

# Introduction of Chemical Regulations in Japan

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# Overview of Japan Chemical Regulation



# Overview of Chemical Regulation



# PRTR (Law concerning pollutant Release and Transfer Register)

## ➤ Purpose:

To promote voluntary improvement of management of chemical substances by business operators and to prevent any impediments to the preservation of the environment through

- Establishment of the Pollutant Release and Transfer Registers (PRTR) system, which confirms release amounts, etc. of specific chemical substances in the environment;
- Safety Data Sheets (SDS) system, which provides information concerning the properties and the handling of specific chemical substances.

## ➤ Competent Authority:

- METI(Ministry of Economy, Trade and Industry)
- MOE(Ministry of the Environment )



English Information Resource for PRTR Law:

<http://www.japaneselawtranslation.go.jp/law/detail/?printID=&re=01&id=101&vm=02>

PRTR

# Regulated Substances (PRTR)

Category and #	Requirement
Specific Class I (15 substances) Designated Chemical Substances	<ul style="list-style-type: none"><li>• Selected from Class I designated chemical substances due to their carcinogenic properties ;</li><li>• Subject to both <b>PRTR reporting (<math>\geq 0.5\text{t/a}</math>)</b> and <b>SDS requirement (<math>\geq 0.1\text{wt\%}</math>)</b>.</li></ul>
Class I (447 substances) Designated Chemical Substances	<ul style="list-style-type: none"><li>• Subject to both <b>PRTR reporting (<math>\geq 1\text{t/a}</math>)</b> and <b>SDS requirement (<math>\geq 1\text{wt\%}</math>)</b>.</li></ul>
Class II (100 substances) Designated Chemical Substances	<ul style="list-style-type: none"><li>• Subject to <b>SDS requirement only (<math>\geq 1\text{wt\%}</math>)</b>.</li></ul>

## Exemptions :

- Products that contain the specified chemical substances but less than specified concentration limits;
- A product's chemical substances are sealed and is used with the specified chemical substances sealed;  
Products for general consumers (example: detergents, lubricants, insecticides, insect repellents) ; Recyclable resources (example: empty can, waste metal);
- Solid products (example: tubes, plates )

English Information Resource for Specific Substances list under PRTR:

[https://www.nite.go.jp/en/chem/chrip/chrip\\_search/intSrhSpclst?\\_e\\_trans=&slScNm=RJ\\_02\\_001](https://www.nite.go.jp/en/chem/chrip/chrip_search/intSrhSpclst?_e_trans=&slScNm=RJ_02_001)

**PRTR**

## ➤ **PRTR Reporting:**

- Business operators whose operations fall under the 24 types of business operations specified in the government ordinance; or
- Business operators who employ over 21 employees during their regular business operations; or Business operators who handle  $\geq 1\text{t /a}$  of any chemical substance specified in the "Class I Designated Chemical Substances" (or  $\geq 0.5\text{ t/a}$  of the Specific Class I Designated Chemical Substances).

## ➤ **Providing SDSs (Obligation)**

- Specified Class I Designated Chemical Substances ( $\geq 0.1\text{wt\%}$ );
- Class I Designated Chemical Substances ( $\geq 1\text{wt\%}$ ); Class II Designated Chemical Substances ( $\geq 1\text{wt\%}$ ).

## ➤ **Labeling on such products is strongly recommended (Make Efforts)**

# ISHL (Industrial Safety and Health Law)

➤ **Purpose:**

To secure the safety and health of workers in workplaces, as well as to facilitate the establishment of a comfortable working environment.

➤ **Competent Authority:**

- MHLW (Ministry of Health, Labour and Welfare)



English Information Resource for ISHL Law:

<http://www.japaneselawtranslation.go.jp/law/detail/?id=1926&vm=&re>



# Regulated Substances(ISHL)

Category and #	Requirement
New Chemicals Substances	<ul style="list-style-type: none"><li>• Approval required before manufacturing or importing.</li></ul>
Prohibited to Manufacturing (8 substances)	<ul style="list-style-type: none"><li>• Prohibited from manufacturing or importing.</li></ul>
Requiring Permission for Manufacture(8 substances)	<ul style="list-style-type: none"><li>• Permission required before manufacturing or importing.</li></ul>
Requiring Labeling and Delivery of Documents(SDSs) (640 Substances)	<ul style="list-style-type: none"><li>• Required to labeling and delivery of documents(SDSs)when transferring or providing any of the subject chemical substances.</li></ul>
Others (Specified Chemical Substances; Organic Solvents etc.)	<ul style="list-style-type: none"><li>• Specific measures required during manufacturing and handling (e.g. Local ventilation ; Protective equipment, Medical checkup etc.)</li></ul>

