





Senior Regulatory Consultant

### Who is CIRS?





- CIRS is an individual consulting firm founded in 2007 and headquartered in China;
- Over 350+ employees in 5 different countries;
- Has branch offices in Dublin(Ireland), London (UK), Arlington(US), Seoul(Korea), Nanjing(China), Beijing(China), Hangzhou(China);
- Provide regulatory compliance consulting, testing and training services.
- Shares more than 70% of Chinese consulting markets;
- Serving 4000+ Clients/Companies across the world.

#### **CIRS China (HQ)**

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#### **CIRS Europe**

Add: CIRS, Regus Harcourt Centre D02 HW77, Dublin, Ireland

#### **CIRS US**

Add: #200-092, 3100 Clarendon Blvd., Arlington, VA 22201

#### **CIRS Korea**

Add: B-2310, 583, Yangcheon-ro, Gangseo-gu, Seoul, Republic of Korea

#### **CIRS UK**

Studio 310, Pill Box, 115 Coventry Road, London, E2 6GG



Korea GHS Update

**SDS Submission** 

## **Korea GHS Update**



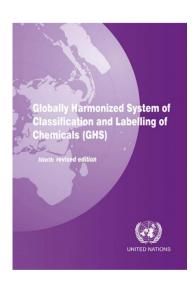
### **GHS**



### GHS: Globally Harmonized System of Classification and Labelling of Chemicals

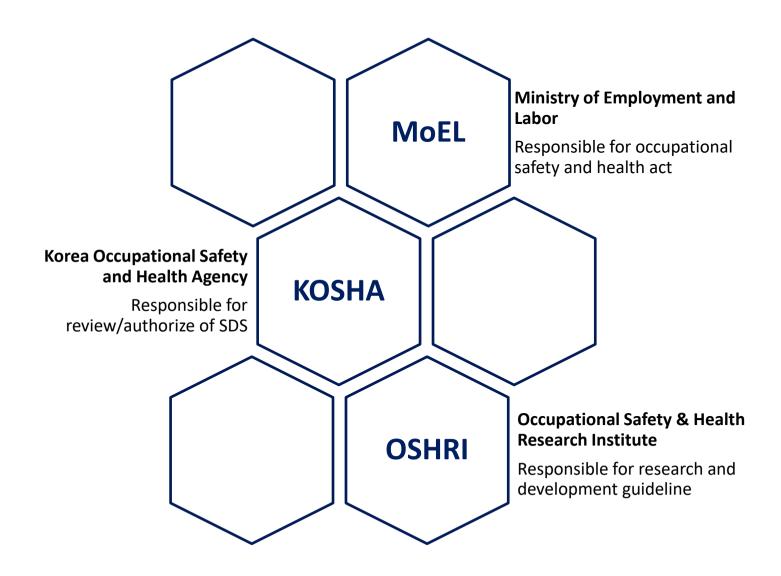
- Classification
- Safety Data Sheet
- Labelling

Country/Region	Standard
China	GB/T 17519-2013 & GB/T 16483-2008
Japan	JIS Z 7253-2012
Korea	MOEL No 2020-130
Taiwan	CNS 15030
Turkey	SEA No28848
Malaysia	CLASS 2013
Thailand	B.E 2555
Indonesia	GHS regulation No 23/M-IND/PER/4/2013
Philippines	DENR Administration Order 2015-09 Rules and the Procedures
	for the Implementation of the Globally Harmonized System
	(GHS)
Vietnam	Circular no. 04/2012/TT-BCT stipulating the regulations on
	classification and chemical labelling
Australia	Work Health and Safety Regulations (WHS Regulations)
New Zealand	Hazardous Substances and New Organisms Act



