A Thorough Introduction on

New Chemical Substance Registration for China IECSC

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The revised version of the Measures on Environmental Administration of New Chemical Substances (the decree No. 7) was published on 19 Jan. 2010 by Ministry of Environmental Protection of China (MEP). According to this regulation, no chemical products containing NEW chemical substance are allowed to be imported/manufactured/used in Mainland China, before the new chemical substance is registered to MEP–a pre-marketing / pre-manufacturing principle, also known as Chinese REACH/TSCA system.

Similar to any other new chemical management system in other countries or to EU REACH, New Chemical Substance (NCS) Registration to MEP requires a set of documents (including properties of these new chemical substances, their estimated effects to environment, to human, etc.) for evaluation and approval.

This document show you our years of experience in how to comply with NCS registration in China, step by step.

1. Confirm whether a chemical substance is new to China

New Chemical Substances are these chemical substances not listed in IECSC (Inventory of Existing Chemical Substance of China). IECSC has been revised several times. The latest one was released on 14 Jan., 2013, which is known as IECSC 2013. There are totally 45609 substances in IECSC 2013, among which 42342 are open to the public (Publication of Inventory) and 3270 are confidential (Confidential of Inventory).

Companies can verify themselves by searching in IECSC. IECSC 2013 can be downloaded at: http://www.randis.cn/html/ywb/Ezlxz_264_175.asp.

As 3270 existing substances' exact identification are not disclosed in the above version for confidentiality reasons, so it is recommended that a formal verification be submitted to MEPSCC to check whether a substance is new or not before conducting tests for new chemical registration in China.

2. Check if a chemical is exempted

There are four major categories for exemption of registration:

(1) Finished products already regulated by other laws and regulations

These include medicine, pesticide, veterinary drug, cosmetics, food, food additive, feed and feed additive, radioactive substance, military product, explosive product, initiating explosive products and tobacco etc.

(2) Natural substances

1) Natural substances that are unprocessed, or only processed/treated in manual, mechanical,

gravity, water dissolving, water flotation, thermal dehydration and other physical ways;

2) Natural substances extracted from air in various ways;

3) Natural polymers, except those subject to chemical processing and treatment;

4) Living substance, such as ribonucleic acid, deoxyribonucleic acid, protein and other biomacromolecules.

(3) Substances of noncommercial purposes or unintentionally produced.

1). Impurities (<20w/w% in total, <10w/w% for each impurity);

2). Substances from accidental or un-designed reaction;

3). Waste water, waste gas, solid waste, and by-products.

(4) Other special substances

1). Glass;

2).Frit;

3). Pottery raw materials and ceramic ware;

4). Steel and steel products;

5). High-alumina cement;

6). Portland cement;

7). Homogeneous and heterogeneous alloys, except for metal compounds and precisely defined intermetallic compounds

8). Non-isolated intermediates.

(5). Articles.

3. Determination of notifier

Notifiers can be china local companies or overseas companies.

