Worldwide Registration



Summary and Look Ahead of Chemical Substance Regulation under Taiwan TCSCA/OSHA



CONTENTS



- 01 Registration of New/Existing Chemicals in Taiwan
 - New Guidance Documents and Strategic Remarks

02 GHS Implementation in Taiwan

-In Comparison with Hazards Management in Other Asia Countries/regions



Registration of New/Existing Chemicals in Taiwan

- New Guidance Documents and Strategic Remarks

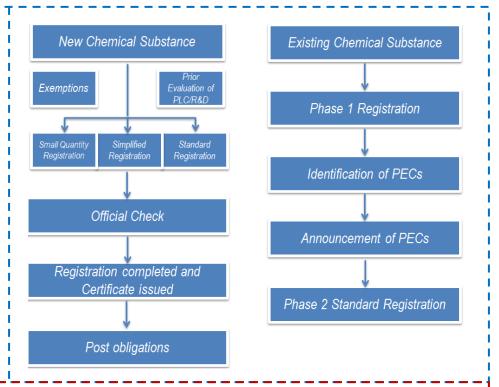


Brief Introduction and Overview of the New/Existing Chemical Registration Scheme



Brief Introduction of Basic Concepts, Registration Scheme and Procedure

Official Name	Regulation of New and Existing Chemical Substances Registration(TCSCA Regulation of Registration)	
Authorized by	TCSCA Article 7-6	
Applicable Scope	New Chemical Substance Existing Chemical Substance	
Competent Authority	EPA's Department of Environmental Sanitation and Toxic Substance Control	
Official Name	Regulations on New Chemical Substances Registration(OSHA Regulation of Registration)	
Authorized by	OSHA Article 13	
Applicable Scope	New Chemical Substance	
Competent Authority	MOL/OSHA	





Receipt of **Materials**



Technical

Review









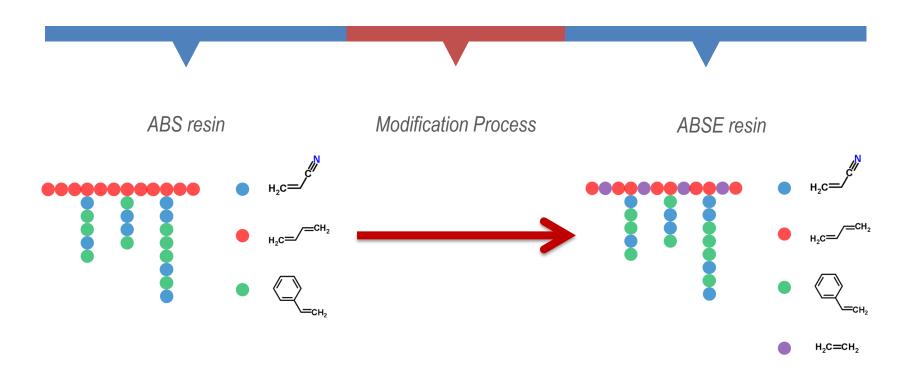
www.knoell.com



2% polymer principle



Further Interpretation and Clarification on 2% Polymer Principle



Registration strategy for ABSE resin?



Identification information requirements



Determination of Registration Type and Keynote Points on New Data Requirements

MT/y	Polymer of Low Concern	Substance for SRD ¹	On-site Isolated Intermediate; Polymer; Substance for PPORD ²	Regular New Chemical Substance	CMR ³
0	Drior Ev	aluation	Small Quantity Posistration	Small Quantity Registration	Standard Registration
0.1	PIIOI EV	aluation	Small Quantity Registration	Simplified Registration	(Level I)
1		Sir	nplified Registration	Standard Registration (Level I)	Standard Registration (Level II) ++ ⁴
10	Small			Standard Registration (Level II) ++4	Standard Registration (Level III) ++4
100	Quantity Registration	Standard Registration		Standard Registration (Level III) ++4	Standard Registration
100				Standard Registration (Level IV) ++4	(Level IV) ++4

¹ SRD: Scientific Research and Development.

² PPORD: Product and Process Orientated Research and Development.

³ CMR: Substance of Carcinogenic, Mutagenic or Toxic to Reproduction.

⁴ ++: plus Hazard Assessment and Exposure Assessment.