### **Korea Chemical Regulations – Authorities**







### MoEL Notice No. 2020-130

- Ministry of Employment and Labour (MoEL) has amended its standard under the Occupational Safety and Health Act (K-OSHA)
- MoEL Notice No. 2016-19 has been updated to MoEL Notice No. 2020-130 as of January 16<sup>th</sup>, 2021 and is currently in effect
- Korea has adopted the standard 16-section SDS aligning with UN GHS 4th Revision
- The SDS and Label should be authored in the Korean language
- Emergency Contact Info of Korean legal entity (but not the same as 24h number)
- Hazardous ingredients should be listed in section 3
- Apply for CBI before SDS submission, if approved, the CBI authorization number and expiry date should be indicated in section 3 of the SDS
- If there are updates to an SDS, the supplier must provide the latest version to the buyer immediately



### MoEL Notice No. 2020-130 - New Updates!

- 48 categories of use to choose from. See appendix 5 for list of uses and descriptions of use
- Must indicate SDS number issued by MoEL on upper right side
- If CBI is applicable, the 'authorization number' and 'expiry date' provided by MoEL should be stated in section 3
- SDS standards under K-OSHA revised including P/H phrases, added definition of hazardous to ozone layer, clearer definitions of each hazard category etc.
- Not all substances may apply for CBI protection such as prohibited substances, substances requiring permission, hazardous substances subject to management, harmful factors subject to measurement of the work environment, hazardous factors subject to a special health examination and substances having a physical hazard, health hazard or environmental hazard under K-REACH
- The concentration range in section 3 is wider:
  - 1) If concentration is below 25%, the range can be ±10%
  - 2) If concentration is equal or above 25%, the range can be ±20%



### MoEL Notice No. 2020-130 - Revised Cut-off Values

Classification	Health and environment hazard class and category code(s)	Cut-off limit
Human health hazard	1. Acute toxicity	1%
	2. Skin corrosion/skin irritation	1%
	3. Serious eye damage/eye irritation	1%
	4. Respiratory sensitisation	0.1%
	5. Skin sensitisation	0.1%
	6. Germ cell mutagenicity* 1A & 1B	0.1%
	Germ cell mutagenicity 2	1%
	7. Carcinogenicity *	0.1%
	8. Reproductive toxicity*	0.1%
	9. Specific target organ toxicity – single exposure	1%
	10. Specific target organ toxicity – repeated toxicity	1%
	11. Aspiration hazard	
Environmental hazard	12. Hazard to aquatic environment	1%
	13. Hazard to the ozone layer	0.1%



### Labelling - MoEL No.2020-130

- In Korean language
- Options to choose 4 pictograms and 6 precautionary statements if there are more.
- Korean supplier info required
- For low volume(below 100ml), simplified label applied

Capacity	Size of label	Size of pictogram		
500 L ≤ Capa.	450 cm <sup>2</sup>			
200 L ≤ Capa. ≤ 500L	300 cm <sup>2</sup>	✓ 1/40 of surface		
50 L ≤ Capa.≤ 200L	180 cm <sup>2</sup>	area;		
5 L ≤ Capa. ≤ 50L	90 cm <sup>2</sup>	✓ Min. 0.5cm <sup>2</sup>		
Capa. ≤ 5L	>5% of area			

## **Korea SDS Submission**





### Korean SDS Submission

All hazardous chemicals importers and manufacturers in Korea should submit the SDS

- For newly imported or manufactured chemicals, submit before import/manufacture;
- For existing chemicals which already authored SDS, following the grace period;
- Submit through an online IT system;
- Detailed use is requested;
- Korean Importer information;
- Updated/revised SDS should be re-submitted ASAP.