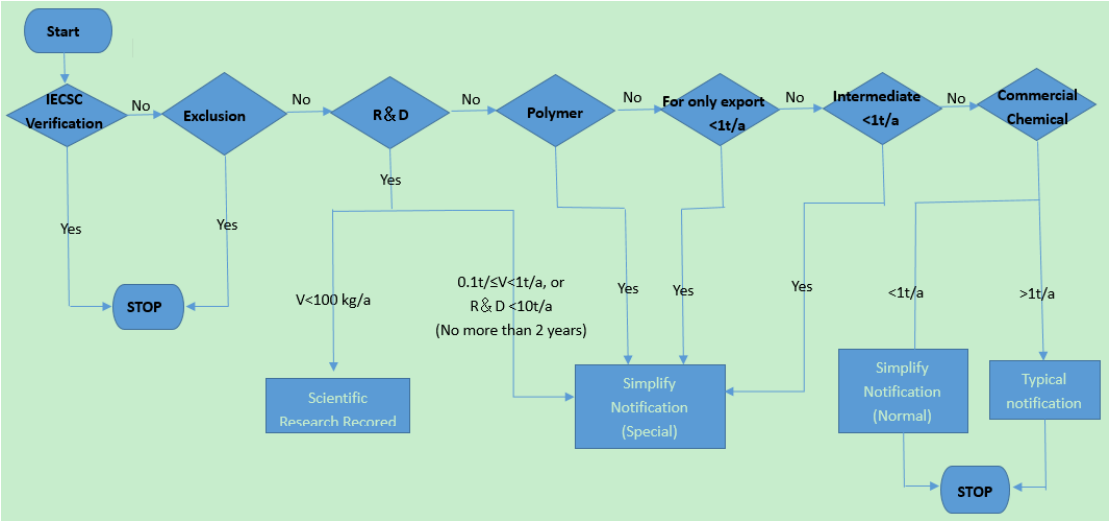
China local notifiers are the manufacture or importer of NCS registered in mainland China.

Oversea notifiers are the foreign companies selling new substances to China (including companies registered in Taiwan, Hongkong, Macau).

Note: Oversea notifiers shall entrust a local Chinese agent to function as Representative of the notifier for new chemical substance registration.

4: Determination of the Registration Type

The chart below show how to determine the registration type:



For example, a domestic company A expect to manufacture new chemical substance B (NCS B):

(1) If NCS B is used for Research and Development purpose (R＆D), and the registration quantity is under 100 kg per year, a Scientific Research Record Registration can made; If the registration quantity is between 0.1 to 1 tonne per year; or under 10 tonne per year for 2 years, a Simplified Registration (special type) can be made.

(2) A Simplified Registration (special type) can be made for situations below.
   I. Annul tonnage of the intermediate manufactured/imported is less than 1 ton per year;
   II. For exporting only, and its annual quantity is less than 1 ton per year;
   III. For scientific research, annual manufacture/imported quantity is above 0.1 ton and below 1 ton;
   IV. Polymer with monomers among which less than 2% are not listed in IECSC and Low concern polymer;
   V. For the purpose of process and product research & development, annual manufacture/import quantity is below 10 tons for less than 2 years.

(3) If NCS B is used for commercial purpose, and does not meet above two conditions, the registration type will depend on the registration quantity: for less than 1 tonne per year, Simplified registration (Basic type) can be made; for more than 1 tonne per year Typical Registration should be made.
   The Typical Registration has four registration levels: level 1 (1~10 t/a), level 2 (10~100 t/a), level 3(100~1000t/a), level 4 (>1000t/a).

For different registration types above, the latter the registration type is, the longer time is needed for the registration and the more costly the registration is. So choose of the registration type is suggested reversed order to the above based on the substance's suitability to these registration types.

- ●Scientific Record Registration (no Certificate is issued)
- ●Simplified Registration (Certificate is issued)
  - ★Special Type
  - ★Basic Type
- ●Typical Registration (Certificate is issued. Registered substances will be listed into IECSC after 5 years)

5: Requirement Evaluation and data gap analysis

Different registration types have different data requirement.

Normally, the majority of total registration cost is cost for obtaining data.

For Scientific Record Registration, no test data are mandatory.

For special type Simplified Registration, normally no test data are mandatory either (except for the molecular weight distribution analysis report for polymer).

For basic type Simplified Registration, as basis, biodegradation test conducted in China is mandatory.

For typical Registration, dozens of test reports for physical-chemical property, toxic and eco-toxic property obtained through tests in qualified labs are mandatory.

The paragraphs below have summarized the data requirements for different types of registration. You shall evaluate existing data based on the principles listed as below and carry out data gap analysis.

1). Data source

Data from the following source are theoretically acceptable for the China NCS registration: test report by qualified labs, published authoritative literatures, authoritative databases, or data generated from method including QSAR, cross reference, etc. (including expert statement). While data from non-testing reports (literature, etc.) are regarded generally only as reference, unless the testing could not be conducted scientifically.

