



GLOBAL REGULATORY
COMPLIANCE



Chemical Compliance

Asia Guide - Taiwan

Hazardous Chemicals and Dangerous Goods Expert, GBK China



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Guide Development Team Introduction

What is GBK China?



GBK China

Regulatory Compliance Consultant

GBK GmbH Global Regulatory Compliance was founded in 1986, Germany, specialising in hazardous chemicals and dangerous goods compliance consulting with over 30 years industrial experience.

GBK China established its branch office in Shanghai, focusing on the consultancy business in Asia-Pacific region as China, Japan, Korean, etc.



Guide Development Team Introduction

Why you can believe us

750+

Global Partners & Customers

BMW, L'Oreal, Schneider...

12+

Countries We Do

Japan, Singapore, Australia...



Competitiveness
Experience
Reliability



10+

Type of Our Services

24h Emergency Telephone,
GHS and SDS Consulting,
Company Training ...

And...

- **Seats We Hold**
Members or counsellors in
FIATA, ESMCG, SCBA...
- **Services Online**
Live broadcast, webinar,
weekly compliance report...



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#01

Taiwan GHS

Hazard Chemicals

GHS in Taiwan is being implemented in four stages, with the Ministry of Labor (MoL) having published three lists of hazardous substances subject to GHS compliance.



#01 Taiwan GHS

GBK - Your Hazardous Chemicals and Dangerous Goods Compliance Consultant

Regulations

01

Classification - *Classification and Labelling of Chemicals – General Rules (CNS 15030); The CNS 15030 serial standards (CNS 15030-1 to 15030-27)*

02

Scope - *Regulation of Labelling and Hazard Communication of Hazardous Chemicals (Nov 9th, 2018)*

03

Additional - *Taiwan's Occupational Safety and Health Act*



#01 Taiwan GHS

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GHS 1+1

SDS and Label

Manifestations of GHS Hazard Communication

Required

Taiwan's GHS is managed by [two departments](#) due to the different regulatory scope, the Ministry of Labour (MoL) and the Environmental Protection Administration.

However, [all hazardous chemical](#) in the list should have GHS classification and label.

SDS/MSDS

Safety Data Sheets (SDS)

1. SDS should be completed in accordance with the relevant document - [Content and Template for Safety Data Sheet.doc](#)
2. The text for the SDS shall be primarily in [Chinese characters](#), and if necessary, foreign languages can be the supplement for workers to understand

Label

1. [Hazard pictograms](#) must be included
2. [Contents](#): Name; hazardous ingredients; signal words; hazard statements; precautionary statements; name, address, and telephone number of manufacturer, importer or supplier



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GHS Exemptions Scope

1. Industrial waste
2. Tobacco or tobacco products
3. Food, beverages, drugs, cosmetics
4. Manufactured articles
5. General domestic consumer products not for industrial uses
6. Fire extinguishers
7. Intermediate products undergoing chemical reactions in reactors or processes
8. Others designated by the central competent authority

Mandatory Classification List

https://ghs.osha.gov.tw/CHT/masterpage/index_CHT.aspx



#02

SDS Withholding

Product Security and Confidentiality Measures

Taiwan allows manufacturers/importers to apply for a withholding disclosure of SDS if there are ingredients in the product that involve trade secrets or national security.



#02 Taiwan SDS Withholding

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Informations can apply to withhold the disclosure

Ingredient Name

Official component name of the hazardous chemical which requiring confidentiality



CAS Number

CAS number of the ingredients requiring confidentiality

Ingredient Concentration

Concentrations of hazardous chemical ingredients in the product/mixture



Manufacturer, Importer, or Supplier Name

Name of the company/responsible person who needs this application



#02 Taiwan SDS Withholding

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01

Chemicals Affecting Worker Safety

Workplaces allowed to expose the chemical substances listed in the standard.

02

Substances Under the CNS15030 Classification

- Acute toxicity (category 1, 2, 3)
- Skin corrosion or irritation (category 1)
- Serious eye damage/eye irritation (category 1)
- Respiratory and skin sensitization
- Germ cell mutagenicity
- Carcinogenicity
- Reproductive toxicity
-

03

Specified Chemical Substances

Other hazardous chemical substances designated or announced by the local competent authority in Taiwan that are not applicable to the withholding disclosure application.

