Introduction of Chemical Regulations in China

18/07/2024

Bryan Zhou
Senior Regulatory Consultant
CIRS Europe
Bryan.zhou@cirs-group.com

ABOUT US

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500+ Employee

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50+ Serving countries

18000+ Clients

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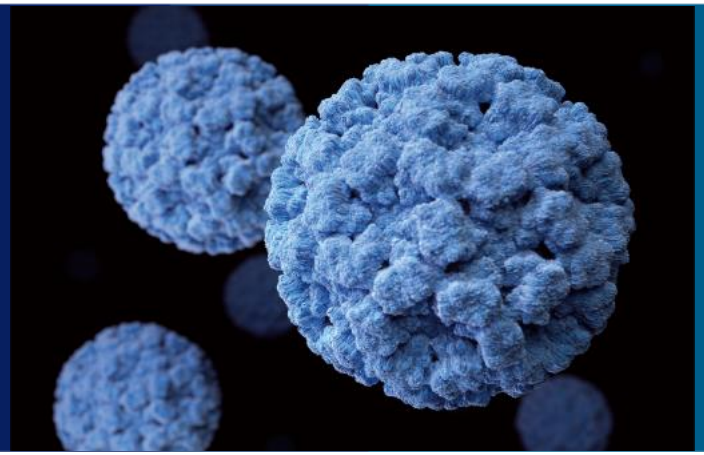
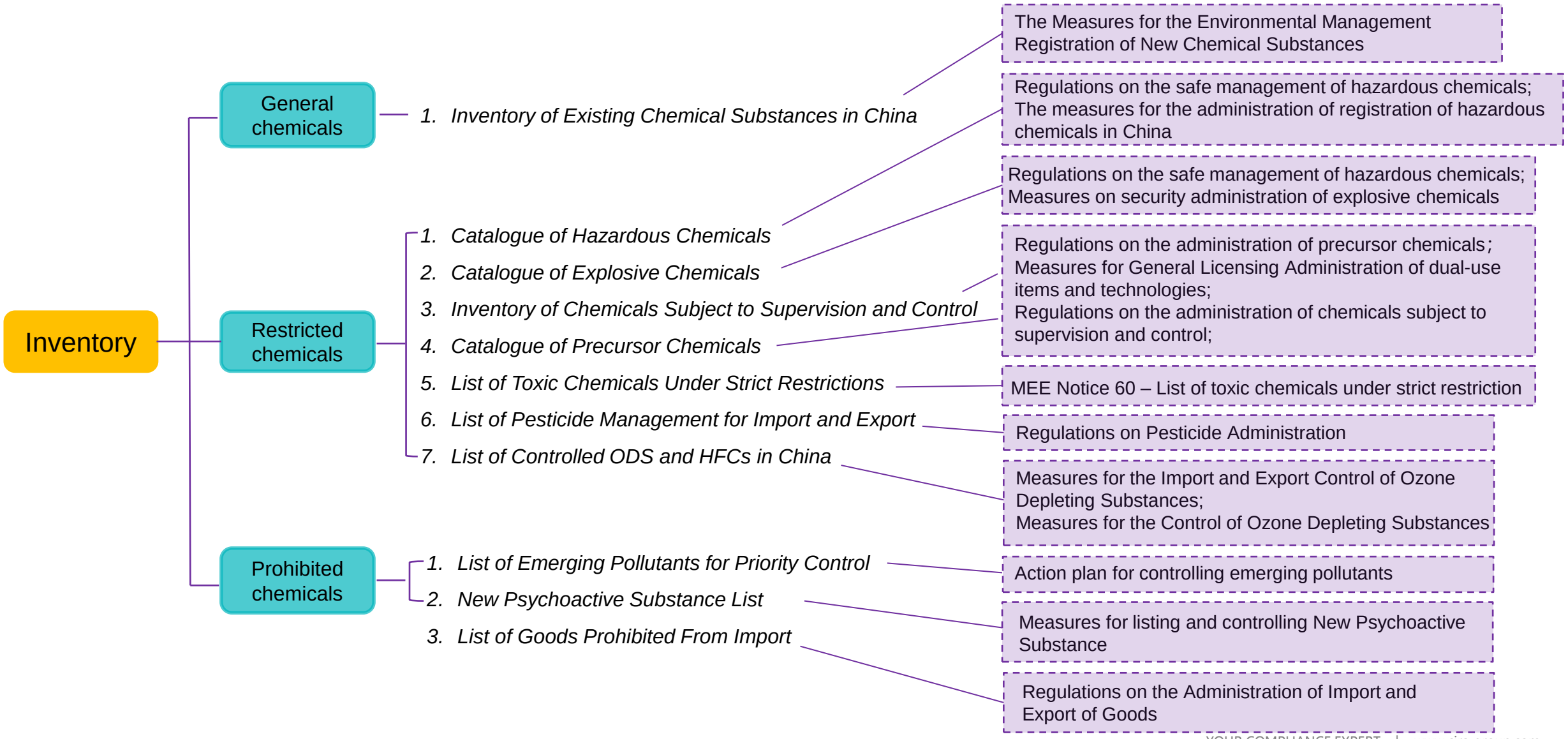
CONTENT