For different data sources, the required supporting documents are different. If data generated from tests through accepted test methods, qualification certificates of test organization shall be attached and test reports in Chinese or English should be provided; if data are from published literature, full text of original literature including abstract or quotation shall be provided; if data are from database, relevant information including database name, issue institution, version, etc. shall be submitted; if data are from QSAR estimate, information including estimate model and parameter used, model recommendation or developing institution, version and effectiveness of the results etc. shall be submitted; and if such data are from expert statement, brief introduction of expert shall be provided, including title/post, employer, research field, major research findings, etc.

2). Data sharing

Making registrations using test reports entitled by a different company name is allowed and does not lead to consequences for simplified registration, while for typical notification it would cause the latter notifier to accumulate the notification quantity of the previous notifier.

3). Tests that must be conducted in China

For basic type Simplified Registration and Typical Registration, normally readily biodegradation test and 1 toxic test to aquatic organism (generally acute fish toxicity test) must be conducted in China by labs recognized by MEP. The other tests can be conducted by recognized labs (normally GLP labs) in other countries.

4). Data Requirement for Different Types of Registration

For the three types of registrations: Scientific Research Record, Simplified Registration (Special type and Basic type) and Typical Registration (Level 1, 2, 3, 4), the difference between Scientific Research Record Registration and other two types of registrations is that for the former the related activities could be started once the registration form is submitted but for the latters related activities (manufacturing or importation) can only be started after the registration is approved and Registration Certificate is issued.

(1). For Simplified Registration (Basic type), 1~3 tests must be conducted in China by recognized labs.

For organic substances, biodegradation test shall be conducted. If not biodegradable, acute toxicity test of aquatic organisms (fish is preferred) also shall be submitted.

For inorganic substances, acute toxicity test of aquatic organisms (fish is preferred) shall be submitted.

If the substance's water solubility is less than 100mg/L and its LC_{50} to aquatic organisms is above its saturated concentration, then acute toxicity test of terrestrial life (earthworm is preferred) shall be provided.

(2). For typical registration, there are four levels depending on the tonnage band: 1-10t/y, 10-100t/y, 100-1000t/y and 1000t+/y.

The data requirement is increasing with tonnage band increases. The table below shows typical necessary tests for different levels.

No.	Test Item	State/Level			
Physi-chemical property		Gas.	Liq.	Sld.	
1.	NMR/IR/UV	✓	✓	✓	
2.	Melting point			✓	
3.	Boiling point		✓		
4.	Flash point*		✓		
5.	Density		✓	✓	
6.	LogKow		✓	✓	
7.	Vapor pressure		✓		
8.	Surface tension*		✓		
9.	pH		✓		
10.	Water solubility		✓	✓	
11.	Particle size*			✓	
12.	Oxidizing property*	✓	✓	✓	
13.	Self-ignition temperature*	✓	✓	✓	
14.	Flammability	✓	✓	✓	
15.	Explosivity*		✓	✓	
16.	Explosive limit	✓			
17.	Critical point	✓			
Toxicity		L1	L2	L3	L4
18.	Acute oral toxicity*	✓	✓	✓	✓
19.	Acute dermal toxicity*	✓	✓	✓	✓
20.	Acute inhalation toxicity*	✓	✓	✓	✓
21.	Acute skin irritation*	✓	✓	✓	✓
22.	Acute eye irritation*	✓	✓	✓	✓
23.	Skin sensitization*	✓	✓	✓	✓
24.	28d repeated oral toxicity*	✓			
25.	AMES test	✓	✓	✓	✓
26.	In vitro chromosome aberration	✓	✓	✓	✓
27.	In vivo Micronucleus assay/Mammalian bone marrow chromosome aberration test		✓	✓	✓

