Christina Widodo – Manager, Asia Pacific Regulatory Affairs**

**Miki Nishimura – MSDS Author**

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The Ariel logo features the word "Ariel" in a bold, black, sans-serif font. A small, shaded sphere is positioned above the letter 'i'.

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# Web Seminar Instructions



- Click Q&A button to submit your questions. Questions will be answered at the end of the presentation.
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**Christina Widodo:**

*Manager, Asia Pacific Regulatory Affairs*

- Currently manages Asia Pacific regulatory affairs, acting as a primary regulatory analyst focusing on the Asia Pacific region
- Maintains Asia Pacific EH&S regulatory information services
- Assists and addresses Asia Pacific chemical regulatory issues, writing regulatory compliance guides for various countries
- Main point-of-contact for the development of Asia Pacific regulatory content as well as for providing regulatory support for SAP implementation services
  
- Bachelor of Arts in Asian Studies from Connecticut College
- Juris Doctor from the George Washington University of Law

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**Miki Nishimura:**  
*MSDS Author*

- Responsible for authoring MSDSs for EU countries, North America, Japan, Taiwan, China and Korean GHS MSDSs
- Joined 3E Company/Ariel in the Fall of 2005
- Worked as an engineer in research and development of semiconductor gas sensors, prior to joining 3E Company
- Bachelor of Science in Engineering from Kyushu University, Japan

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# Introduction (UN GHS)

Globally Harmonized System of Classification and Labeling of Chemicals (GHS) ("Purple Book")

Scope (all hazardous chemical substances and mixtures with certain exceptions)

Key Provisions of the GHS:

- Hazard Classification (health, environmental, physical hazards)
- Hazard communication (labels & SDS)

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# Introduction (UN GHS)

GHS Building Block Approach (for Transport, Industrial Workplace, Agriculture, Consumer Products sectors)

- GHS Hazard Classes (e.g. Corrosive to metals, explosives, environmental hazard, etc.)
- GHS Hazard Categories (e.g. Acute toxicity Cat.4, Skin corrosion Cat. 1A, Cat. 1B, Cat. 1C, etc.)
- Hazard Communication (SDS/MSDS)

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## Introduction (Japan GHS)

- Activities for GHS Implementation in Japan:
  - GHS Committee (MHLW, METI, MoE, MIC, MAFF, MLIT and MOFA) was established in 2001
  - Translation of GHS Purple Book text into Japanese
  - PDSCL recommended GHS labeling system (2005)
  - ISHL was amended in 2005 in order to implement GHS labeling and SDS, replacing the current national requirements (Enforcement date: Dec. 1, 2006)
  - Guidelines for classification of chemicals

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# Introduction (Japan GHS)

## Activities for GHS Implementation in Japan (cont.)

- Classifying 1,500 regulated chemicals according to GHS criteria [Based on PDSCL, ISHL and PRTR lists]  
(<http://www.nite.go.jp/>)
  - NITE classification results are not mandatory (Industry can use their own data in classifying substances)
- Japan has adopted all GHS Building Block Categories

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# Introduction (Japan GHS)

- Adopt GHS classification criteria, pictograms, signal word, and hazard statements for the listed substances

Except: Mixture rules are not currently required or enforced  
(Non-listed components can be ignored)

- Japanese Industrial Standards (JIS) based on GHS:
  - JIS for Labeling of chemicals based on GHS (JIS Z 7251:2006) is established
  - JIS for Safety data sheet for chemical products is revised.  
New standard: JIS Z 7250:2005  
(The old Japanese MSDS format in JIS Z 7250:2000 may be used until Dec. 31, 2010)

# Japan Chemical Control Overview

- Over 30 chemical Laws and Regulations
- A number of ministries involved
- Industrial Safety and Health Law (ISHL)
  - First legislation to introduce GHS
  - Implemented a new hazard communication system on Dec.1, 2006
- Other chemical control laws have not changed to GHS

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# Japan Chemical Control Overview

Various laws governing chemical control, hazard communication, and occupational safety

- Chemical Substances Control Law (CSCL)
  - Prevention of damage to human health caused by environmental pollution derived from industrial chemicals.
- Industrial Safety and Health Law (ISHL)
  - Protection of workers.
- PRTR and Promotion of Chemical Management Law (PRTR)
  - Improvement of the chemical substance management by business operators and to protect the environment.