Overview

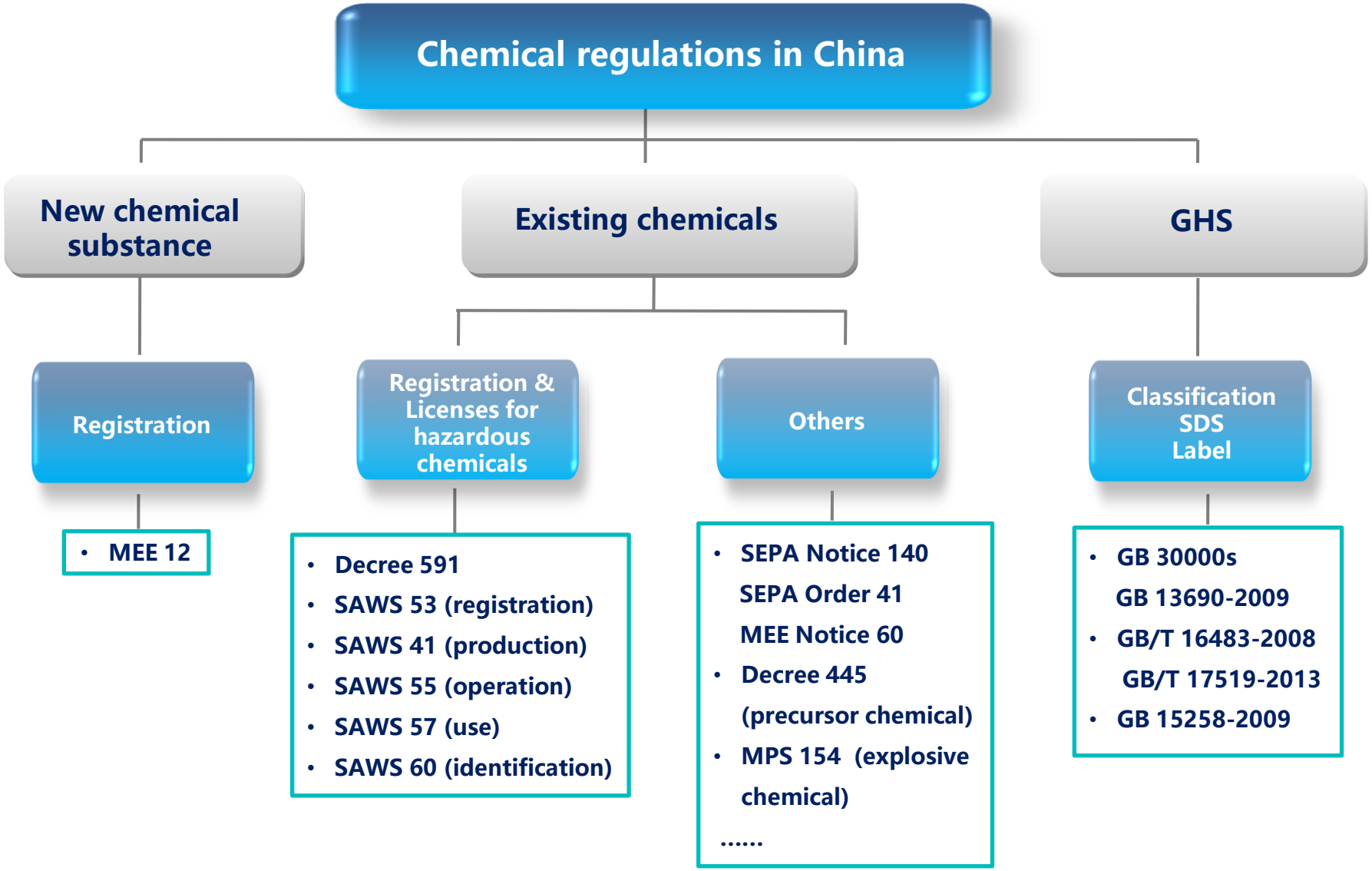


01

Overview of chemical management regulations in China



Chemical management framework in China



Chemical management framework in China

China REACH

02

Substances subject to new chemical substance registration

New chemical substance

Substances not listed on IECSC, except those not applicable or exempted

Existing chemical substance

IECSC substance with new use management (i.e. use for other non-permitted industrial uses)

序号	中 文 类 名	英 文 类 名	流水号	新用途环境管理范围
9.	(乙酰氧基亚氨基-二氧代-烷氧基烷基)-烷基-甲苯甲酰基杂多环	(Acetoxyimino-dioxo-alkoxyalkyl)-alkyl-toluoylheteropolycyle	9769	允许用途外其他工业用途。 允许用途：光聚合引发剂

Statistics on additions to the IECSC

31 substances added 01/03/2016

45 substances added 22/11/2018

28 substances added 11/01/2019

47 substances added 03/01/2020

156 substances added 06/05/2020

28 substances added 15/10/2020

238 substances added 21/12/2020

204 substances added 16/04/2021

115 substances added 21/04/2021

255 substances added 18/06/2021

8 substances added 08/07/2021

15 substances added 18/08/2021

23 substances added 18/10/2021

11 substances added 22/12/2021

18 substances added 03/03/2022

22 substances added 19/07/2022

42 substances added 05/12/2022

43 substances added 02/06/2023

29 substances added 18/12/2023

7 substances added 22/01/2024

★ 28 substances
New use management

IECSC 2013 – 45,612 substances

IECSC 2023 – 46,977 substances

关于已登记新化学物质列入《中国现有化学物质名录》（2022年第2批 总第10批）的公告

按照《新化学物质环境管理登记办法》（生态环境部令第12号）和《关于发布〈新化学物质环境管理登记指南〉及相关配套表格和填表说明的公告》（生态环境部公告2020年第51号）的相关要求，现将已登记的36种符合要求的新化学物

关于增补《中国现有化学物质名录》（2022年第2批 总第8批）的公告

根据《新化学物质环境管理登记办法》（生态环境部令第12号）相关规定，按照《关于发布〈新化学物质环境管理登记指南〉及相关配套表格和填表说明的公告》（生态环境部公告2020年第51号）中有关化学物质增补列入《中国现有化学

关于已登记新化学物质列入《中国现有化学物质名录》（2022年第1批 总第9批）的公告

按照《新化学物质环境管理登记办法》（生态环境部令第12号）和《关于发布〈新化学物质环境管理登记指南〉及相关配套表格和填表说明的公告》（生态环境部公告2020年第51号）的相关要求，现将已登记的18种符合要求的新化学物质列入《中国现有化学物质名录》，按现有化学物质管理，并对标注新用途环境管理范围的化学物质实施新用途环境管理。

特此公告。

附件：列入《中国现有化学物质名录》的18种符合要求的已登记新化学物质

生态环境部

2022年3月2日

Who Can Register?

Overseas Enterprises

Chinese importer acts as applicant

Chinese agent (OR)

~~The certificate holder: Agent~~

The certificate holder: Applicant (overseas enterprise)

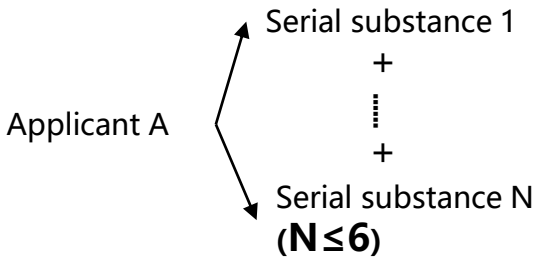
The following provisions shall be clarified in the Agency Agreement or Contract:

1. The agent and the applicant shall carry out the relevant obligations together, as well as bear the legal responsibilities.
2. The responsibilities and obligations when transferring the OR from A to B.
3. Validity period of agency relationship.

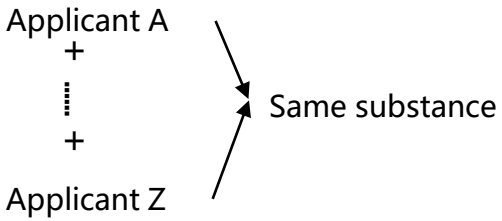
Streamlined Registration Type

Registration Type	Requirements
Record Filing	• Tonnage level < 1t/y • Polymers with new monomers/reactants concentration less than 2% or PLC (polymer of low concern) and do not fall under the polymer record filing exclusion
Simplified Registration	• Tonnage level 1-10 t/y
Regular Registration	• Tonnage level >=10 t/y

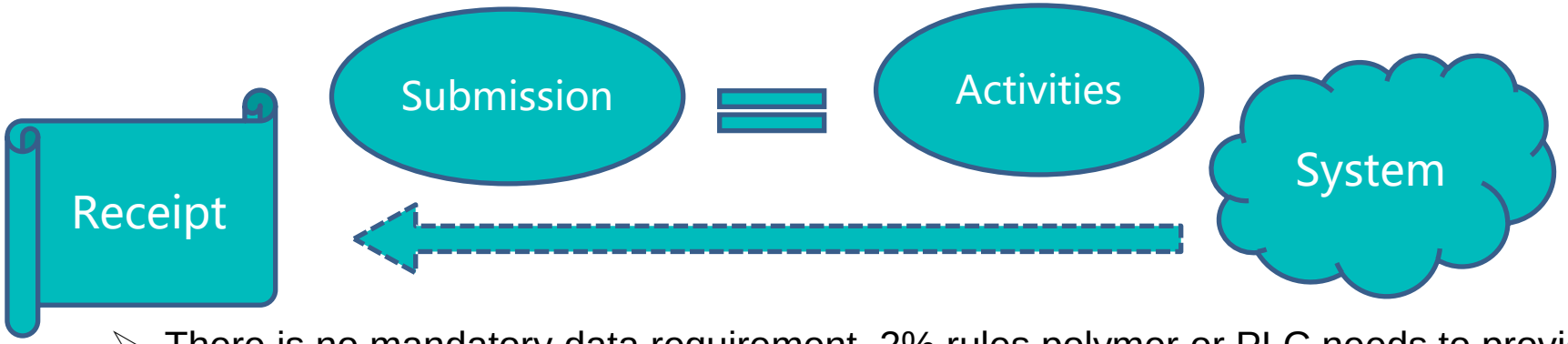
Series Registration



Joint Registration



Record Filling



- There is no mandatory data requirement, 2% rules polymer or PLC needs to provide supporting documents, including:
  - List of monomers/reactants, molecular weight and distribution (GPC) and reaction mechanism;
  - Exclusion of polymer filing (a total of five, as follows) identification descriptions:

    1. Cationic (including polymers in natural water environment);
    2. Degraded or unstable;
    3. Water absorbent polymers with Mn≥10000Da;
    4. Certain types of fluoropolymers;
    5. Containing elements other than permitted elements.

Exclusion conditions of polymer filing

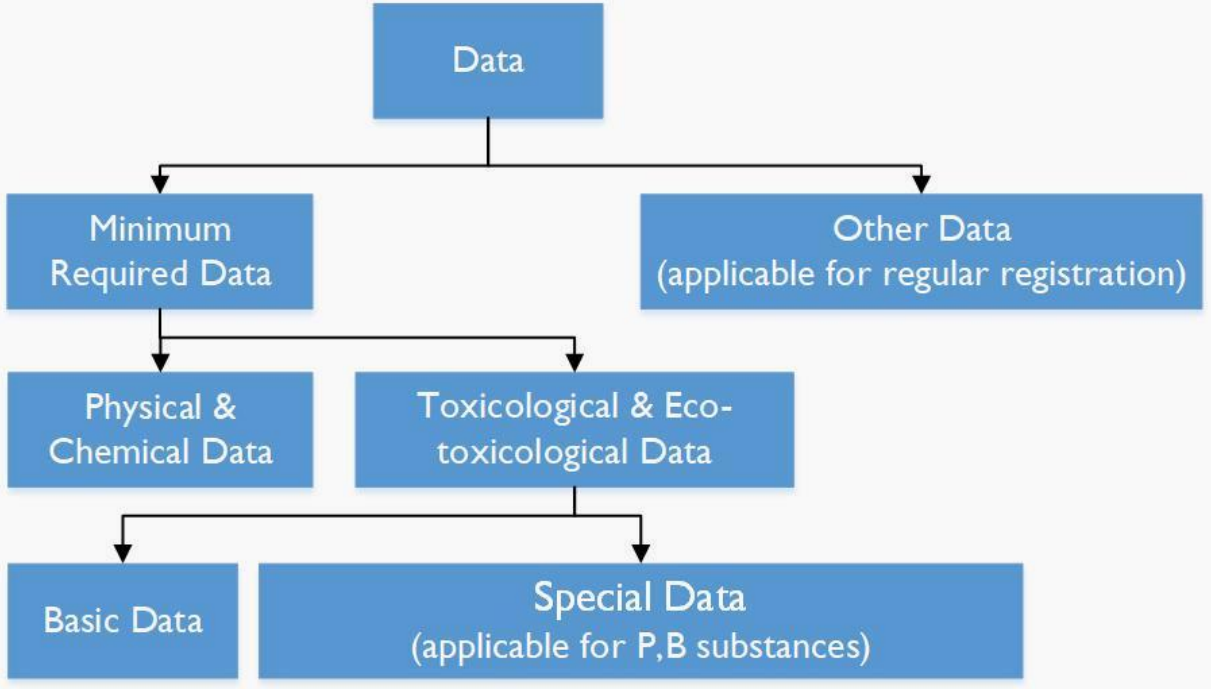
Exclusion of polymer filing (Polymers meeting one of the following conditions shall not be filed)

- **Cationic polymer**
- **Degradable or unstable polymers**
- **Water absorbing polymers with a Mn of 10,000 or more**
- **Fluorine-containing polymers**
- **Containing elements other than the following permitted elements except impurities**

Recommendation:

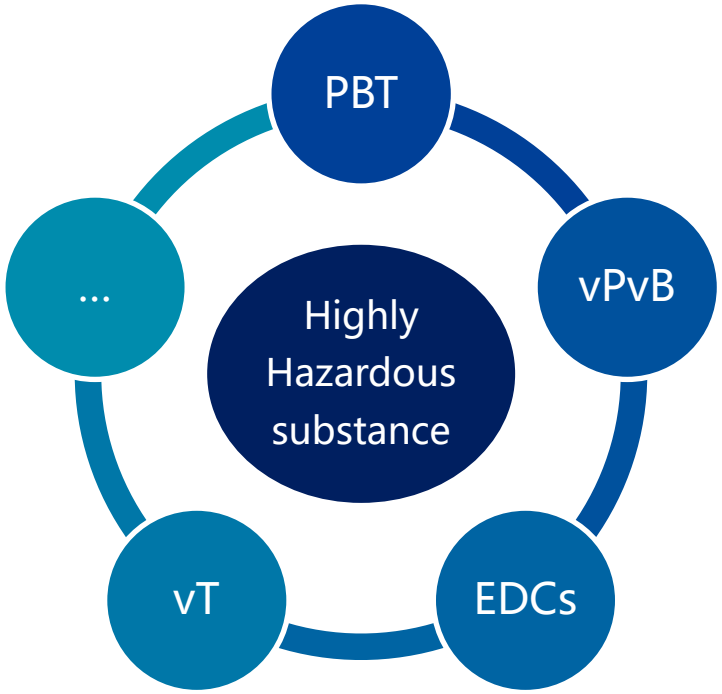
Thermal stability	TGA
Photostability	UV light aging test (1 week, 2 weeks, 4 weeks)
Oxidation stability	Molecular weight changes are measured at 1 week, 2 weeks and 4 weeks under air conditions
Hydrolytic stability	Molecular weight changes at pH4, pH7, pH9 (1.2) for a certain period of time
Solvent stability	Molecular weight changes in solvents (octanol, n-heptane, THF and DMF) for a certain period of time
Water absorption	put in water for 24h

Minimum Data Requirements



1. **For the minimum required data, testing reports are mandatory**; for other data, testing reports are preferable to other sources (QSAR, READ-ACROSS, Systematic literature review, etc.).
2. Non-testing data can only be accepted if the testing is unable to be conducted. Required info: explanations on infeasibility of testing, methods or data sources, basis, etc.
3. Determination of P/B is based on the basic data, further conduct the testing to meet the special data requirements.

Highly Hazardous Substances



P: refers to persistence, indicating that it is not readily degradable in the environment and the determination of persistence does not apply to inorganic substances.
B: refers to bioaccumulation, indicating a tendency to accumulate in an organism.
T: refers to toxicity, indicating more severe acute or chronic toxicity.
EDCs: refers to endocrine disruptors.
v: A substance that indicates an enhancement of a property, such as very severe toxicity, is called a very toxic substance (vT substance).