### **Grace period:**

≥1,000 ton: by 2022.1.16

100-1,000 ton: by 2023.1.16

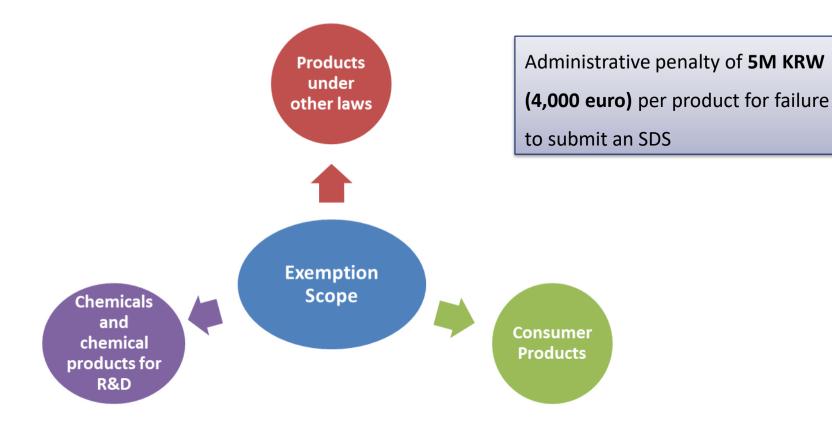
10-100 ton: by 2024.1.16

1-10 ton: by 2025.1.16

<1 ton: by 2026.1.16



### **Exemption**



**Products under other laws:** dietary supplements (Health Functional Food Act), raw material substance (Act on Safety Control of Radioactive Rays), household chemicals products for general consumers, hygiene products and advanced biomedicines



Non-Korean companies cannot submit an SDS by themselves or apply for CBI

They have two options:

- 1) Korean importer
- 2) Appoint an Only Representative (OR) such as CIRS Korea
  The OR can only be appointed by the manufacturer or formulator The OR fulfils the role of a domestic importer.

The scope of the OR workload is preparation and submission of MSDS, MSDS CBI application and extension approval, rejected application appeal and delivery of approved MSDS to importers in Korea.

### CIRS

### **Letter of Confirmation**

Form no. 62 Confirmation of Chemical									
※ 색상이 어두운 칸은 신청인이 적지 않으며, [ ]에는 해당되는 곳에 √표를 합니다.									
접수번호	접수일시 처리일			처리기간	즉시				
	①Only representative								
	[ ] O - OR appointment nu	mber (	)	[ ]×					
	Company name	CEO		②Industry					
Importers	Business number	Number o	of staff						
	Address (E-mail:								
	Tel.	Fax.			<u>,</u>				
③ Category	[ ] R&D [ ] Non R&D								
<pre>④Product name</pre>									
Overseas manufactu	Company name	Country							
manuractu rers	Address								
	(Tel.:		)						
⑤Confirm	I declare that the product doesn't conta in Section 3 of SDS.	in classif	ied chemi	cal other than	n described				

Date:
Letter of Confirmation
To whom it may concern:
Product Name :
After careful review of the Certificate of Composition of the above-identified product, I/we here by confirm that all composition of the product, excluding the listed in the MSDS(SDS) do not fall under the harmful factor's classification standards under the Korean Occupational safety and health ACT.
Name:(Signature or Seal)
Title:
Name of Department:
Company:
Address:
Tel:
Fax:
E mail

YOUR COMPLIANCE EXPERT



### **CBI Protection**

The ingredient name and the exact concentration can be protected.

- Not all hazardous ingredients can apply CBI.
- Once approved, authorisation number and expiry date will be replied by MoEL.
- The original protection period will be 5 years. Applicants can apply for an extension every 5 years (at least 1 month in advance)

### **Application information**

- Applicant info
- CBI reason
- Alternative data (generic name/conc. range)
- 100% ingredient info (substance name + concentration) and the hazardous information
- SDS document
- Name and content of chemicals that are not classified
- Other documents required by MoEL

Form no. 63 (via IT system)