# Japan Chemical Control Overview

Various laws governing chemical control, hazard communication, and occupational safety

- Poisonous and Deleterious Substances Control Law (PDSCL)
  - Protection of human health
- Aviation Law – Air transport
  - ICAO TI (IATA) classification is adopted
- Ship Safety Law – Ship transport
  - IMDG classification is adopted
- Fire Service Law – Land transport and storage
  - Its own classification based on the physical/chemical hazards

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## Japanese Laws requiring MSDS

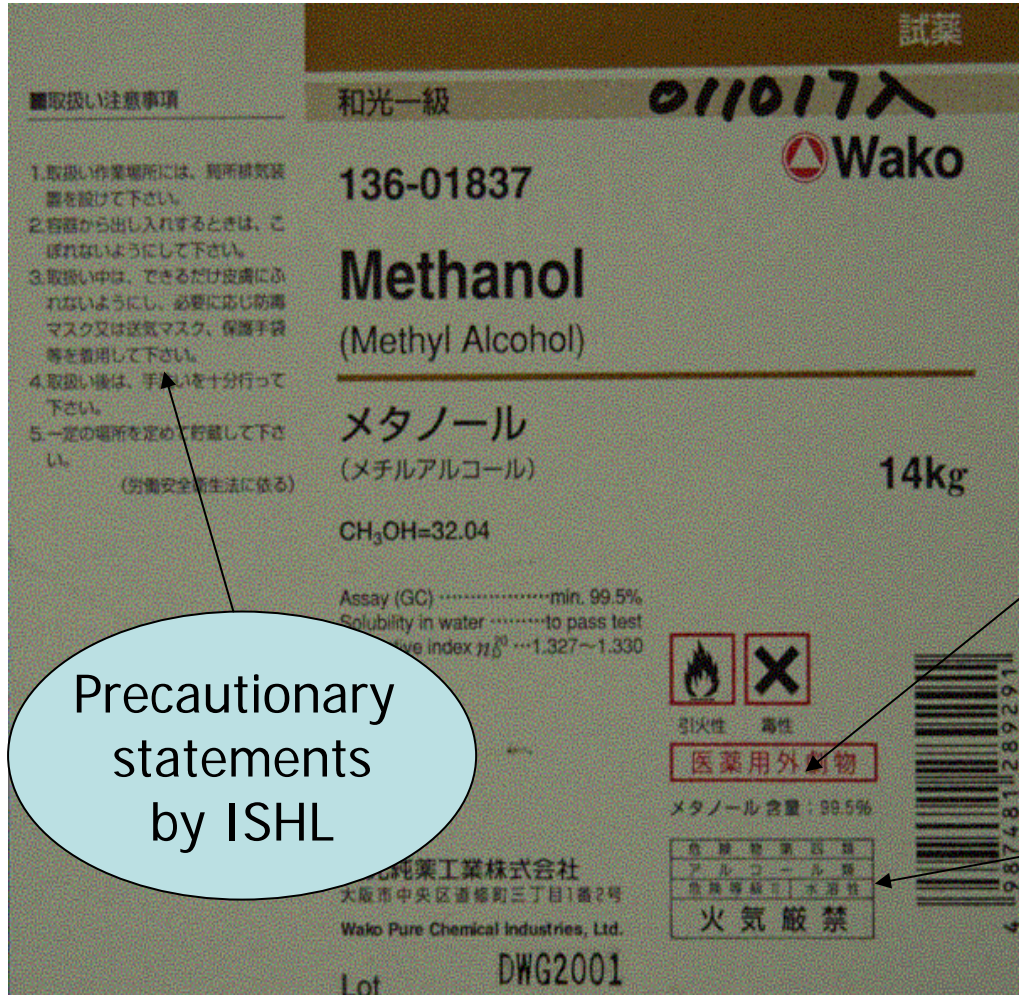
- Industrial Safety and Health Law (ISHL)
- Pollutant Release and Transfer Registry (PRTR)
- Poisonous and Deleterious Substances Control Law (PDSCL)

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# Japanese Laws requiring labels

- ISHL
- PDSCL
- Explosive Control Law
- High Pressure Gas Control Law
- Fire Services Law
- Chemical Substance Control Law
- Ship Safety Law
- Aviation Law

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- Pictograms (voluntary)

Precautionary statements by ISHL

Classification by PDSCL

Physical property classification and precautionary statement by FSL

# GHS Legal Implementation in Japan

- MSDS
  - ISHL (as amended in 2005, and implemented on Dec. 1, 2006)
- Label
  - ISHL (as amended in 2005, and implemented on Dec. 1, 2006)

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## GHS Legal Implementation in Japan

- ISHL amendment key elements
  - Articles 57-1 (concerning label) and 57-2 (MSDS) were amended to conform with GHS
  - GHS label and MSDS are required for ISHL listed substances (non-listed substances maybe regulated under PDSCCL and PRTR)