English Information Resource for Regulated Substances list under ISHL:

[https://www.nite.go.jp/en/chem/chrip/chrip\\_search/sltLst](https://www.nite.go.jp/en/chem/chrip/chrip_search/sltLst)



## ➤ Notification of New Chemical Substances:

Category	Requirement
Standard Notification	<ul style="list-style-type: none"><li>• Tonnage <math>\geq</math> 100kg/y;</li><li>• AMES testing is required;</li><li>• Other information (manufacturing process, reaction formula, etc.);</li><li>• The substance name will be published within 1 year after approval.</li></ul>
Small Volume Notification	<ul style="list-style-type: none"><li>• Tonnage <math>&lt;</math> 100kg/y ;</li><li>• No testing is required;</li><li>• Apply per year or Apply for 2 years at one time.</li></ul>
Confirmation	<ul style="list-style-type: none"><li>• Measures have been taken to prevent workplace exposure ;</li><li>• The substance is not well known as carcinogen in foreign country.</li><li>• Contact with MHLW before proceeding confirmation is necessary.</li></ul>
Full Exemption	<ul style="list-style-type: none"><li>• Substance for testing and research purposes, reagent, sample for business, sealed in machine, substance in consumer goods and existing chemical substances under ISHL.</li></ul>

## ➤ **Providing SDSs and Labeling:**

### [Obligation]

Appended Table 3 & Table 9 of Order of Enforcement of ISHL(640 substances); Mixtures containing any of the above  
(The cut-off value is defined for each substance).

### [Make Efforts]

Substances/mixtures which are classified as hazardous according to JIS Z7253.

### [Exemption]

- Regulated by other laws: Pharmaceutical Medical Equipment Law , Agricultural Chemicals Control Law,....
- Solid products (a product which stays as a solid whilst being handled and never turns into powder or granulated form);
- A product's chemical substances are sealed;
- Products for general consumers.

ISHL

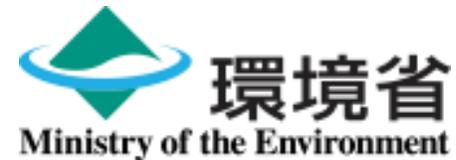
# CSCL (Chemical Substances Control Law)

## ➤ Purpose:

To prevent environmental pollution by chemical substances that pose a risk to human health or the environment.

## ➤ Competent Authority:

- MOE(Ministry of the Environment )
- METI(Ministry of Economy, Trade and Industry)
- MHLW(Ministry of Health, Labour and Welfare)



English Information Resource for CSCL Law:

<http://www.japaneselawtranslation.go.jp/law/detail/?id=1957&vm=&re=>

# Regulated Substances(CSCL)

Category and #	Requirement
New Chemicals Substances	<ul style="list-style-type: none"> <li>• Approval required before manufacturing or importing.</li> </ul>
Class I Specified Chemicals (33 substances) persistent, bio-accumulative, toxic	<ul style="list-style-type: none"> <li>• Permission required before manufacturing or importing. (virtually prohibited except essential uses)</li> </ul>
Monitoring Chemical Substances(38 substances) persistent and bio-accumulative	<ul style="list-style-type: none"> <li>• Annual report required if the volume of M/I is <math>\geq 1\text{kg/y}</math>;</li> <li>• Authority may ask manufacturers /importers to investigate long-term toxicity.</li> </ul>
Class II Specified Chemicals (23 substances) toxic and high risk	<ul style="list-style-type: none"> <li>• Notification of planned M/I quantity required before M/I and actual amounts after M/I.</li> </ul>
Priority Assessment Chemicals (226 substances)	<ul style="list-style-type: none"> <li>• Annual report if the volume of M/I is <math>\geq 1\text{t/y}</math>;</li> <li>• Authority may ask manufacturers/importer to provide more hazard data.</li> </ul>
General Chemicals (approx. 28,000 substances)	<ul style="list-style-type: none"> <li>• Annual report required if the volume of M/I is <math>\geq 1\text{t/y}</math>.</li> </ul>