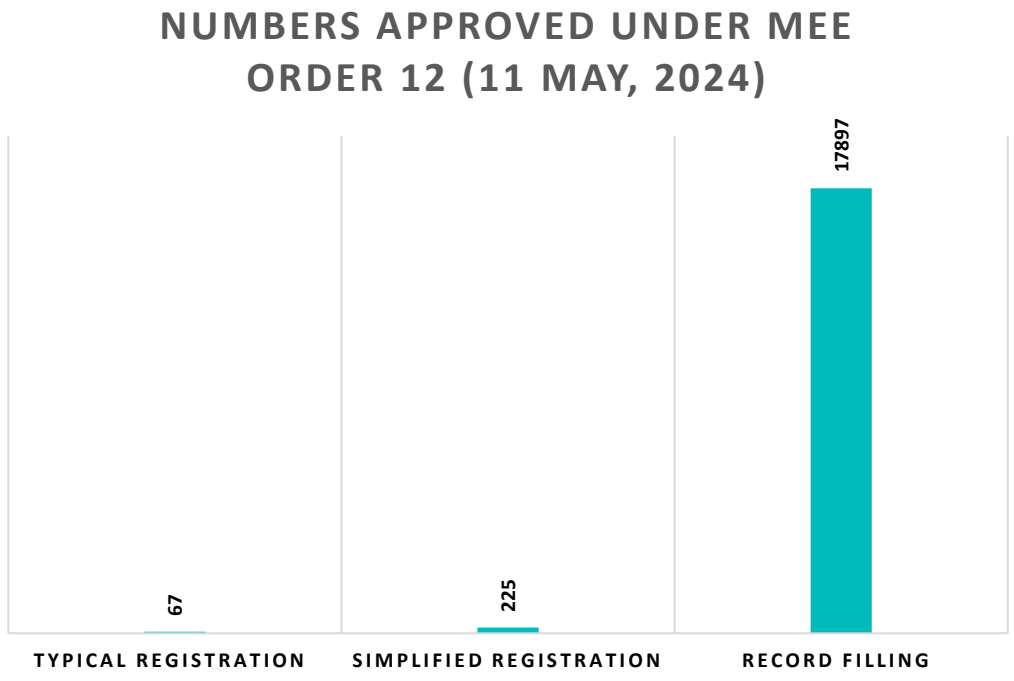
Estimated Time Period

Registration Type	Time Cost	Note
Record Filing	Once application is submitted, activity can be started	It will take 1-2 weeks for supporting documents preparation.
Simplified Registration	8-14 months (Testing period and authority review period included)	PB substances will take longer time on testing.
Regular Registration	14-30 months (Testing period and authority review period included)	PB substances will take longer time on testing.

Post Registration Management-Information Change and Re-registration

Registration Information Change		Regular Registration	Simplified Registration	Record Filling
Applicant/Agent Name		Apply for registration certificate change	Apply for registration certificate change	Apply for change through the online registration system, obtain a new receipt No.
Agent Transfer				
Substance Identity Information				
Activity Type	Manufacture -> Import			
	Manufacture -> Manufacture & Import			
	Import -> Manufacture	Re-registration		
Quantity Increase				
Registration Use				
Environmental Risk Control Measures				
Other circumstances leading to increased environmental risks (changes in process conditions, production site or environmental management requirements, etc.)				

Registration statistics under MEE Order 12



Typical Registration approved under MEE Order 12 (11 May, 2024)

Batch	Date	Numbers	New Use Management	CBI
2023-3	2023.6.20	7	Y(3)/N(4)	Y(1)/N(6)
2023-4	2023.7.23	7	Y(1)/N(6)	Y(1)/N(6)
2023-5	2023.8.18	6	Y(0)/N(6)	Y(0)/N(6)
2023-6	2023.9.11	6	Y(3)/N(3)	Y(1)/N(5)
2023-7	2023.11.7	5	Y(2)/N(3)	Y(0)/N(5)
2023-8	2024.1.3	18	Y(8)/N(10)	Y(0)/N(18)
2024-1	2024.2.21	6	Y(1)/N(5)	Y(0)/N(6)
2024-2	2024.2.29	7	Y(3)/N(4)	Y(1)/N(6)
2024-3	2024.4.9	5	Y(2)/N(3)	Y(1)/N(4)

Current Challenges under MEE Order 12

The approval for CBI applications is quite strict.

No standard testing methods to judge polymer exclusion conditions in terms of its stability.

No clear criteria to judge “accumulative environmental risks of new substance”.

No guidance for “Social Economic benefit analysis report”.

Requirements for carcinogenicity evaluation report.

Hazardous Chemical Management

03

Definitions of Hazardous Chemicals

- Hazardous chemicals are defined as highly toxic chemicals and other chemicals which are toxic, corrosive, explosive, flammable and do harm to human body, facilities and environment.

- Chemicals meeting GHS hazard classification criteria and within 81 categories among 28 GHS classifications shall be regarded as hazardous chemicals under Decree 591.

Definitions of Hazardous Chemicals

Classification		Category						
Phsico-chem properties	Explosives	Unstable	1.1	1.2	1.3	1.4	1.5	1.6
	Flammable gases	1	2	A	B			
	Aerosols	1	2	3				
	Oxidising gases	1						
	Gases under pressure	Compressed	liquefied	Refrigerated liquefied	Dissolved			
	Flammable liquids	1	2	3	4			
	Flammable solids	1	2					
	Self-reactive substances and mixtures	A	B	C	D	E	F	G
	Self-heating substances and mixtures	1	2					
	Pyrophoric liquids	1						
	Pyrophoric solids	1						
	Emit flammable gases in contact with water	1	2	3				
	Corrosive to metals	1						
	Oxidising liquids	1	2	3				
	Oxidising solids	1	2	3				
	Organic peroxides	A	B	C	D	E	F	G