Hazardous chemical ingredients **excluded** from Taiwan protection provision



#03

Chemical Registration

Chemical Substance Control Law

Both existing and new chemical substances should be registered when entering Taiwan. Substances not listed in the Existing Chemical Substance Inventory (Taiwan ECSI) are new chemical substances.



#03 Taiwan Chemical Registration

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Main Regulations

Chemical Substances Control Law



Taiwan Toxic and Chemical Substances of
Concern Control Act (TCCSCA) - New and Existing
Chemical Substances Management

Taiwan's Occupational Safety and Health Act
(OSHA) - New Chemical Substances Management





#03 Taiwan Chemical Registration

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Registration Body

The Only representative (OR) rules is **not adopted** in Taiwan.

1. Taiwan local applicants can either register **directly** or appoint a **Third-Party Representative** (TPR)
2. **Foreign applicants cannot** submit the registration themselves or appoint OR
3. The (potential) local Taiwan importer **must** register the substance

Exemptions Scope

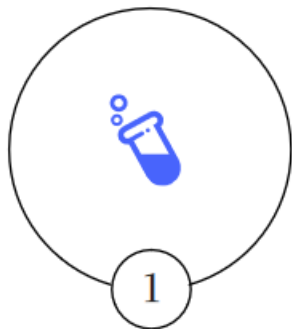
1. Substances which **occur in nature**
2. Chemical substances in machines **for test run purposes**
3. **Inseparable intermediates** from chemical reactions in the reaction vessel or production process
4. Chemical substances for **national security / defense**
5. Chemical substances **under customs supervision**
6. **Chemical wastes**
7. **By-products or impurities** with no commercial use
8. Mixtures (but individual constituents of mixtures still need the registration)
9. Polymers that the 2% Rule is Applicable and listed on the inventory of existing chemical substances



#03 Taiwan Chemical Registration

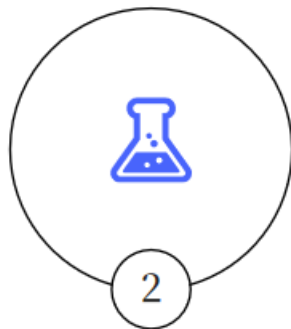
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Existing Chemicals Registration Management



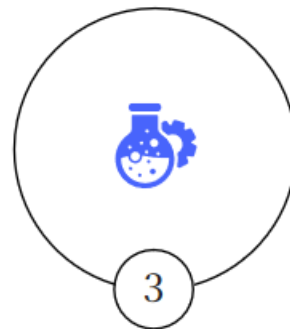
2015.09.01 - 2016.03.31

Phase 1 Registration
(Pre-registration)



After 2016.03.31

Phase 1 Registration
(Late Pre-registration)



2020.01.01 - 2022.12.31

Phase 2 Registration
First batch of priority existing
chemical (PEC) substances
published (106 in 27000)

All existing chemical substances
manufactured or imported at
 ≥ 100 KG per year

All PEC ≥ 1 ton per year should be registered



#03 Taiwan Chemical Registration

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New Chemicals Registration Type

	0.1 t/y	1 t/y	10 t/y	100 t/y	1000 t/y
CMR Substances	Standard Registration Level 1	Level 2	Standard Registration + Hazard & Exposure Assessment Level 3	Level 4	
Regular New Chemical Substances	Small Quantity Registration	Simplified Registration	Standard Registration Level 1	Standard Registration + Hazard & Exposure Assessment Level 2	Level 3 Level 4
On-site Intermediate Substance	Small Quantity Registration	Simplified Registration	Standard Registration Level 1		
Product & Process R&D Usage	Small Quantity Registration	Simplified Registration	Standard Registration Level 1		
Science R&D Usage		Simplified Registration	Standard Registration Level 1		
Polymer	Small Quantity Registration	Simplified Registration	Standard Registration Level 1		
Polymer of Low Concern				Small Quantity Registration	



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www.gbk-china.com vicky.yao@gbk-china.com

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