# Requirements for Importers

## ➤ Notification of New Chemical Substances:

Category	Requirement
Standard Notification	<ul style="list-style-type: none"><li>• Data required: Biodegradability study, Partition coefficient; Bioaccumulation study etc.</li><li>• The substance name will be published in 5 years after approval;</li><li>• Foreign company allowed to be notifier.</li></ul>
Low Volume Confirmation (Amended January 2019)	<ul style="list-style-type: none"><li>• Tonnage ≤ 10t/y;</li><li>• Data required: Biodegradability study, Bioaccumulation study;</li><li>• Only domestic manufacturer/importer could be notifier.</li></ul>
Small Volume Confirmation (Amended January 2019)	<ul style="list-style-type: none"><li>• Tonnage ≤ 1t/y;</li><li>• No testing data required;</li><li>• Only domestic manufacturer/importer could be notifier.</li></ul>
Other Prior Confirmation	<ul style="list-style-type: none"><li>• For intermediate, substances used in closed system, and polymer of low concern;</li><li>• Relevant supporting documents are required;</li><li>• Only domestic manufacturer/importer could be notifier.</li></ul>

# Requirements for Importers

➤ Amendment to LVC and SVC:

Category	Upper Limit per Manufacturer/Importer	Upper Limit across Japan
Small Volume Confirmation(SVC)	1t/y As M/I volume	1t/y As M/I volume
Low Volume Confirmation(LVC)	10t/y As M/I volume	10t/y As M/I volume



Category	Upper Limit per Manufacturer/Importer	Upper Limit across Japan
Small Volume Confirmation(SVC)	1t/y As M/I volume	1t/y <b>As environmental emission volume</b>
Low Volume Confirmation(LVC)	10t/y As M/I volume	10t/y <b>As environmental emission volume</b>

## ➤ **Amendment to LVC and SVC:**

Use Certificate are required and could be either of:

- Contract, Quality Assurance Form, Invoice etc.;
- SDS stating specific use, with signature/seal of user;
- Template developed by authority.

## **Information requirement for Use Certificate:**

- Name of the new chemical substances;
- Use number and use category;
- User information.

Emission Factor:

<https://www.nite.go.jp/chem/kasinn/tokureikeisuu.pdf>

Template for Use Certificate:

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/todoke/shinki\\_shoryo\\_index.html](https://www.meti.go.jp/policy/chemical_management/kasinhou/todoke/shinki_shoryo_index.html)

# Requirements for Importers

## ➤ Annual Reporting:

### Subject to Annual Reporting:

- More than 1t/y of General Chemical Substances( $\geq 10\text{wt}\%$ );
- More than 1t/y of Priority Assessment Chemical Substances( $\geq 1\text{wt}\%$ );
- More than 1kg/y of Monitoring Chemical Substances;
- More than 1kg/y of Class II Specified Chemical Substance.

### Submission Period:

From April 1 and June 30

(Note: Submission by using hard copy is extended to July 31 in this year)

### **Check the schedule and requirements here:**

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/general-chemical.html](https://www.meti.go.jp/policy/chemical_management/kasinhou/general-chemical.html)

# PDSCCL (Poisonous and Deleterious Substances Control Law)

➤ **Purpose:**

To provide necessary control on Poisonous Substances and Deleterious Substances from the viewpoint of health and hygiene.

➤ **Competent Authority:**

- MHLW (Ministry of Health, Labour and Welfare)



English Information Resource for PDSCCL Law:

<http://www.japaneselawtranslation.go.jp/law/detail/?id=2595&vm=04&re=01>

# Regulated Substances(PDSCL)

Category and #	Description
Poisonous Substances (approx. 130)	<ul style="list-style-type: none"><li>• Defined as substances which may cause <a href="#">severe damage</a> to human physiological function;</li><li>• Designated in Table 1 of the Law and Article 1 of the Cabinet Order for the Designation of the Poisonous and Deleterious Substances.</li></ul>
Deleterious Substances (approx. 400)	<ul style="list-style-type: none"><li>• Defined as substances which may cause <a href="#">relatively light damage</a> to human physiological function;</li><li>• Designated in Table 2 of the Law and Article 2 of the Cabinet Order for the Designation of the Poisonous and Deleterious Substances.</li></ul>
Specified Poisonous Substances (approx. 10)	<ul style="list-style-type: none"><li>• These are extremely poisonous among poisonous substances and are defined as substances which have <a href="#">high possibility of the harm</a> for the person depending on the direction for uses;</li><li>• Designated in Table 3 of the Law and Article 3 of the Cabinet Order for the Designation of the Poisonous and Deleterious Substances.</li></ul>