Definitions of Hazardous Chemicals

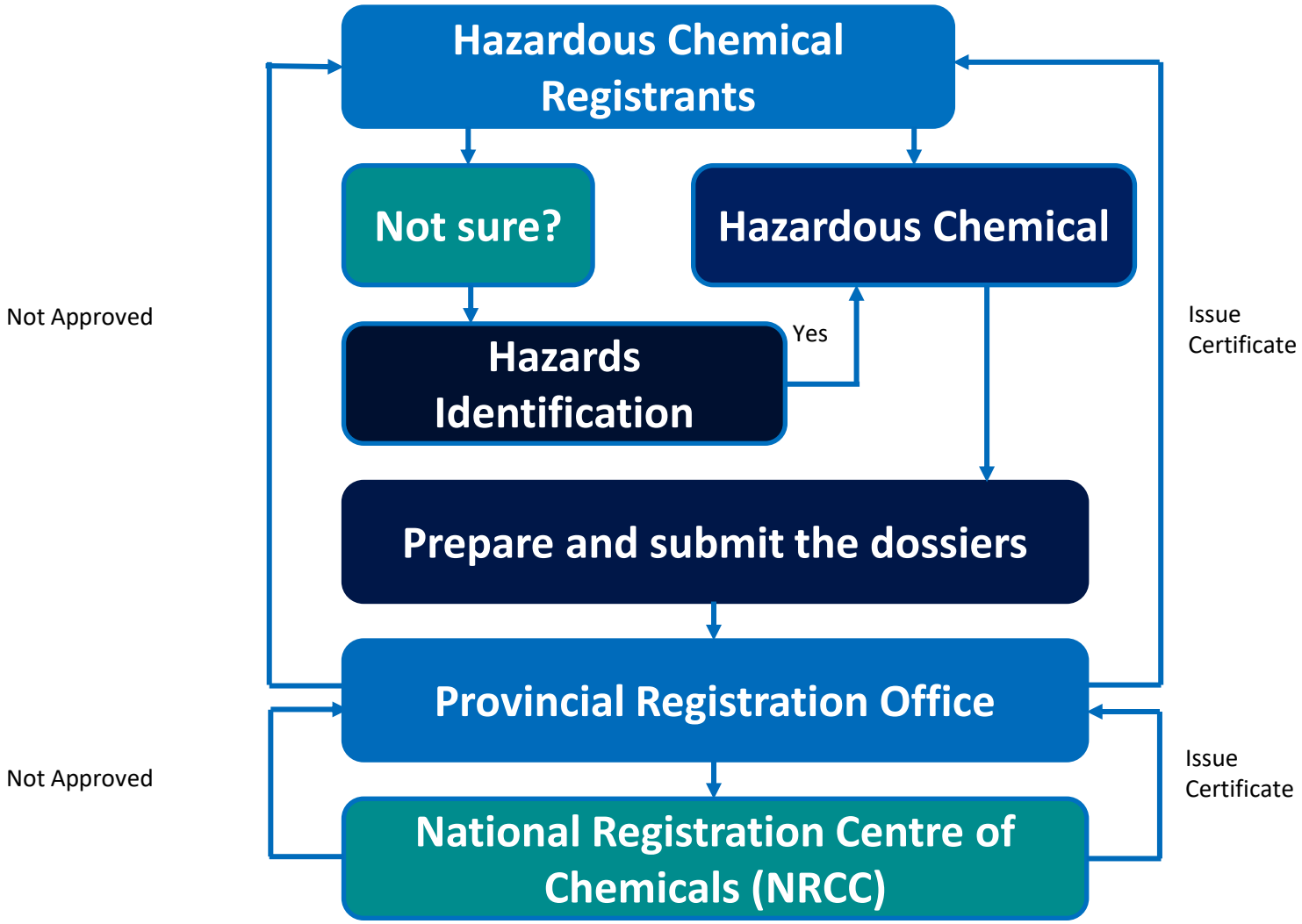
Classification		Category						
Health Hazard	Acute toxicity	1	2	3	4	5		
	Skin corrosion/irritation	1A	1B	1C	2	3		
	Serious eye damage/eye irritation	1	2A	2B				
	Respiratory or skin sensitization	Respiratory sensitization 1A	Respiratory sensitization 1B	Skin sensitization 1A	Skin sensitization 1B			
	Germ cell mutagenicity	1A	1B	2				
	Carcinogenicity	1A	1B	2				
	Reproductive toxicity	1A	1B	2	Additional category (Nursing effect)			
	Specific target organ toxicity – single exposure	1	2	3				
	Specific target organ toxicity – repeated exposure	1	2					
	Aspiration hazard	1	2					
Environmental Hazard	Hazardous to the aquatic environment	Acute 1	Acute 2	Acute 3	Chronic 1	Chronic 2	Chronic 3	Chronic 4
	Hazardous to the ozone layer	1						

Hazardous Chemical Registration - SAWS Order 53

The measures for the administration of registration of hazardous chemicals in China, effective from August 1, 2012

Scope	• Inventory of Hazardous Chemicals • Chemicals meet the definition of hazardous chemical
Registration body	• Domestic manufacturer • Importer
Registration of hazardous chemicals	• Mandatory
Domestic 24h emergency number	• Mandatory
GHS SDS/Label	• Mandatory
Responsible authority	• National Registration Centre of Chemicals (NRCC) of Ministry of Emergency Management (MEM)

Hazardous Chemical Registration - SAWS Order 53

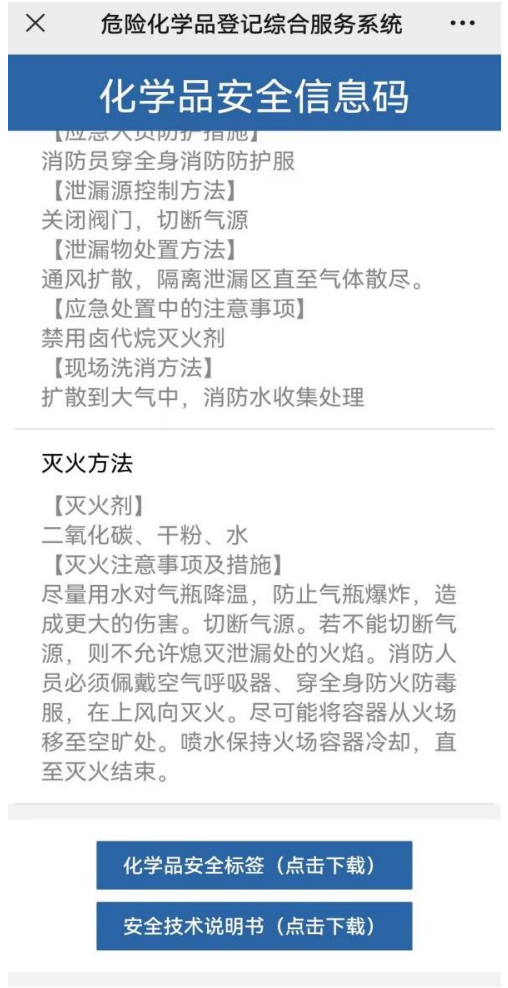


One enterprise, one product, one code

- Every kind of hazardous chemical in every enterprise has a unique two-dimensional code, this code is the hazardous chemical safety information code

  (QR code).

- The safety information code shall be printed or posted on the packaging (including the outer packaging) of the hazardous chemical and can also be printed in the blank space of the chemical safety label.



The issues to be considered

- **How to download and manage the code**
  → NRCC system vs. company's internal information system

- **How to add the code**
  → Print vs. paste

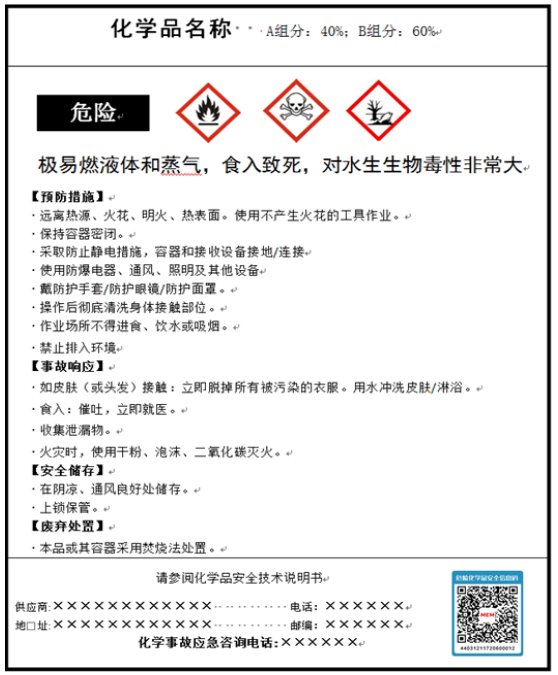
- **Where to add the code**
  → Inner & outer package vs. blank space in the safety label