General Introduction on the Data Requirements

Simplified Registration

Small Quantity Registration

- ✓ Basic registrant & substance identification information
- ✓ Substance manufacture & use information

- ✓ Basic registrant & substance identification information
- ✓ Substance manufacture & use & exposure information
- ✓ Hazard classification & labeling element
- ✓ Safe use information
- ✓ Physicochemical properties

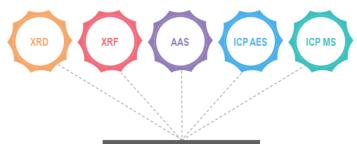
Standard Registration

- Basic registrant & substance identification information
- ✓ Substance manufacture & use & exposure information
- ✓ Hazard classification & labeling element
- ✓ Safe use information
- ✓ Physicochemical properties
- ✓ Toxicological properties
- ✓ Eco-toxicological properties
- ✓ Hazard assessment
- ✓ Exposure assessment

Dr. Knoell Consult Shanghai Co. Ltd

Further Interpretation and Clarification on Requirements for Spectrum, PC, Health and Environmental Data

	General Requirements for Spectrum(general new chemical, non-polymer)					
	Small Quantity Registration	Simplified Registration	Standard Registration			
Structure/ Chemical Group No specific spectrum requirement but provided spectrum should sufficient for typical structure/chegroup identification		IR, UV-Vis and (NMR/MS)	IR, UV-Vis and (NMR/MS)			
X	Specific spectrum	will be required by authority if ne	cessary			
Purity	3001 -		HPLC/GC			
2 CO	General Requirements for Spectrum(general new chemical, polyme	r)			
0.00	Prior Evaluation of PLC	Small Quantity Registration	Simplified Registration/ Standard Registration			
PLC	GPC	GPC and (IR/NMR)				
General New Polymer	W /	GPC and (IR/NMR)	GPC, IR and NMR			



Recommended spectrum for the identification of inorganic chemical substances



Practical experiences sharing for certain endpoints

Dr. Knoell Consult Shanghai Co. Ltd		Simplified		Standard R	egistration k		rldwide stration
	Physicochemical Properties	Registration	Band 1	Band 2	Band 3	Band 4	
1	Physical state	0	0	0	0	0	
2	Melting/freezing point	0	0	0	0	0	
3	Boiling point	0	0	0	0	0	
4	Density	0	0	0	0	0	
5	Partition coefficient: n-octanol/water	0	0	0	0	0	
6	Water solubility	0	0	0	0	0	
7	Vapor pressure		0	0	0	0	
8	Flash point		0	0	0	0	
9	Flammability		0	0	0	0	
10	Explosiveness		0	0	0	0	
11	Oxidation properties		0	0	0	0	
12	pH value		0	0	0	0	
13	Auto-ignition temperature		0	0	0	0	
14	Viscosity				0	www.knoell	com
15	Corrosiveness to metals				0	0	14

Dr. Knoell Consult Shanghai Co. Ltd



		Simplified		Standard R	Registration	
	Toxicological Properties	Registration	Band 1	Band 2	Band 3	Band 4
1	Acute toxicity		0	0	0	0
2	Skin corrosion/irritation		0	0	0	0
3	Eye irritation		0	0	0	0
4	Skin sensitization		0	0	0	0
5	Gene toxicity		0	0	0	0
6	Basic toxicokinetics				•	
7	Repeated dose toxicity: oral, inhalation, dermal			0	0	0
8	Reproductive/developmental toxicity			0	0	0
9	Carcinogenicity					•

Note: "

"means that testing proposal can be submitted instead of the complete test report