English Information Resource for Regulated Substances list under PDSCL:

<http://www.nihs.go.jp/law/dokugeki/edokugeki.html>



# Requirements for Importers

## Manufacture/Import, Sales Registration:

- Business operators acquire license of manufacture/import(renewal required every 5years), sales(renewal required every 6years)of Poisonous Substances, Deleterious Substances, or Specified Poisonous Substances;
- The conditions of storage and transfer should meet the requirements under the law.

## Providing SDSs and Labeling (Obligation)

- Poisonous Substances, Deleterious Substances, or Specified Poisonous Substances and the
- substances with concentration exceeding the specified limit value where they are present in mixtures;
- The word "Poisonous substance" or "Deleterious substance" should be indicated on labels.

医薬用外毒物

医薬用外劇物

**NOTE: PDSCL is applicable to the intentionally added substances. If the product containing Poisonous/ Deleterious Substances, or Specified Poisonous Substances as an impurity, then it is out of the scope of PDSCL.**

**PDSCL**

# Overview: Relevant Standards for SDS/Label



02

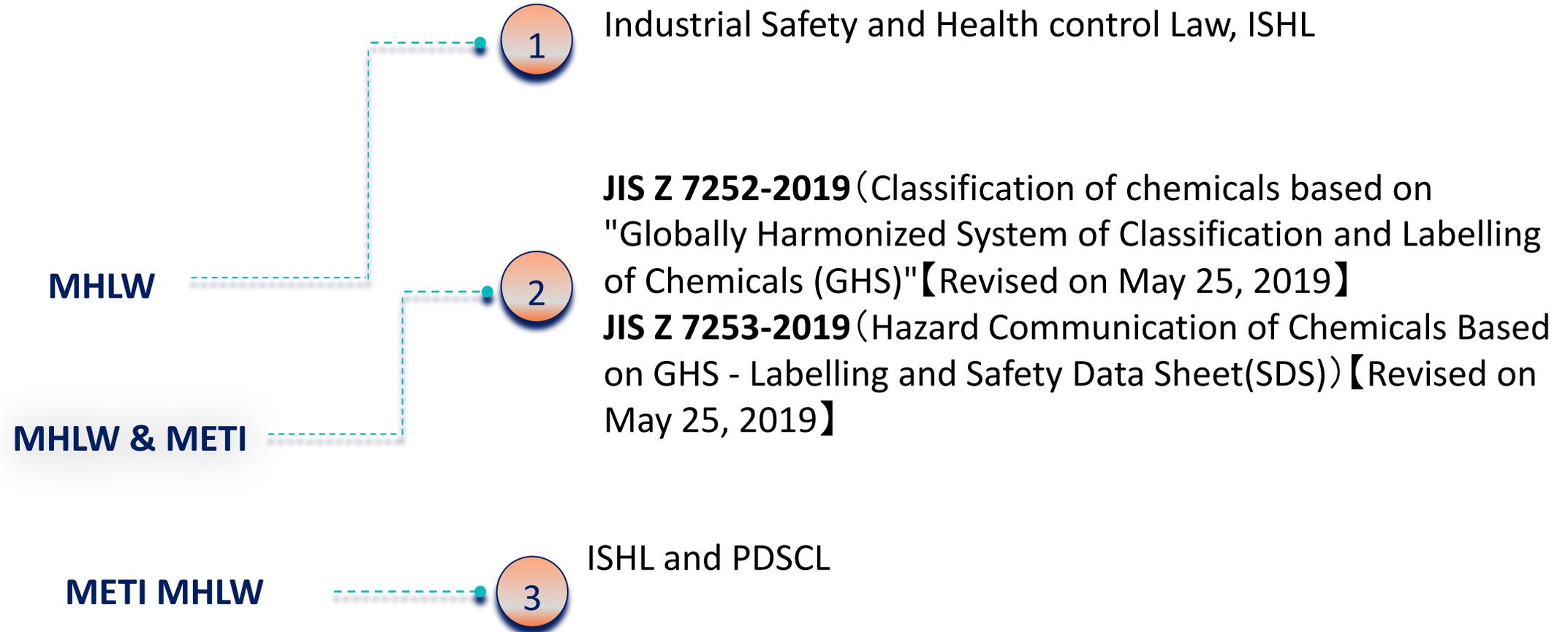


## Authority:

- MOE: Ministry of the Environment
- METI: Ministry of Economy, Trade and Industry
- MHLW: Ministry of Health, Labour and Welfare

## Laws:

- PRTR: Law concerning Pollutant Release and Transfer Register
- ISHL: Industrial Safety and Hygiene Law
- PDSCCL: Poisonous and Deleterious Substance Control Law



MHLW: Ministry of Health, Labour and Welfare  
METI: Ministry of Economy, Trade and Industry

# Japan GHS Scope

Regulation	Substances	SDS	Label
Law concerning Pollutant Release and Transfer Register (PRTR)	Class I: 515 substances Class II: 134 substances	Mandatory	Optional
Industrial Safety and Health Law (ISHL)	896 substances (2024.4.1)	Mandatory	Mandatory
	Other classified substances and mixtures	Optional	Optional
Poisonous and Deleterious Substances Control Law (PDSCL)	Toxic substances, hazard substances, etc.	Mandatory	Mandatory

The Japanese government has classified about 3,800 substances which are subject to SDS/Label. The classifications have been published on the NITE website.