28.	90d repeated oral toxicity		✓	✓	✓
29.	Reprod./devel. Screening		✓		
30.	Teratogenicity			✓	✓
31.	Two-generation reproduction			✓	✓
32.	Toxicokinetics information *		✓	✓	✓
33.	Chronic toxicity*				✓
34.	Carcinogenicity*				✓
Eco-toxicity		L1	L2	L3	L4
35.	Algae growth inhibition	✓	✓	✓	✓
36.	Daphnia acute toxicity	✓	✓	✓	✓
37.	Acute fish toxicity	✓	✓	✓	✓
38.	Activated sludge*	✓	✓	✓	✓
39.	Adsorption/desorption*	✓	✓	✓	✓
40.	Ready biodegradation test	✓	✓	✓	✓
41.	Inherent biodegradation *		✓	✓	✓
42.	Hydrolysis as a Function of pH *		✓	✓	✓
43.	Acute earthworm toxicity*	✓	✓	✓	✓
44.	14d fish toxicity*		✓		
45.	Daphnia magna reproduction		✓	✓	✓
46.	Fish bioaccumulation *		✓	✓	✓
47.	Chronic fish toxicity			✓	✓
48.	Seed Germination/Root Elong. *			✓	✓

Remark:

*: can be exempted if certain condition is met.

L1: 1~10 ton; L2: 10~100 ton; L3: 100~1,000 ton; L4: >1,000 ton

6: Filling Data Gaps

After collecting all the available information of the substance and analyzing the data gaps based on the tonnage band, a plan shall be made to fill the data gaps. This might involve arranging tests by recognized labs, searching for literatures, etc. based on the requirement and known properties of the substance. This will involve also,

•Application of Scientific Research Record Registration before introducing sample to China for testing;

•Determination of recognized labs, confirm the test schedule.

•Delivery of sample to labs and signature of test contract;

•Approval of test protocol;

•Finalization of testing reports.

7: Preparation and Submission of Registration Dossier

After all needed information and documents are gathered, registration dossier shall be prepared, which might include:

•Signature of Registration Form;
• GHS classification of the substance;
• Risk assessment report;
• Other documents needed;

8: Post-registration Obligations

For Scientific Research Record, NCS should be conducted in designated facilities under direction of professionals, by strictly following relevant management rules. NCS can only be manufactured and imported for the purpose of scientific research.

For the simplified registrations, there are mainly two requirements for Post-registration Obligations：

1). Annual report about the actual manufacturing or importing status of the NCS for the previous year;
2). NCS registration dossier, as well as NCS' manufacturing/importing status etc. shall be archived for more than 10 years.

For Typical Registration, there are different post-registration obligations depending on different management categories.

According to standards on chemical hazard identification and classification, NCS is classified into 3 management categories: General New Chemical Substance, Hazardous New Chemical Substance, and Critical New Chemical substance.

Category	Post-registration Obligations
General New Chemical Substance (6 requirements)	1. Hazard of the NCS shall be described clearly in SDS, and SDS shall be passed to the downstream users; 2. Implementation of risk control measures according to the requirements on the Certificate； 3. Submission of the first-activity report; 4. NCS registration dossier, as well as NCS' manufacturing/importing status etc. shall be archived for more than 10 years; 5. Prohibition of selling chemicals to downstream users that are not capable of implementing risk control measures; 6. Reporting of newly obtained hazard information of the substance;
Hazardous New Chemical Substance (9 requirements)	7. Annual report ; 8. Application for listing the substance into IECSC in about 5 years; 9. Supervision by local EPA;
Critical Environment-Risk NCS (11 requirements)	10. Monitor on NCS' release to environment; 11. report of NCS transfer to each different user.

Service on New Chemical Registration in China by

Randis ChemWise (Shanghai) Co., Ltd.

Randis ChemWise (Shanghai) Co. Ltd. is located in Shanghai, established in 2004 by several former senior EHS and Product Stewardship managers of well-known multinational chemical companies. Our professional expertise offers comprehensive service in Product Stewardship field especially in New Chemical Registration in China IECSC. Randis' expertise have been intensely working with China New Chemical Registration system (China REACH) since its draft consultation stages, since 2002.