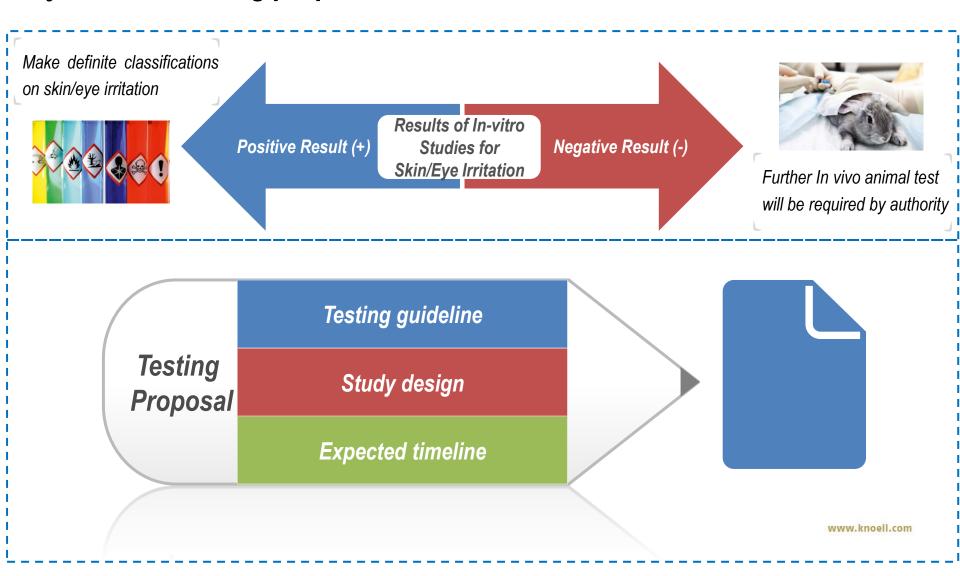
Dr. Knoell Consult Shanghai Co. Ltd



	Eco-toxicological Properties	Simplified	,	Standard F	Registration	l
		Registration	Band 1	Band 2	Band 3	Band 4
1	Short-term toxicity to invertebrate (daphnia)		0	0	0	0
2	Toxicity to aquatic algae and cyanobacteria		0	0	0	0
3	Biodegradation in water: screening tests		0	0	0	0
4	Short-term fish toxicity			0	0	0
5	Hydrolysis			0	0	0
6	Toxicity to microorganisms					
7	Adsorption/desorption					
8	Long-term toxicity to invertebrate (daphnia)				•	•
9	Long-term fish toxicity					
10	Toxicity to soil macroorganisms except arthropods					•
11	Toxicity to terrestrial plants					
12	Toxicity to soil microorganisms					
13	Biodegradation in water and sediment: simulation tests					•
14	Biodegradation in soil					
15	Bioaccumulation: aquatic/sediment					
16	Sediment toxicity				www.k	noell.com



Keynotes for testing proposal and alternative studies





Qualified labs

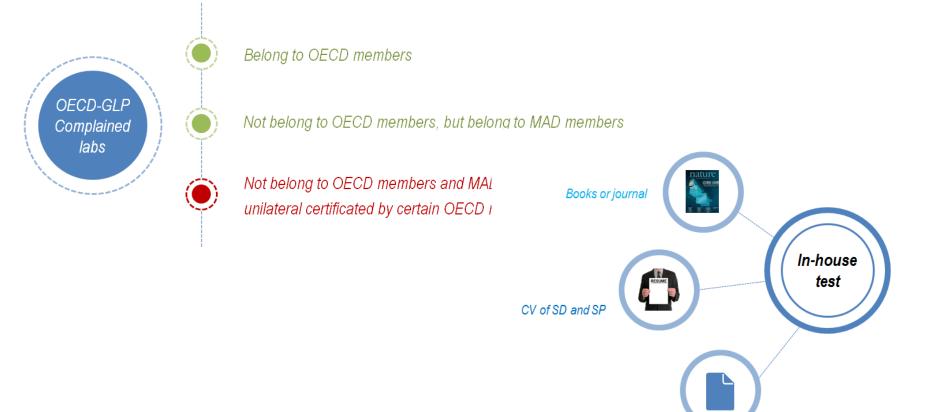


Authorized Testing Facility for Chemical Substance Registration

	PC properties/Spectrum	Toxicological	Eco-toxicological
(in-house test)		×	*
150 17025 17025			*
OECD GLP Compliant			
GLP Compliance			



Further Interpretation and Clarification on "Qualified" Labs



Internal SOP



Hazard assessment and exposure assessment



New Requirements on Hazard Assessment and Exposure Assessment

		Simplified	Standard Registration			
	Hazard Assessment Registrat		Band 1	Band 2	Band 3	Band 4
1	HUMAN HEALTH HAZARD		\circ			
` I	ASSESSMENT		U	•		
	HUMAN HEALTH HAZARD					
2	ASSESSMENT OF PHYSICO-		0	•	•	•
	CHEMICAL PROPERTIES					
2	ENVIRONMENTAL HAZARD		0			
3	ASSESSMENT		O	•		
4	PBT AND vPvB ASSESSMENT		0	•	•	
		Simplified		Standard F	Registration	
	Exposure Assessment	Registration	Band 1	Band 2	Band 3	Band 4
1	Exposure scenario		0	•	•	•
2	Exposure estimation		0	•	•	•
3	RISK CHARACTERISATION		0	•	•	www.knoell.co

a knoell company

表 2.1.1 危害物質之分類表註

類型	種類	級別
物化特性危害	爆炸物	1.1 組 有整體爆炸危險之物質或物品。
	爆炸物	1.2 組 有拋射危險,但無整體爆炸 危險之物質或物品。
	爆炸物	1.3 組 會引起火災,並有輕微爆炸
		或 加州公司 巴巴 體爆炸危險之物質或 物品。
h	azards	1.4 組 無重大危險之物質或物品。
	爆炸物	1.5 組 很不敏感,但有整體爆炸危
		險之物質或物品。
N C	o designated h	neath mazard
	assifications	不穩定爆炸物
Cl	る S M M M M M M M M M M M M M	第 1 級
	易燃氣體	第 2 級
N Co	^{易燃息} signated 6	* viçonmental
h	Zato classifica	tions
	且做治験	第 7 級



Supporting material for hazard assessment & exposure assessment







Draft version available

Scenarios under which exposure assessment can be exempted



Re-definition of "official review time"



Comparison on the Review Timeline for Authority







Glance at review time required by authority

Standard Registration: 45WD Simplified Registration: 14WD Small Quantity Registration: 7WD

Glance at supplementary time limited to registrant

The registratant is required to complete supplementary within 30WD, the application **shall be rejected** if the registrant fails to make supplementation within the allotted time.