- According to JIS Z7252:2019 for the classifications – **6<sup>th</sup> version of UN GHS**
- Using the classifications is not legally binding.
- The classifications are not always the same as the harmonised classifications of the CLP regulation.

# Useful information and tool for Classification

Name	Link
Classification by GHS related Ministries	<a href="http://www.safe.nite.go.jp/english/ghs/ghs_download.html">http://www.safe.nite.go.jp/english/ghs/ghs_download.html</a> (EN&JP)
GHS classification guidance	<a href="http://www.meti.go.jp/policy/chemical_management/int/files/ghs/h25ver1.1jenter_re.pdf">http://www.meti.go.jp/policy/chemical_management/int/files/ghs/h25ver1.1jenter_re.pdf</a> (JP)
The GHS Mixture Classification System (GHS ver4; JIS Z7252:2014;GHS Classification guidance )	<a href="http://www.meti.go.jp/policy/chemical_management/int/ghs_auto_classification_tool_ver4_EG.html">http://www.meti.go.jp/policy/chemical_management/int/ghs_auto_classification_tool_ver4_EG.html</a> (EN&JP) <b>*The System dose not classify Physical hazards automatically. Users have to enter the data on their own for Physical hazards. For the Health hazards and the Environmantal hazards, the System provides classification automatically.</b>
SDS/Label model	<a href="http://anzeninfo.mhlw.go.jp/anzen_pg/GHS_MSD_LST2.aspx">http://anzeninfo.mhlw.go.jp/anzen_pg/GHS_MSD_LST2.aspx</a> (JP)

# Japan - Recommended GHS Classifications

- National Institute of Technology and Evaluation (NITE) in Japan published recommended GHS classifications for 170 chemical substances.
- This is in accordance with JIS Z 7252: 2019 (Classification of chemicals based on the United Nations' GHS).
- Japan has already classified over 3,000 substances, which can be searched via(NITE-Gmiccs).
- These classifications can be used as references for companies when preparing labels and SDSs.
- Although there is no obligation for companies to indicate the same information on labels and SDSs in Japan, the government aims to make information more accurate through these classifications