## GHS Legal Implementation in Japan (MSDS)

### ISHL

- 640 listed substances
- Under the “old regime”, cut-off values: 1%, 0.5% (Benzotrichloride), other substances 1%
- From Dec. 1, 2006 (For each of the listed substances, the disclosure limit is set by the regulation)
  - Mutagenic substances: 0.1%
  - Human carcinogenic substances or suspected human carcinogen: 0.1%
  - Respiratory sensitizing and skin sensitizing substances: 0.1%
  - Toxic substances to human reproduction or suspected toxic substances to human reproduction: 0.1%
  - Other hazardous Substances: 1%

## (GHS) Legal Implementation in Japan (MSDS)

### PRTR

- Class I Designated Chemical Substances (342 substances)
  - Cut-off: 1%
- Specified Class I Substances (12 substances)
  - Cut-off: 0.1%
- Class II Designated Chemical Substances (81 substances)
  - Cut-off: 1%

### PDSCL

- Poisonous Substances (About 60 substances)
- Specified Poisonous Substances (About 10 substances)
- Deleterious Substances (About 280 substances)

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## MSDS Preparation

- 1. Check if your product needs MSDS and which components should be disclosed**
  - Industrial Safety and Health Law (ISHL)
  - PRTR and Promotion of Chemical Management Law (PRTR)
  - Poisonous and Deleterious Substances Control Law (PDSCCL)
  
- 2. Classify your product and allocate GHS elements**
  - Collect information (NITE, own data)
  - Use GHS purple book (all hazard categories are applied in Japan)

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### 3. MSDS

- Japanese Industrial Standard (JIS) for MSDS (Z 7250:2005)
- GHS purple book: Annex 4 Guidance on the Preparation of SDS

#### Section 3: Composition/information on ingredients

Chemical name	Concentration	Serial number		CAS no.
		ENCS no.	ISHL no.	
Ethylene glycol	3.2%	(2)-230, (2)-2267	(2)-230, (2)-2267	107-21-1
n-Butanol	50-60%	(2)-3049	2-(8)-299	71-36-3

#### Section 8: Exposure controls/personal protection

OEL values:

- Workplace Environment Assessment Standards (ISHL)
- Recommendation of Occupational Exposure Limits (JSOH)
- ACGIH

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## Section 15: Regulatory information

- **Industrial Safety and Health Law, Article 57-2 MSDS required substances:** Ethylene glycol, n-Butanol
- **PRTR and Promotion of Chemical Management Law, Class 1 Substance:** Ethylene glycol (Cabinet Order No. 43)
- **Poisonous and Deleterious Substances Control Law:** Not regulated
- **Fire Service Law:** Dangerous goods Class 4. Group 2, Flammable Liquid (Not water-soluble).
- **Waste Disposal and Public Cleaning Law:** Law article2, paragraph 5, Enforcement Order article 2-4, Industrial waste subject to special control

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## Fire Service Law (Dangerous goods)

Class 1: oxidizing solids

Class 2: combustible solids

Class 3: spontaneously combustible materials and water reactive materials

Class 4: flammable liquids

Class 5: self-reactive materials

Class 6: oxidizing liquids

## Waste Disposal and Public Cleaning Law

Specially Controlled Industrial Waste:

- Waste oil (Flash point below 70 C), Waste acid (pH = < 2), Waste alkali (pH = > 12.5)

- Specified Harmful Industrial Wastes:

Wastes containing hazardous chemicals e.g. Alkyl mercury, Mercury, Cadmium, Lead, Organic phosphate, Chromium (VI).

Industrial Waste: Wastes from business activities that are not applicable to the Specially Controlled industrial Waste

# (GHS) Legal Implementation in Japan (Label)

## **Industrial Safety and Health Law (ISHL)**

- 99 substances

## **Poisonous and Deleterious Substances Control Law (PDSCL)**

- Poisonous Substances
- Specified Poisonous Substances
- Deleterious Substances

## **Chemical Substance Control Law (CSCL)**

- Class 2 Specified Substances (23 substances)

## **Fire Service Law (FSL)**

- Dangerous goods

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# Label Requirements



## ISHL

- Product name
- Chemical name of ISHL label required substance
- GHS Pictogram
- GHS Signal word
- Effects on human (GHS hazard statement for health hazard)
- Stability and reactivity (GHS hazard statement for physical/chemical and eco hazard)
- Storage and handling (GHS precautionary statement)
- Company name, address and telephone number

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# Label Requirements

## PDSCL

- Product name
- Chemical name and concentration of PDSCL listed substances
- Pictogram
  - Poisonous substance: 
  - Deleterious substance: 
- Precautionary phrase (Specific phrases required to liquid cleaners for household containing HCl or H<sub>2</sub>SO<sub>4</sub> and bug repellents containing DDVP)
- Detoxicant
- Company name and address

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# Label Requirements

## Chemical Substance Control Law

- Chemical name of CSCL listed substance
- Class name (Class 2 Specified Substances)
- Precautionary phrase that indicates the product may cause adverse effects to the human health and the environment if large quantity is released.