Glance at review time required by authority

Standard Registration: 45WD(new chemicals); 90WD(PECs)

Simplified Registration: 14WD Small Quantity Registration: 7WD

The authority will **reclock the review time** after the applicant

make their supplementation.

Glance at supplementary time limited to registrant

The registratant is required to complete supplementary within 30WD, if the registrant is not able to make supplementation within the allotted time, they shall issue document to authority and ask for a longer correction time.



CBI protection

knoell

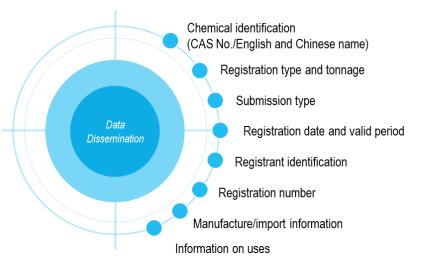
Brief Introduction on the Information Dissemination Platform



Following four items could be protected as CBI:

l	資料保密申請費			
İ	□是■否申請登錄保密			
ł	項目	金額(新臺幣)		
l	一、登錄人資料	□12,500		
l	二、化學物質辨識資料	□12,500		
H	三、化學物質製造或輸入資訊	□12,500		
l	四、化學物質用途資訊	□12,500		
İ	總計			

Detail of the data for publication if with no CBI application:





Validity of confidentiality for Different Registration Types

Registration Types	Current	Upcoming
Standard Registration	5	5
	(extension applicable, no more than 15 years)	(extension applicable, no more than 15 years)
PLC SQR	2	5
	(extension applicable, no more than 15 years)	(extension applicable, no more than 15 years)
General SQR	2	2
	(extension applicable, no more than 15 years)	(extension applicable, no more than 15 years)
Simplified Registration	2	2
	(extension applicable, no more than 15 years)	(extension applicable, no more than 15 years)
Substance include into TCSI 5		5
	(extension applicable, no more than 15 years(EPA), 10years(MOL))	(extension applicable, no more than 10 years(EPA), 10years(MOL))



Post-obligations



Post Obligations for Chemicals Completed the Registration

For chemical applied for PLC SQR and standard registration with exposure assessment, registrant can apply for TCSI include immediately after the obtain of certificate!



For chemical applied for PLC SQR and standard registration, after 5 years, it will be listed into TCSI automatically



Annual reporting

Applied to both new and existing chemical substances;

Open for acceptance of annual reporting periods from Mar. 1st to June 30th each year

Supporting tool and guidance

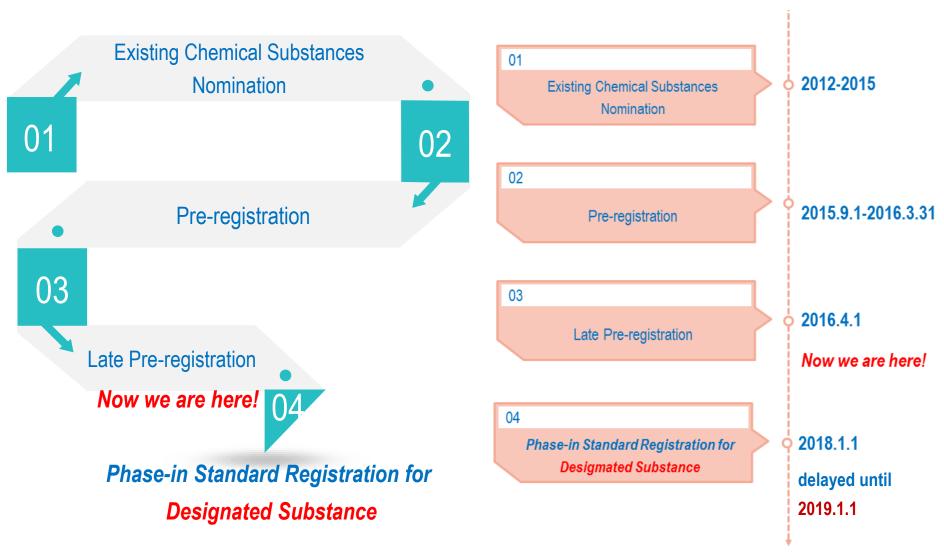
Supporting tool and materials will be available from Jan. 1st, 2019