CAS RN	物質名 (日本語)	備考	更新履歴
50-00-0	ホルムアルデヒド	再分類・見直し	v2_2023.06再分類
50-32-8	ベンゾ[a]ピレン	再分類・見直し	v2_2023.06再分類
51-28-5	2,4-ジニトロフェノール	再分類・見直し	v2_2023.06再分類
53-70-3	ジベンゾ[a,h]アントラセン	再分類・見直し	v2_2023.06再分類
56-55-3	ベンゾ[a]アントラセン	再分類・見直し	v2_2023.06再分類
57-41-0	5,5-ジフェニル-2,4-イミダゾリジジオン	再分類・見直し	v2_2023.06再分類
59-89-2	N-ニトロソモルホリン	再分類・見直し	v2_2023.06再分類
64-18-6	ギ酸	再分類・見直し	v2_2023.06再分類
71-43-2	ベンゼン	再分類・見直し	v2_2023.06再分類
75-08-1	エタンチオール (別名: エチルメルカプタン)	再分類・見直し	v2_2023.06再分類
75-65-0	tert-ブタノール	再分類・見直し	v2_2023.06再分類
76-12-0	1,1,2,2-テトラクロロ-1,2-ジフルオロエタン (別名: CFC-112)	再分類・見直し	v2_2023.06再分類
76-13-1	1,1,2-トリクロロ-1,2,2-トリフルオロエタン (別名: CFC-113)	再分類・見直し	v2_2023.06再分類
78-04-6	マレイン酸ジブチルスズ	再分類・見直し	v2_2023.06再分類
79-16-3	N-メチルアセトアミド	再分類・見直し	v2_2023.06再分類
80-09-1	4,4'-スルホニルジフェノール (別名: ビスフェノールS)	新規分類	v1_2023.06新規
80-46-6	4-tert-ペンチルフェノール	再分類・見直し	v2_2023.06再分類
84-74-2	フタル酸ジ-n-ブチル	再分類・見直し	v2_2023.06再分類
90-94-8	4,4'-ビス(ジメチルアミノ)ベンゾフェノン	再分類・見直し	v2_2023.06再分類
91-17-8	デカヒドロナフタレン	再分類・見直し	v2_2023.06再分類
91-97-4	3,3'-ジメチルヒフエニル-4,4'-ジイル=ジイソシアネート	再分類・見直し	v2_2023.06再分類
92-84-2	フェノチアジン	再分類・見直し	v2_2023.06再分類
93-83-4	(Z)-N,N-ビス(2-ヒドロキシエチル)オレアミド	再分類・見直し	v2_2023.06再分類
96-13-9	2,3-ジプロモ-1-プロパノール	再分類・見直し	v2_2023.06再分類
96-24-2	3-クロロ-1,2-プロパンジオール	再分類・見直し	v2_2023.06再分類
96-29-7	ブタン-2-オン=オキシム	再分類・見直し	v3_2023.06再分類
96-33-3	アクリル酸メチル	再分類・見直し	v3_2023.06再分類
99-87-6	p-シメン	再分類・見直し	v2_2023.06再分類
99-97-8	N,N-ジメチル-パラ-トルイジン	再分類・見直し	v2_2023.06再分類
101-80-4	4,4'-ジアミノジフェニルエーテル	再分類・見直し	v2_2023.06再分類
103-23-1	アジピン酸ビス(2-エチルヘキシル)	再分類・見直し	v3_2023.06再分類
103-24-2	ビス(2-エチルヘキシル)=アゼラード (別名: ノナン=酸ビス(2-エチルヘキシル))	再分類・見直し	v2_2023.06再分類
104-67-6	5-ヘプチルオキシソラン-2-オン	再分類・見直し	v2_2023.06再分類
104-76-7	2-エチル-1-ヘキサノール	再分類・見直し	v2_2023.06再分類
105-06-6	p-ジヒニルベンゼン	再分類・見直し	v2_2023.06再分類
105-95-3	1,4-ジオキサシクロヘプタデカン-5,17-ジオン	再分類・見直し	v2_2023.06再分類

- 1 Identification of the substance or mixture and the supplier
- 2 Hazard identification
- 3 Composition
- 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 information
- 14 Transport information
- 15 Regulatory information
- 16 Other

- 1 化学品及び会社情報
- 2 危険有害性の要約
- 3 組成及び成分情報
- 4 応急措置
- 5 火災時の措置
- 6 漏出時の措置
- 7 取扱い及び保管上の注意
- 8 ばく露防止及び保護措置
- 9 物理的及び化学的性質
- 10 安定性及び反応性
- 11 有害性情報
- 12 環境影響情報
- 13 廃棄上の注意
- 14 輸送上の注意
- 15 適用法令
- 16 その他の情報

## Section3: Composition

### ➤ PRTR:

- Indicate the 'designated chemical substances' name on SDS is legally binding.
- The percentages of 'designated chemical substances' in products is legally binding to indicate in two significant figures. (Example: 8% **X** ; 8.0% **O**)
- CBI :Attached as a separate sheet.