## Fire Service law

- Product name or chemical name
- Dangerous goods, hazard class and hazard rank
- Quantity (weight or volume)
- Precautionary word (Depends on the hazard class and component)  
e.g. 火氣嚴禁, 禁水, 可燃物接觸注意, 水溶性 .

# Japanese Label

Signal word

Hazard statements

Precautionary statements

キシレン Xylene 成分:キシレン 100%	CAS No. 1330-20-7 UN No. 1307 内容量:〇〇〇g
危険	
<b>危険有害性情報:</b> <ul style="list-style-type: none"> <li>- 引火性液体及び蒸気</li> <li>- 飲み込むと有害のおそれ(経口)</li> <li>- 皮膚刺激</li> <li>- 強い眼刺激</li> <li>- 生殖能又は胎児への悪影響のおそれ</li> <li>- 呼吸器、肝臓、中枢神経系、腎臓の障害</li> <li>- 眠気及びめまいのおそれ</li> <li>- 長期又は反復ばく露による呼吸器、神経系の障害</li> <li>- 飲み込み、気道に侵入すると有害のおそれ</li> <li>- 水生生物に毒性</li> <li>- 長期的影響により水生生物に毒性</li> </ul>	
<b>注意書き:</b> 【安全対策】 <ul style="list-style-type: none"> <li>- すべての安全注意を読み理解するまで取り扱わないこと。</li> <li>- 使用前に取扱説明書を入手すること。</li> <li>- この製品を使用する時に、飲食又は喫煙をしないこと。</li> <li>- 熱、火花、裸火、高温のもののような着火源から遠ざけること。- 禁煙。</li> <li>- 防爆型の電気機器、換気装置、照明機器を使用すること。静電気放電や火花による引火を防止すること。</li> <li>- 個人用保護具や換気装置を使用し、ばく露を避けること。</li> <li>- 保護手袋、保護眼鏡、保護面を着用すること。</li> <li>- 屋外又は換気の良い区域でのみ使用すること。</li> <li>- ミスト、蒸気、スプレーを吸入しないこと。</li> <li>- 取扱い後はよく手を洗うこと。</li> <li>- 環境への放出を避けること。</li> </ul> 【救急処置】 <ul style="list-style-type: none"> <li>- 火災の場合には適切な消火方法をとること。</li> <li>- 吸入した場合、空気の新鮮な場所へ移動し、呼吸しやすい姿勢で休息させること。</li> <li>- 飲み込んだ場合、無理して吐かせないこと。</li> <li>- 眼に入った場合: 水で数分間注意深く洗うこと。コンタクトレンズを容易に外せる場合には外して洗うこと。</li> <li>- 皮膚に付着した場合、多量の水と石鹸で洗うこと。</li> <li>- 皮膚(又は毛髪)に付着した場合、直ちに、すべての汚染された衣類を脱ぐこと、取り除くこと。</li> <li>- 汚染された保護衣を再使用する場合には洗濯すること。</li> <li>- ばく露又はその懸念がある場合、医師の診断、手当てを受けること。</li> <li>- 漏出物は回収すること。</li> </ul> 【保管】 <ul style="list-style-type: none"> <li>- 容器を密閉して涼しく換気の良いところで施設して保管すること。</li> </ul> 【廃棄】 <ul style="list-style-type: none"> <li>- 内容物や容器を、都道府県知事の許可を受けた専門の廃棄物処理業者に業務委託すること。</li> </ul>	
〇〇〇〇株式会社 千〇〇〇-〇〇〇〇 東京都△△区△△町△△丁目△△番地 Tel. 〇3-1234-5678 Fax. 〇3-1234-5678	

PDSCL →

医薬用外劇物

気厳禁

第四類

引火性液体

第二石油類

非水溶性液体

危険等級III

← Fire Service Law

## Conclusion

- Three laws require MSDS, only one of which has adopted GHS
- A number of laws require label, only one of which has adopted GHS
- Various ministries involved in chemical control and hazard communication with different perspectives
- JIS for Labelling of chemicals based on GHS (JIS Z 7251:2006)
- JIS for SDS for chemical products (JIS Z 7250:2005, the old Japanese MSDS format JIS Z 7250:2000 may be used until Dec. 31, 2010)
- About 1500 chemicals classified in accordance with GHS by Japanese government – Use of the classification result is not mandatory.

## Useful Links

- [http://www.unece.org/trans/danger/publi/ghs/ghs\\_welcome\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html) (GHS documents/information)
- <http://www.nite.go.jp/> (NITE)
- <http://www.jsa.or.jp/> (Japanese Standard Association)
- <http://www.jaish.gr.jp/menu2.html> (in Japanese)

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Q&A

**[info@3ecompany.com](mailto:info@3ecompany.com)**

**Ariel**