Progress of PECs registration



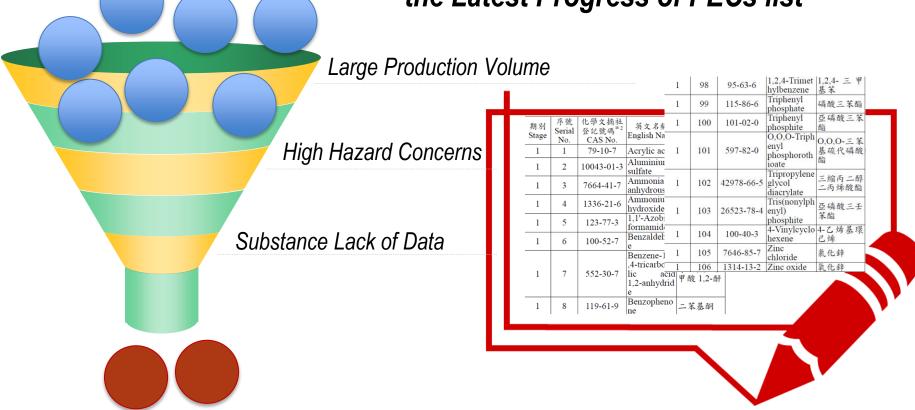
Registration Scheme of Existing Chemical Substance





Existing Chemical Substances







Criteria for Designated Substance and the Latest Progress of PECs list

Pilot project

Detail prioritization cirteria
Plan for regulation scheme of PECs

Opinions solicit and communication

Knoell communicate with on behalf of enterprise intrest





1st draft list of PECs

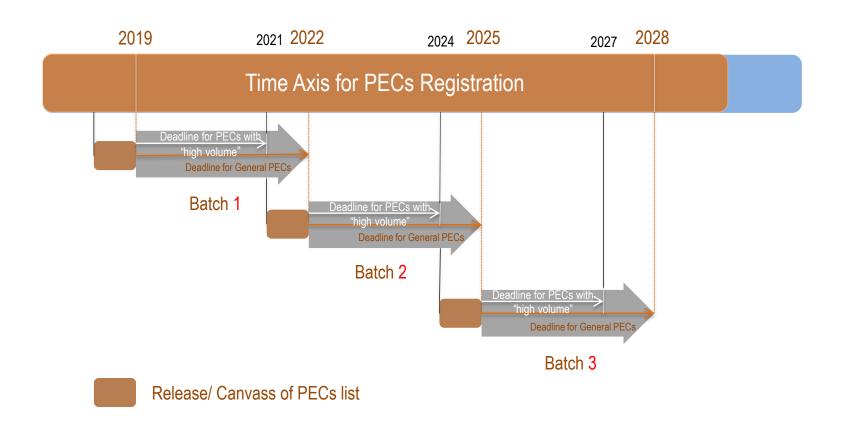
Issued in June 9, 2017 Including 122 chemicals

2nd draft list of PECs

Issued in Mar. 27, 2018 Including 106 chemicals



Phase-in Registration Scheme for PECs





Schedule and strategy of interagency supervision



Supervision System

- Fine: NT\$30,000 to NT\$300,000;
- Repeated infringement: business suspension or returned export

Penalties

platform

- New Chemical Substance
 - Fine: NT\$200,000 to NT\$2,000,000;
 - Repeated infringement: business suspension or returned export.

Existing Chemical Substant.

Currently, CCIP is voluntary, but it will serve as a basis for postmarket inspection.
The inspection of Taiwan EPA will focus on those who didn't provide information on CCIP platform.