Randis ChemWise offers an integrated package of service for New Chemical Registration, incl.,

- Function as Chinese Notification Agent.
- Initiate and coordinate the notification process
- Define testing needs and coordinate tests
- Prepare and submit the dossier
- Liaise with authorities till registration Certificate is obtained.
- Follow-up management of the registered New Chemical Substances

Other professional services Randis provides.

GHS
Globally Harmonised System
化学品分类及标记全球协调制度

GHS in China, SDS and Safety Label

- GHS hazard classification of chemicals
- GHS version Safety Data Sheet (SDS) preparation for China and other countries
- Safety Label preparation for China and all over the world
- China recognized 24h Emergency Telephone Number
- Recognized by China Customs and Entry-Exit Inspection and Quarantine Bureau, SAWS

Chemicals

- Registration of Hazardous Chemicals according to SAWS Order No. 53
- Registration of Toxic Chemicals for the import and export according to MEP Order No. 22.
- Registration of the import and export of Ozone Depleting Substance
- Registration of Environment Microbe Microbial Inoculum
- Disinfectant, Food Packaging Materials GB9685 Registration etc.
- China chemical regulatory consulting service
- Cosmetics registration to SDFA
- Hazardous Chemical Business License
- Others

Service Mission： One-stop services. Think on behalf of clients.
Service Policy： Professional, Efficient, Confidential.

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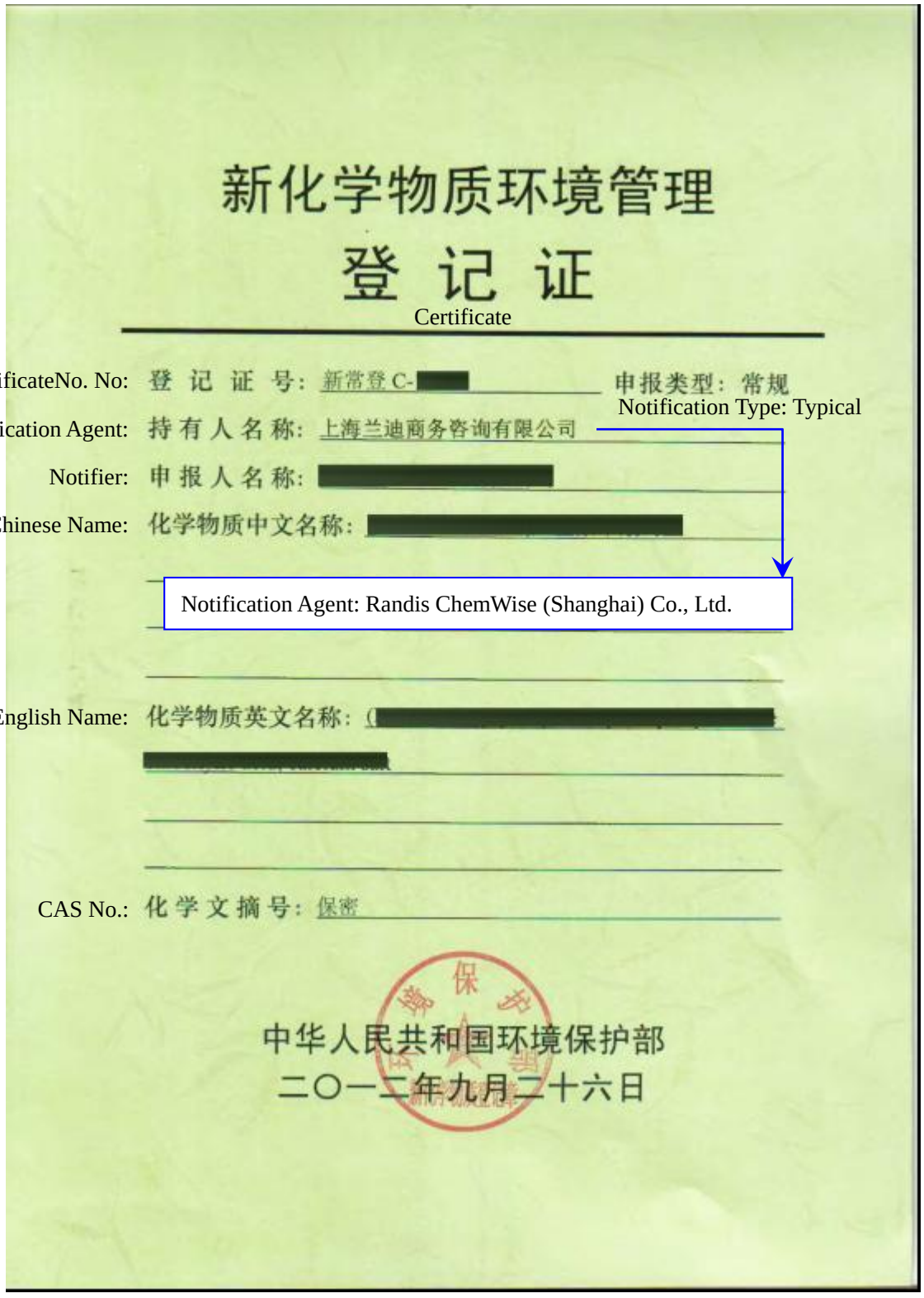
Example：Scanned New Chemical Normal Registration Certificate of China, obtained via Randis