### ➤ ISHL:

- Indicate the 'substances listed on Table 3&9 'name on SDS is legally binding.
- Indicate the 'substances listed on Table 3&9 'name on Label is reasonable efforts according to the revision of the ISHL(Effective on June 1, 2016).
- CBI :Using product name, a range of percentages etc.

## Section3: Composition

### ➤ PDSCL:

- Indicate the 'poisonous or deleterious substances' name and its percentages on SDS /Label is legally binding.
- Label on container and at storage space as 'Poisonous' or 'Deleterious' by red character.

医薬用外毒物

医薬用外劇物

- CBI :Using a range of percentages(10-90% **X** ;10-20% **O**).

# Section8: Exposure controls/personal protection

How to check exposure limit values?

Japan Society for Occupational Health  
(日本産業衛生学会)

<http://www.sanei.or.jp/>

The screenshot shows the homepage of the Japan Society for Occupational Health (JSOH). The header includes the organization's name in Japanese and English, and a navigation menu with links for '学会概要', '入会案内', '定款・規定', '産業保健専門職の倫理指針', and 'リンク'. Below the header is a login section for members, followed by a 'コンテンツ' (Content) menu. The 'コンテンツ' menu is expanded, showing various categories like 'English', '行事', '話題', '報告', '情報検索', '部会コーナー', 'J Occup health', '産業衛生学雑誌', 'Occupational Exposure Limits', and 'よくある質問'. A red arrow points to the '産業衛生学雑誌' link, which is highlighted with a red box. The main content area on the right features a blue banner with a message about disaster response and a '更新履歴' (Update History) section listing recent updates with dates and descriptions.

## Section15: Regulatory information

### ➤ JICA (Japan Chemical Industry Association)

#### GHS compliance guidelines:

- PRTR(化管法)
- ISHL(安衛法)
- PDSCL(毒劇法)
- Explosives Control Law(火薬類取締法)
- High Pressure Gas Safety Law(高压ガス保安法)
- Fire Defense Law(消防法)
- CSCL(化審法)
- Ships Safety Law(船舶安全法)
- Marine Pollution Prevention Law(海洋汚染防止法)

### ➤ Recommended to list in section 15 if relevant:

- Air pollution control Law(大気汚染防止法);
- Water pollution control Law(水質汚濁防止法);
- Food Sanitation Law(食品衛生法)
- Pharmaceutical Affairs Law(薬事法) etc.



# When/How to provide SDS

- **How to provide SDS**

- SDS can be provided in hard copy or digital format. A supplier can provide an SDS by fax, e-mail or by placing directly on a supplier's website, if the recipient agrees.

- **When to provide SDS**

- SDS must be provided before supplying the product which includes the specified substances.
- The supplier of the SDS must provide the recipient with an updated SDS promptly if there are amendments to the SDS.

# FAQ



03

- **Is it necessary to prepare the SDS/Label for testing sample?**
  - Yes, if the testing sample including the subject substances under the PRTR, ISHL or PDSCL.
- **If the container is too small to stick the label, how to do it?**
  - In Japan, there are no regulations for label size and simplified label.
  - Tie with tag(label).
- **Is it possible to stick the label on the outer package with 10 containers in it?**
  - Label must be stick on each container.
- **Is it necessary to prepare the SDS/Label for medical diagnostic agent (example:30% formalin- Specific Class I)?**
  - Yes, there are no exemption provision depending on use under PRTR.

METI Q&A: [http://www.meti.go.jp/policy/chemical\\_management/law/qa/3.html](http://www.meti.go.jp/policy/chemical_management/law/qa/3.html)

MHLW Q&A: <http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000124297.html>

# THANKS !

[www.cirs-group.com](http://www.cirs-group.com)

## CIRS Service



EU REACH



UK REACH



China Chemical Management



Korea REACH



Taiwan TCSCA



Global GHS



Training & Testing

## Why CIRS



4000+ global SDS & Label every year



3000+ K-REACH pre-registration



2000+ EU REACH registration



2000+ China REACH typical notification



Designed TPR(Third Party Representative) service



Full one-stop compliance service in China



Customized on-site/online training service



LinkedIn

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