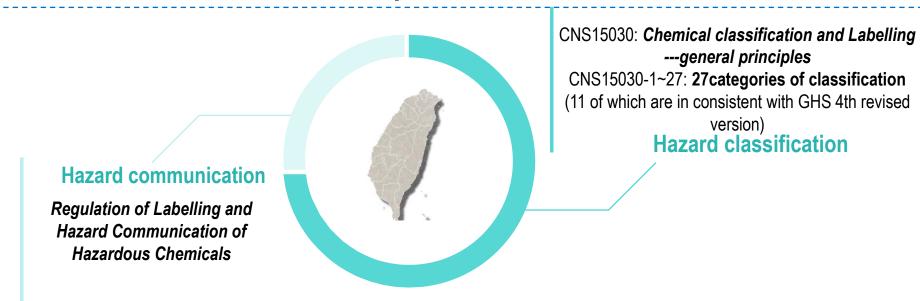


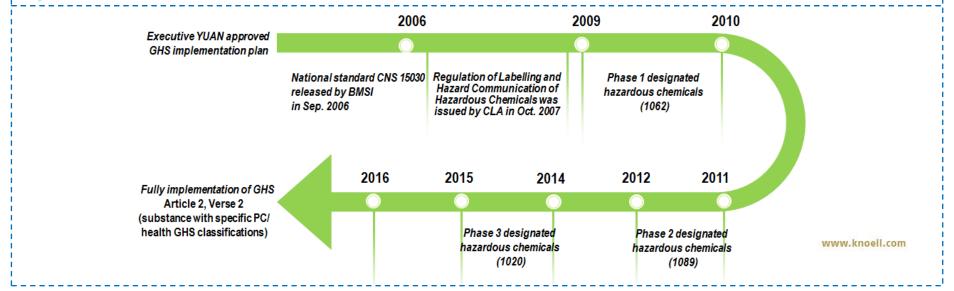
GHS Implementation in Taiwan

–In Comparison with Hazards Management in Other Asia Countries/regions



Brief Introduction of the GHS Implementation in Taiwan







Brief Introduction of the GHS Implementation in Mainland China



Hazard classification

Classification

28 Hazard Classes

GB 30000.2~30000.29-2013

(UN GHS rev 4)

From Nov. 1, 2014

Inventory of Hazardous Chemicals (2015)

- new version, 2828 substances

Guidance of the Inventory (C&L)

Issued Aug 19, 2015

Hazard communication

SDS

SDS Guidance

GB/T 17519-2013 From Jan. 1, 2014

Label/Packaging

Label:

GB 15258-2009

Packaging:

GB 190-2009

GHS-Related Regulations/Measures in China

Hazard Identification & Classification	Implementation Guidance of the Inventory Physical Hazard Identification and Classification (SAWS Order 60)
Registration	HazChem Registration (SAWS Order 53); New Chemical Substance Registration (MEP Order 7)
Administrative Licensing	 Safe Manufacturing Permit (<u>SAWS Order 41</u>); Safe Operation Permit (<u>SAWS Order 55</u>); Safe Use Permit (<u>SAWS Order 57</u>)
Entry-Exit Inspection & Quarantine	Statutory Check: Declaration of conformity, inhibitor/ stabilizer info, GHS labels and SDSs in Chinese, etc. (AQSIQ Announcement 30 of 2012) www.knoell.com



Brief Introduction of the GHS Implementation in Japan



Hazard classification

2009: JIS Z7252-2009 (consistent with GHS 3id revised version);

2014.3.25: JIS Z7252-2014 (consistent with GHS 4th revised version)

2005: JIS Z7250-2005 (consistent with GHS 1st revised version)

2010: JIS Z7250-2010 (consistent with GHS 3id revised version) 2006: JIS Z7251-2006 (consistent with GHS 1st revised version)

2010: JIS Z7251-2010 (consistent with GHS 3id revised version)

National Standard JIS Z 7253 (Hazard communication of chemicals based on GHS-Labelling and Safety Data Sheet (SDS))

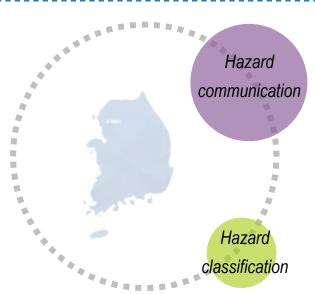
(Integrate former JIS Z 7250 and JIS Z7251, to add information about workplace labelling, and to be consistent with GHS 4th revised version).

Hazard communication

GHS-related regulation	Applicable scope	SDS	Label
ISHL	640 substances (Critical value)	Compulsory(risk evaluation)	compulsory
	10 hazardous substances	Not compulsory	Not compulsory
PRTR	First phase: Specific chemical substances(462) Second phase: Specific chemical substances(100)	compulsory	Substances: from 01/6/2012; Mixtures: from 01/4/2015.
PDSCL	Poisonous substances (110) Deleterious substances (373)	compulsory	compulsory



Brief Introduction of the GHS Implementation in South Korea



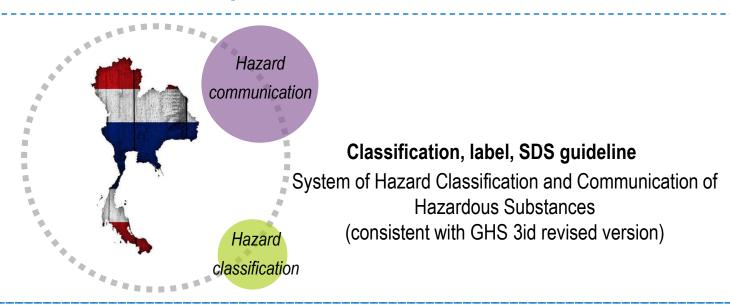
Classification, label, SDS guideline

MOEL Public Notice No. 2016-69 (consistent with GHS 4th revised version)