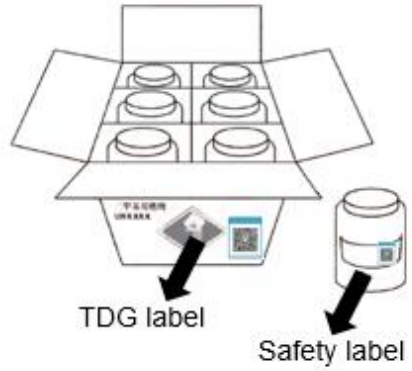
- **Who to add the code**
  → Foreign consigner vs. Chinese importer

- **How to ensure to paste correctly**
  → Each code looks the same vs. one product to several importers

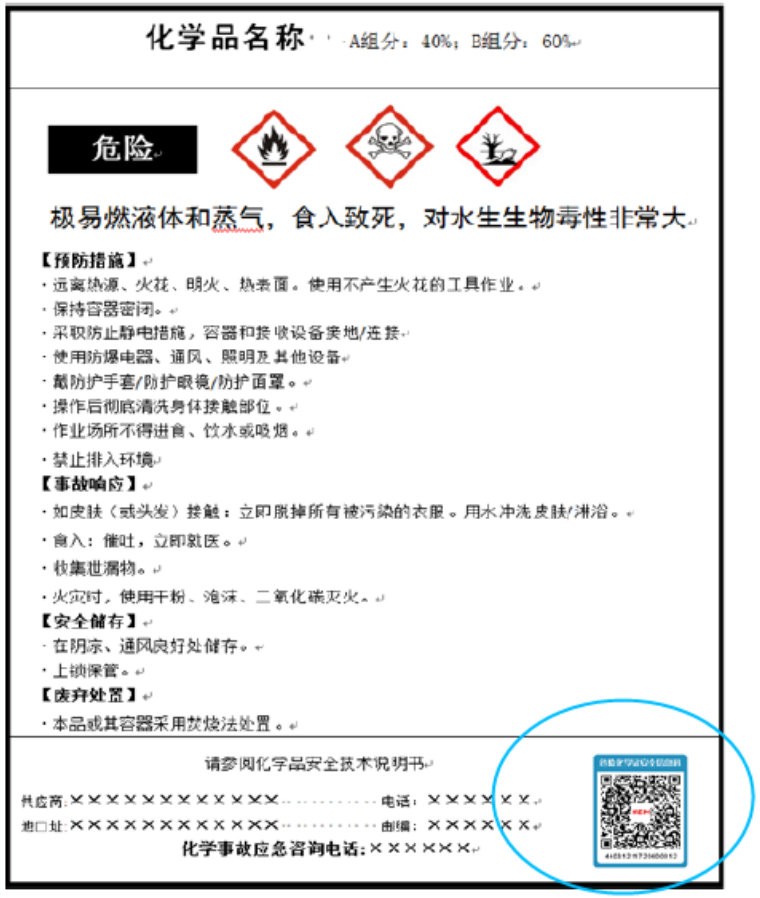
Best practice

Hazardous chemicals registration → Download code from NRCC system → Upload code to internal system and generate a incorporated safety label → Preferred option to paste by foreign consigner, code and incorporated safety label are both provided





New Updates



化学品名称 A组分：40%；B组分：60%

危险

极易燃液体和蒸气，食入致死，对水生生物毒性非常大

【预防措施】
- 远离热源、火花、明火、热表面。使用不产生火花的工具作业。
- 保持容器密闭。
- 采取防止静电措施，容器和接收设备接地/连接。
- 使用防爆电器、通风、照明及其他设备。
- 戴防护手套/防护眼镜/防护面罩。
- 操作后彻底清洗身体接触部位。
- 作业场所不得进食、饮水或吸烟。
- 禁止排入环境。

【事故响应】
- 如皮肤（或头发）接触：立即脱掉所有被污染的衣服。用水冲洗皮肤/淋浴。
- 食入：催吐，立即就医。
- 收集泄漏物。
- 火灾时，使用干粉、泡沫、二氧化碳灭火。

【安全储存】
- 在阴凉、通风良好处储存。
- 上锁保管。

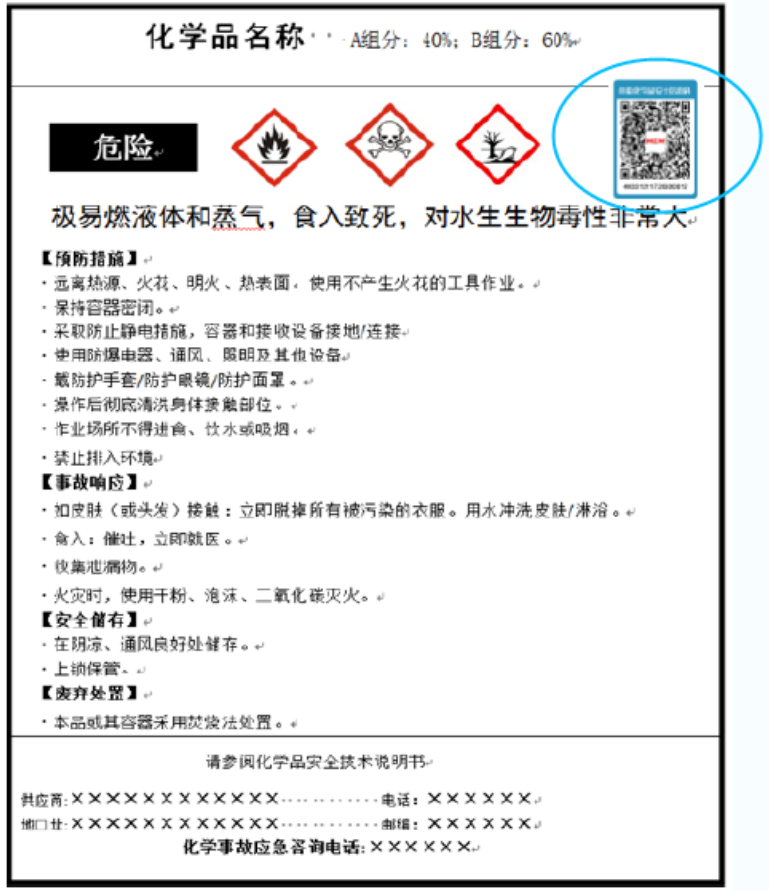
【废弃处置】
- 本品或其容器采用焚烧法处置。

请参阅化学品安全技术说明书

供应商：××××××××××××××……电话：××××××

进口址：××××××××××××××……邮编：××××××

化学事故应急咨询电话：××××××



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- 操作后彻底清洗身体接触部位。
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请参阅化学品安全技术说明书

供应商：××××××××××××……电话：××××××

进口址：××××××××××××……邮编：××××××

化学事故应急咨询电话：××××××

Traceability Code in Shanghai?