F	orm no.	63 CBI [	Appre	ova Isic	ıl on ap	opro	val	(	Claim
※ 색상이 이	너무운 칸은 신청인	!이 적지 않으며, []에는	- 해당되는 곳	에 √3	표를 합니	다.			(앞쪽)
접수번호		접수일시	처리	1일			처리	기간	1개월(2주)
	①Only repres	entative [ ]O - OR app	ointment n	umbe	er (	]		[ ]>	
	Company nar	n e <b>l</b>		CEO			@Ind	Olndustry	
Applican	Business regi	stration number		Nu	mber o	f Staff			
t	Address								
				(E	-mail:				)
	Tel.			- (-	Fax				
③ Category	[ ] N	Manufacture [	] Import		[	] R	& D	[ ]	non-R&D
@Product									
name	-		05				<u> </u>		
	Classified or not		Chemical name (CAS No.)	<u>CB</u> J	claim	Content (%)	<u>CB</u> J c	lai m	Hazards information
		opticable []not available	1.	. []O[]X			X[ ]O[ ]		
©Full compositi		opticable []not available	2. []O[]X		X[]C		x[]0[]		
on		opticable []not available	3. []O[]X			0[]	[ ]X		
	[ ] O [ ] X- [ ]not ap	oplicable []not available	4. [ ]O[ ]X [ ]O[			[ ]X			
	- Number of	all composition: classified chemicals: CBJ chemicals:							
		Substitute chem	nical name				Subs	titute o	content(%)
<b>®</b>	1.								
Substitut e data	2.								
e uata	3.								
7)	information which you would like to hide  information which you would like to hide  information which you would like to hide								
⊕ Hazards									
informati									
on									
. ® .	★ If you have gotten approval from government, describe approval number and expiry duration								
Approval number									



### **Administration fee**

**General Substances (KRW)** 

Category	Large Enterprise		Medium Enterprise		Small Enterprise	
,	New	Renewal	New	Renewal	New	Renewal
Starting Fee	70,000	35,000	35,000	17,500	14,000	7,000
1 CBI substance	110,000	55,000	55,000	27,500	22,000	11,000
2 CBI substance	150,000	75,000	75,000	37,500	30,000	15,000
3 CBI substance	190,000	95,000	95,000	47,500	38,000	19,000
4 CBI substance	230,000	115,000	115,000	57,500	46,000	23,000
≥5 CBI substance	270,000	135,000	135,000	67,500	54,000	27,000

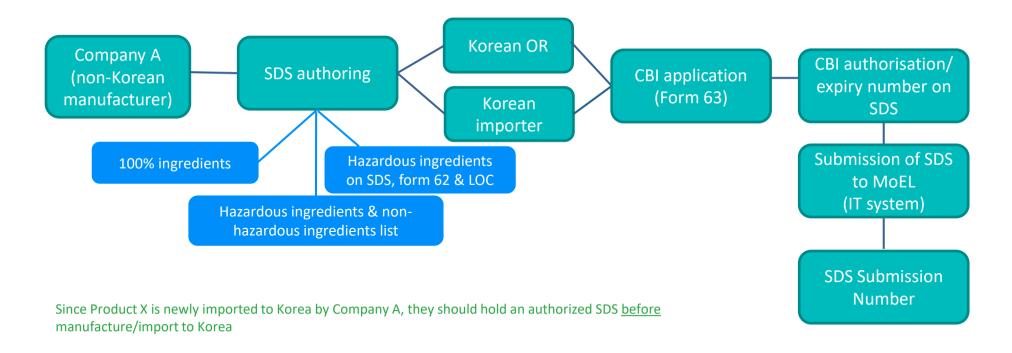
**R&D Substances (KRW)** 

Category	Large Enterprise		Medium Enterprise		Small Enterprise	
	New	Renewal	New	Renewal	New	Renewal
Starting Fee	30,000	15,000	15,000	7,500	6,000	3,000
1 CBI substance	70,000	35,000	35,000	17,500	14,000	7,000
2 CBI substance	110,000	55,000	55,000	27,500	22,000	11,000
3 CBI substance	150,000	75,000	75,000	37,500	30,000	15,000
4 CBI substance	190,000	95,000	95,000	47,500	38,000	19,000
5 CBI substance	230,000	115,000	115,000	57,500	46,000	23,000