GHS-related regulation	Competent authority	Classification	Transitional period
K-REACH and CCA	MOE	Compulsory http://ncis.nier.go.kr/ghs/hcs/en/search/search_en_01.jsp	Substance: 2011.7.1 Mixture: 2013.7.1 New Substance: 2008.7.1
ISHA	MOL	Voluntary http://msds.kosha.or.kr/kcic/english/msdssearch.do	Substance: 2010.7.1 Mixture: 2013.7.1



Brief Introduction of the GHS Implementation in Thailand



Department

DIW, DLPW, MOT, DOA, FDA

GHS related laws and regulations

Hazardous Substance Act B.E. 2535 (1992), revised twice: B.E. 2544(2001) and B.E. 2551(2008).

BE 2555 (2012) Based on 3rdrevised version of GHS

Period of execution

Phase 1: (substance) one year after release of regulation (13/03/2013)

Phase 2: (mixture) five years after release of regulation (13/03/2017)

www.knoell.com



Supporting materials for hazard classifications and hazard communications in different Asia regions

Regions	Classification	SDS	Label	
Taiwan	CNS 15030 series (bases on UN GHS Rev. 2&4)	Regulation of Labelling and Hazardous		
China Mainland	GB 30000 series (bases on UN GHS Rev. 4)	GB/T 16483-2008 GB/T 17519-2013	GB/T 15258-2009	
South Korea	MOEL Public No	otice 2016-69 (bases on UN GF	IS Rev. 4)	
Japan	JIS Z 7252-2014 (bases on UN GHS Rev. 4)	JIS Z 72	53-2012	
Thailand B.E. 2555 (2012) (bases on UN GHS Rev. 3)				



Comparison on the classification in different Asia regions---Building block principle

GHS	Category		UN GHS	Taiwan	China Mainland	Japan	South Korea	Thailar	nd			
	Acute Tox. 3	Derm Inhalat	GHS Cat	egory	Sub-	category	Taiv	van (China Mainland	Japan	South Korea	Thailand
Acute toxicity	Acute Tox. 4	Ora Derm			Flan	n. Gas 1	٠,	,	√	4	√	4
Acute toxicity		Inhalat	E1		Flan	n. Gas 2	٠,	/	√	√	√	√
	Acute Tox. 5	Ora Derm	Flammable	Flammable gases	Chem. l	Jnst. Gas A	×		√	4	×	4
		Inhalat			Chem. l	Jnst. Gas E	3 ×		√	√	×	4
	Skin Corr. 1	1			Flam. A	Aerosols 1	~	/	4	4	1	4
Skin		1A 1B	Flammable aerosols	Flam. A	Aerosols 2	~	1	√	4	√	4	
corrosion/irritation		1C			Flam. A	Aerosols 3	×		✓	√	×	4
	Skin Ir		Oxidising	gases	Ox	Gas 1	~	1	1	4	1	4
		Skin Irrit. 3				essed gas	~	/	√	4	4	4
	Eye Da				Liqui	ified gas	٠	/	√	√	√	1
Serious eye	_,	2 2A	Gases under pressure	Refr	igerated	٠	/	1	4	1	4	
damage/irritation		2B			Disso	lved gas	٧	/	√	√	1	4
		1			Flan	1. Liq. 1	~	1	4	4	1	4
	Resp. Sens. 1	1A	E	Flan	n. Liq. 2	٠	/	√	√	√	√	
Respiratory or skin sensitisation		1B	riammable	Flammable liquids	Flan	n. Liq. 3	٠	,	√	1	√	4
sensitisation	Skin Sens. 1	1 1A			Flan	n. Liq. 4	_	,	1	1	×	1
	OMIT OCTIO. I	1B	1	×	1	1	×	1				•



Comparison on the classification in different Asia regions--Official Classification guideline/inventory

Regions	Official Classification guideline/inventory
Taiwan	OSHA GHS
China Mainland	Inventory of Hazardous Chemicals (2015) Guidance of the Inventory (C&L)
South Korea	MOE Classification List MOEL Classification List
Japan	NITE-CHRIP
Thailand	DIW Classification List



Comparison on the classification in different Asia regions--Take Formaldehyde as example