Third Party APP

WeChat / Alipay redirect to the NRCC page

Enterprise APP

Commodity code information

QR Code APP

EMB APP scanning for traceability operations

Hazardous Chemicals Traceability code

The safety information code for registered hazardous chemicals, the company's commodity information code, and related information required by local regulatory authorities (such as product name, batch, specifications, etc.) are integrated on a fusion platform to generate the hazardous chemical traceability code. For example:

https://yqypym.yjglj.sh.gov.cn:81/qr/lKVz4u?info=00001%7C%7C117

NRCC's QR Code

Commodity code

Hazardous Chemical License Requirements

Scope: Products in the Catalogue of Hazardous Chemicals

Manufacture

Manufacture hazardous chemicals

SAWS Order 41
Manufacture license
Effective from 2011.12.1

Use

Use hazardous chemicals to manufacture

SAWS Order 57
Safe use license
Effective from 2013.5.1

Operation

Import, wholesale, warehouse storage

SAWS Order 55
Operating license
Effective from 2012.9.1

China GHS

04

China GHS Classification

Classification Standards: GB 30000.2~29-2013 (effect on Nov 1, 2014)

Fully adopt UN GHS Rev. 4, 28 hazard classes, including Aspiration hazards and Hazards to the ozone layer;

Physical Hazards **16 Classes**	Explosive, Flammable gases, Flammable aerosols, Oxidising gases, Gas under pressure, Flammable liquids, Flammable solids, Pyrophoric liquids, Pyrophoric solids, Self-heating substances and mixtures, substances and mixtures which are in contact with water emit flammable gases, Oxidising liquids, Oxidising solids, Organic peroxides, Corrosive to metals, Self-reactive substances and mixtures.
Health Hazards **10 Classes**	Acute toxicity, Skin corrosion/irritation, Serious eye damage/irritation, Respiratory or skin sensitization, Germ cell mutagenicity, Carcinogenicity, Reproductive toxicity, Specific target organ toxicity- single exposure, Specific target organ toxicity- repeated exposure, Aspiration Hazard(*)
Environmental Hazards **2 Classes**	Hazardous to the aquatic environment Hazardous to ozone layer

China GHS Classification

Official Classification: Information sheet of hazardous chemicals classification (2015.08)

Chemical Name

Nickname

English Name

CAS No.

Hazardous Classification

Serial No.

Remark

危险化学品分类信息表

序号	品名	别名	英文名	CAS 号	危险性类别	备注
1	阿片	鸦片	opium	8008-60-4	特异性靶器官毒性-反复接触, 类别 2	
2	氨	液氨；氨气	ammonia;liquid ammonia	7664-41-7	易燃气体, 类别 2 加压气体 急性毒性-吸入, 类别 3* 皮肤腐蚀/刺激, 类别 1B 严重眼损伤/眼刺激, 类别 1 危害水生环境-急性危害, 类别 1	
3	5-氨基-1,3,3-三甲基环己甲胺	异佛尔酮二胺；3,3,5-三甲基-4,6-二氨基-2-烯环己酮；1-氨基-3-氨基甲基-3,5,5-三甲基环己烷	5-amino-1,3,3-trimethyl-cyclohexanemethanamine;isophorone diamine;3-aminomethyl-3,5,5-trimethylcyclohexylamine;isophoronediamine;3,3,5-trimethyl-4,6-diamino-2-enecyclohexanone;4,6-diamino-3,5,5-trimethyl-2-cyclo-hexen-1-one	2855-13-2	皮肤腐蚀/刺激, 类别 1B 严重眼损伤/眼刺激, 类别 1 皮肤致敏物, 类别 1 危害水生环境-长期危害, 类别 3	
4	5-氨基-3-苯基-1-[双(N,N-二甲基氨基氧膦基)]-1,2,4-三唑[含量>20%]	威菌磷	5-amino-3-phenyl-1,2,4-triazol-1-yl-N,N,N',N'-tetramethylphosphonic diamide(more than 20%);triamiphos;wepsyn	1031-47-6	急性毒性-经口, 类别 2* 急性毒性-经皮, 类别 1	剧毒
5	4-[3-氨基-5-(1-甲基胍基)戊酰氨基]-1-[4-氨基-2-氧代-1(2H)-嘧啶基]-1,2,3,4-四脱氧-β,D赤己-2-烯吡喃糖醛酸	灰霉素	3-(3-amino-5-(1-methylguanidino)-1-oxopentylamino)-6-(4-amino-2-oxo-2,3-dihydro-pyrimidin-1-yl)-2,3-dihydro-(6H)-pyran-2-carboxylic acid;blasticidin-s;blas;blaes	2079-00-7	急性毒性-经口, 类别 2*	
6	4-氨基-N,N-二甲基苯胺	N,N-二甲基对苯二胺；对氨基-N,N-二甲基苯胺	4-amino-N,N-dimethylaniline;N,N-Dimethyl-p-phenylenediamine;p-Amino-N,N-dimethylaniline	99-98-9	急性毒性-经口, 类别 3* 急性毒性-经皮, 类别 3* 急性毒性-吸入, 类别 3*	

2828 entries!

Minimum Obligated harmonized classification

http://hxp.nrcc.com.cn/hc_safe_info_search.html

Revise the Rules for Classification and Labelling of Chemicals - GB 30000.1

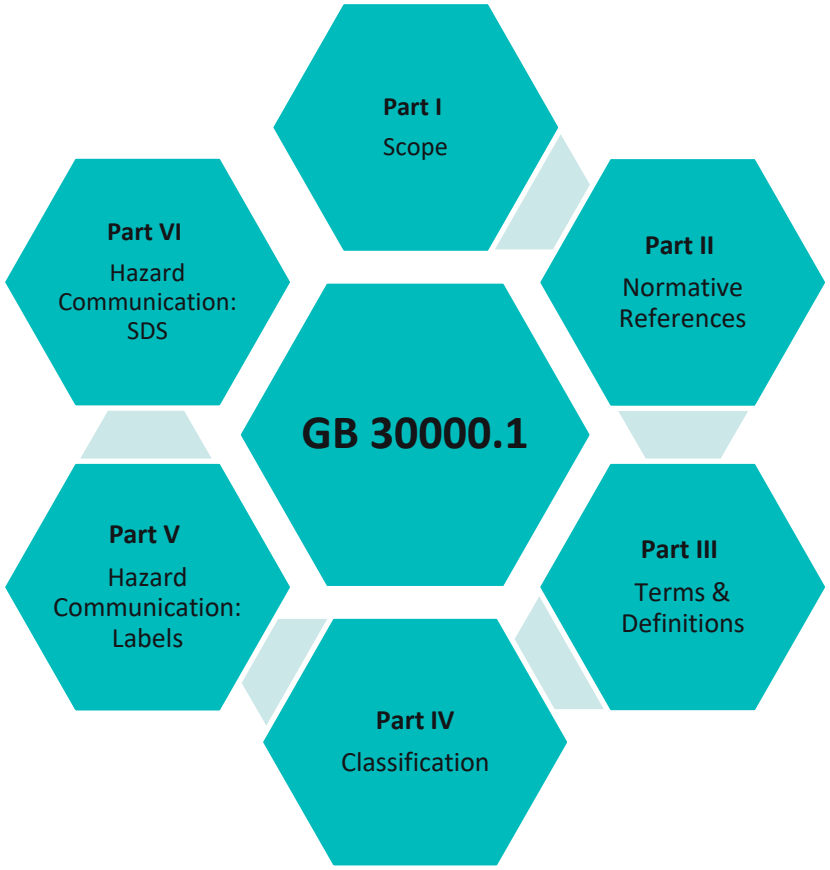
GB 30000.1 is to replace GB 13690-2009 - General rule for classification and hazard communication of chemicals. After the standard takes effect, the chemical classifications in China will more align the UN GHS Rev. 8

- **Part I: Prescribes the scope of application.**
  - Pharmaceuticals, food additives, cosmetics, and pesticide residues in food are not subject to label requirements in GB 30000.1 when ingested intentionally. However, if workers are likely to be exposed to or will potentially contact these substances during transportation, then GB 30000.1 prevails.
  - Labels in the package shall give priority to the requirements of the Recommendations on the Transport of Dangerous Goods, Model Regulations (hereinafter referred to as the "Model Regulations").