## Korea Chemical Regulations – Case Analysis

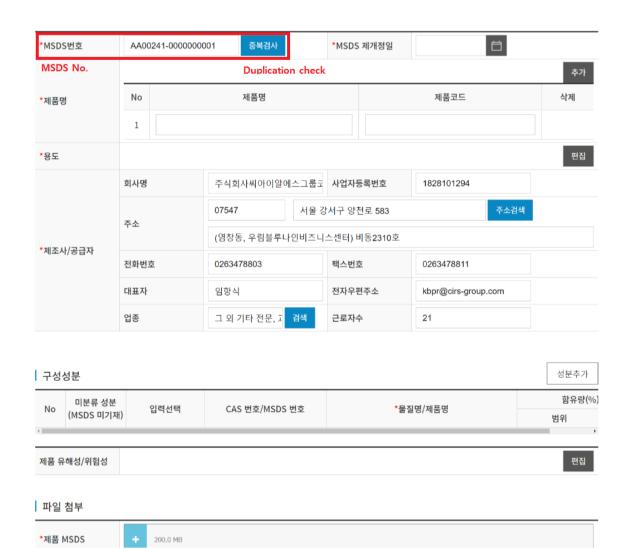


Company A is the manufacturer of product X in Ireland which contains hazardous ingredients. They want to expand their business into Asia and choose South Korea as their target market. Product X is a mixture of hazardous and non hazardous chemical substances and Company A has not sold it into Korea before. Company A does not want to share the complete ingredient information so they can maintain a competitive edge. What options are available to Company A?



### Korea Chemical Regulations – Workflow





1/10

### 물질안전보건자료 (MSDS)

황산(SULFURIC ACID)

Date of issue: 2008-04-01 Revision date: 2021-02-08

Version: R0008

MSDS번호: AA00930-0000000000

#### 1. 화학제품과 회사에 관한 정보

#### 가. 제품명

- 황산(SULFURIC ACID)

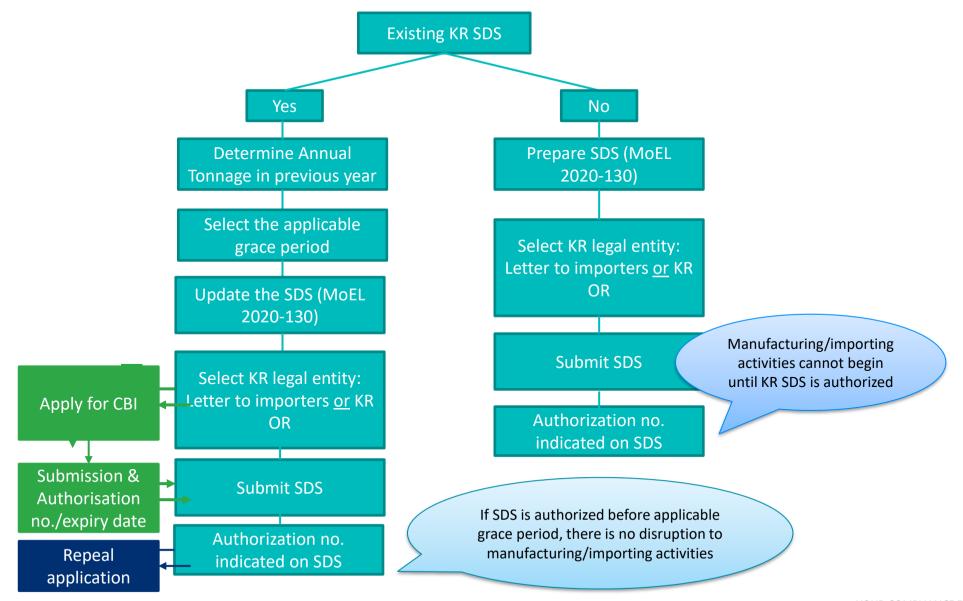
#### 나. 제품의 권고 용도와 사용상의 제한

- 용5

: 비료, 금속야금, 농약, 섬유, 제지, 인산, 화약제조 등

### Korea Chemical Regulations – Workflow





### **CIRS Service**





China REACH, Hazardous Chemical Management, etc.



EU & UK REACH, Only Representative, etc.





Turkey REACH (KKDIK), Only Representative, etc.



Korea REACH, , Only Representative, Korea BPR, SDS submission, etc.



Registration in other regions (Japan, India, Taiwan, Philippines, US, etc.)



Global GHS (SDS, Labelling, Emergency number, Poison Centre Notification, etc.)

# THANKS!

#### **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