Formaldehyde

Molecular Formula CH₂O

Average mass

Da



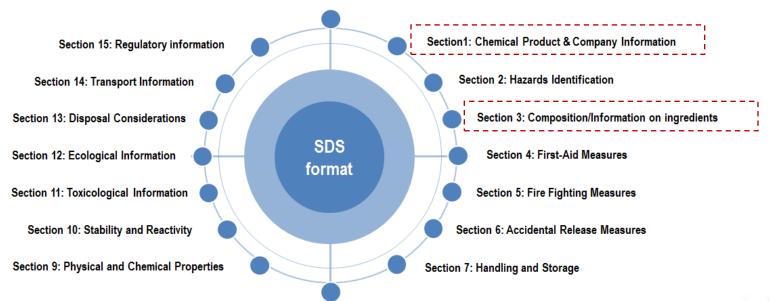
	GHS Category	EU	Taiwan	China Mainland	Japan	South Korea	Thailand
	Flam. Gas	1	1	1	1	1	1
	Flam. Liq.	1	3	1	4	1	4
CH ₂ O	Acute Tox. Oral	3	3	3	4	3	4
CH2O	Acute Tox. Der.	3	3	3	3	3	3
30.026	Acute Tox. Inhal.	3	2	3	2	2	2
	Skin Corr. / Irrit.	1B	1	1B	2	1	2
	Eye Dam. / Irrit.	1	1	1	2A	1	2A
	Resp. Sens.	1	1	1	1	1	1
	Skin Sens.	1	1	1	1	1	1
	Muta.	2	2	2	2	1	2
	Carc.	1B	1	1A	1A	1	1A
	STOT-SE	1	1	3	1	1	1
	STOT-RE	1	1	1	1	1	1
	Repro-Tox	1	1	1	1	1	1



Elements of SDS and Noteworthy Points

Regions	Language	Format
Taiwan	Traditional Chinese	16-GHS
China Mainland	Simplified Chinese	16-GHS
South Korea	Korean	16-GHS
Japan	Japanese	16-GHS
Thailand	Thai	16-GHS

Section 16: Other information





Elements of SDS and Noteworthy Points

A Section1:
Chemical Product & Company
Information

Eemergency Phone

Taiwan: Required

Mainland: Required with specified

requirements

South Korea: Required

Japan: Required

Thailand: Required (Indicate the limited

time)

Section 3: Composition/Information on ingredients

Claim confidentiality for GHS-classified ingredients

Taiwan: Not available for ingredients with certain GHS-classifications

Mainland: Available South Korea: Available

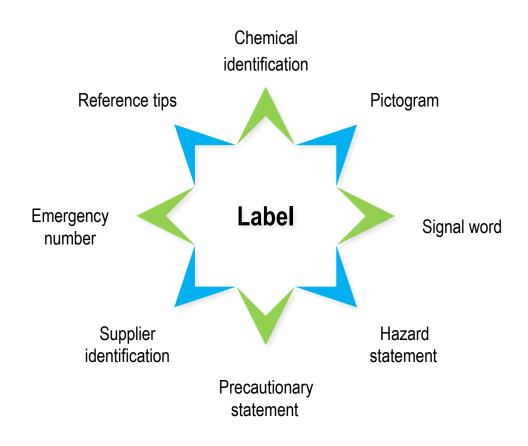
Japan: Available

Thailand: Available (however detailed information of ingredients up to 100%

has to reported to the Customs)



Elements of Label and Noteworthy Points





Elements of Label and Noteworthy Points

Label Elements		Taiwan	China Mainland	Japan	South Korea	Thailand
	Name		Consistent with SDS; The chemical name or common name should be available in both English and Chinese languages		Consistent with SDS	
Chemical identification	Compositions	Consistent with SDS	Consistent with SDS		Consistent with SDS	
	Position	Not specified	In top of label and should be striking		Not specified	
	Color	White base, black word, red boxes	White base, black word, red box; Black box is acceptable in some cases	White base, black word, red box; Black box is acceptable in some cases	White base, black word	d, red boxes
Pictogram	Size	Not specified	Not specified	Not specified	Area should be no less than 0.5 square centimeter	Not specified
Signal word						
Hazard statement			Below signal word; Arrange in certain orders: PC, Health, environment	Not specified	should be striking	Not specified
Precautionary statement		No limitation of number	No limitation of number	No limitation of number	No more than 6; at least one statement for Prevention, Emergency handling, storage and waste disposal, respectively. Unless there is no statement for them.	No limitation of number
Supplier identification			Post code is required			
Emergency number		Better to provide	1. 7*24h available; 2. Within territory of China; 3. Should not be a mobile phone; 4. Handled by professional personnel with related expertise	Better to provide		Better to provide, mandatory for hazardous product
Reference tips		Please refer to SDS for more detailed information 更詳細的資料,請參考 物質安全資料表	Please refer to SDS for more detailed information 详细信息请参阅化学品安全技术说明书	Not specified	For product less than 100 mL Please refer to SDS for more detailed information	Not specified

www.knoell.com



ANY QUESTIONS?

THANK YOU FOR ATTENTION!