- **Part IV: Introduces a new classification category**
  - Desensitized explosives are added, bringing the GHS classifications in China to 29 categories.

- **Part V: Special labels arrangements is given.**
  - For metals and alloys supplied only in bulk instead of being supplied in a distributed way and are compliant with relevant regulations, the competent authority may permit to communicate the hazard information on SDS only.
  - GHS labels shall be pasted in workplaces yet alternative methods are also available. For example, the label may be displayed in the working area rather than on individual containers.
  - Consumer products may adopt consumer product labels based on the likelihood of injury as specified in GB/T 36499
  - Guidance on a consumer product risk assessment for GHS labelling.

- **Other Parts: GB 30000.1 also specifies the cut-off value of hazard category, SDS and labelling requirements.**



Safety Data Sheet

GB 16483-2008 National Standard on Safety Data Sheet For Chemical Products
GB 17519-2013 Guidance on the compilation of safety data sheet for chemical products

- The SDS should be written in Chinese;
- For foreign manufacturer, Chinese domestic 24h emergency number is mandatory to provide in section 1 if it's hazardous chemical ;
- Volume fraction or concentration range of ingredients should follow descending order;
- CBI: the CAS number and exact concentration of each ingredient could be kept as confidential but relevant hazards information shall be indicated.

1.Identification	9. Physical and Chemical Properties
2. Hazard overview	10. Stability and reactivity
3. Composition/information on ingredients	11. Toxicological information
4. First-aid measures	12. Ecological information
5. Fire-fighting measures	13. Disposal
6. Accidental release measures	14. Transport Information
7. Handling and storage	15. Regulatory information
8. Exposure controls/personal protection	16. Other information

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China GHS Labelling

GB 15258-2009 National Standard on General Rules for Preparation of Precautionary Label for Chemicals

Special Requirements:

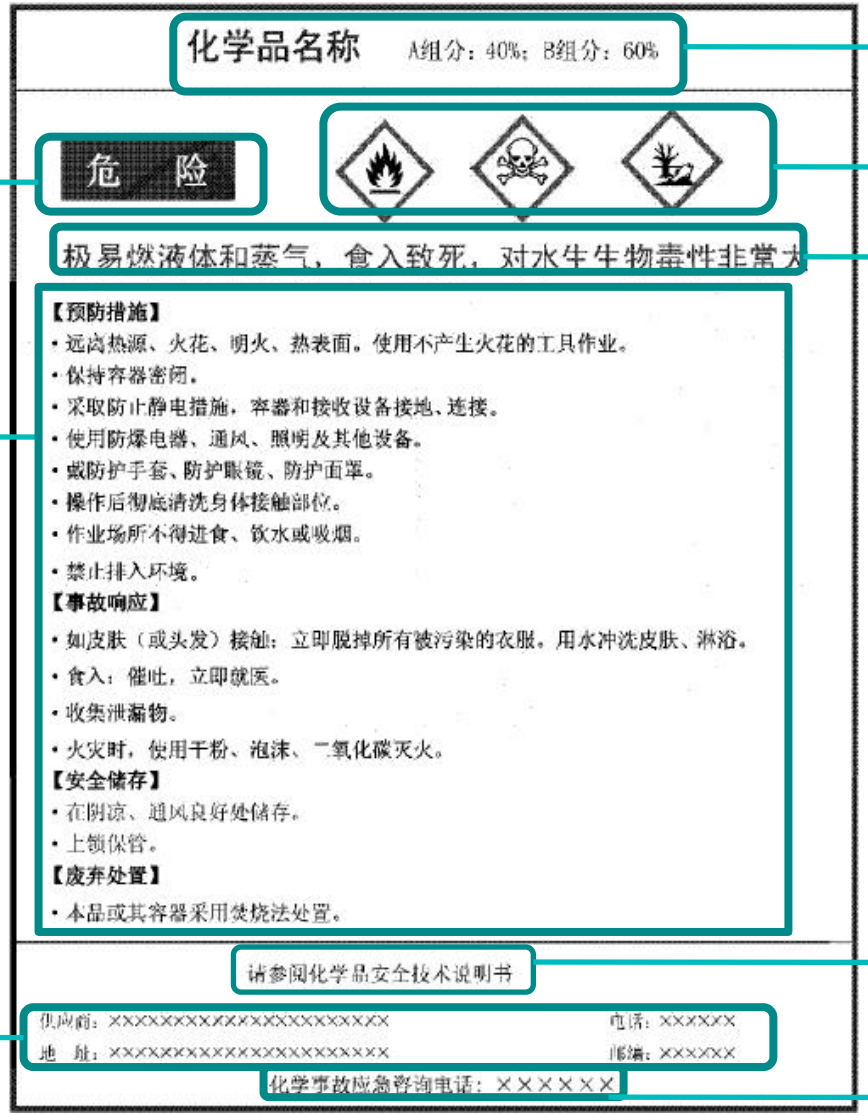
- Chemical name should be in both Chinese and English.
- For foreign manufacturer, a least one Chinese domestic 24h emergency number shall be provided in section 1.
- Order of hazard statements: Physical Hazards ＞ Health Hazards ＞ Environmental Hazards.
- No more than 5 of hazard chemical ingredients should be listed (Not mandatory)
- A simplified label is applied to the package whose volume is less than 100ml.

Label Size

Container or Package capacity (L)	Label Size
Capa. ≤0.1	simplified label
0.1＜Capa.≤3	50*75
3＜Capa.≤50	75*100
50＜Capa.≤500	100*150
500＜Capa.≤1000	150*200
1000＜Capa.	200*300

China GHS Labelling

label



Signal Word

Precautionary Statement

Supplier Information

Product Identification

Pictogram

Hazard Statement

Refer to SDS

Emergency Phone Number

China GHS Labelling

Volume of the container or package/L	Label size（mm × mm）
<0.1	Use simplified labels
＞0.1 ~≤ 3	＞ 50 × 75
＞3 ~≤ 50	＞ 75 × 100
＞50 ~ ≤ 500	＞ 100 × 150
＞500 ~ ≤ 1000	＞ 150 × 200
＞1000	＞ 200 × 300

Simplified label

- Product name
- Signal Word
- Pictogram
- Hazard statement
- Supplier Information
- 24h emergency number (Mandatory)

Precautionary Statement can be omitted!

China GHS Common Errors

- Classification does not conform to Chinese national standards (e.g. GB30000s)
- Lack of domestic 24h emergency telephone number
- Incorrect GHS elements, such as classification, pictograms, signal words, inconsistent data and etc.
- Missing product Chinese name
- Incorrect transport information in part 14, such as missing Chinese shipping name, hazard class and packing group.
- Incorrect or invalid regulation version in part 15.

Thanks!

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Chemical Inspection & Regulation Service Limited

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

T +353 1 477 3710 E service@cirs-group.com