新化学物质环境管理

登 记 证

Certificate

CertificateNo. No: 登 记 证 号：新常登 C-[redacted]　申报类型：常规 Notification Type: Typical

Notification Agent: 持 有 人 名 称：上海兰迪商务咨询有限公司

Notifier: 申 报 人 名 称：[redacted]

Chemical Chinese Name: 化学物质中文名称：[redacted]

Notification Agent: Randis ChemWise (Shanghai) Co., Ltd.

Chemical English Name: 化学物质英文名称：([redacted]

CAS No.: 化 学 文 摘 号：保密

中华人民共和国环境保护部

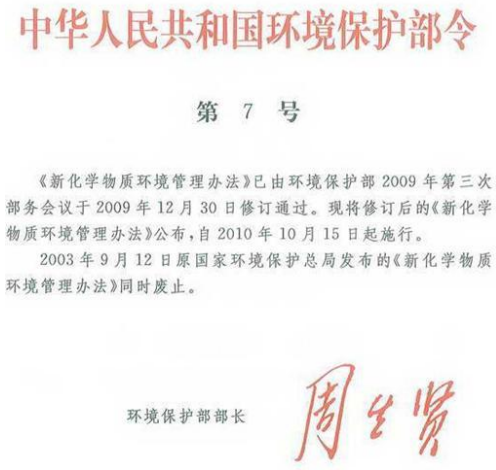
二〇一二年九月二十六日

Background: New Chemical Management in China

'Provisions on Environmental Administration of New Chemical Substances' (Order 17 of SEPA) was first enacted on September 12th of 2003, effective since October 15th of 2003, which was to replace part of 'Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals' issued on March 16th of 1994. It was known as China TSCA or China REACH Regulation.

The revised Provisions (Order 7 of Ministry of Environmental Protection) was enacted on January 19th of 2010, effective from October 15th of 2010, to replace the previous Provisions Order 17.

Order 7 rules that New Chemical Substance (NCS) shall not be manufactured or used inside mainland China, or imported into mainland China, or for Scientific Research activity inside mainland China.



中华人民共和国环境保护部令

第 7 号

《新化学物质环境管理办法》已由环境保护部 2009 年第三次部务会议于 2009 年 12 月 30 日修订通过。现将修订后的《新化学物质环境管理办法》公布，自 2010 年 10 月 15 日起施行。

2003 年 9 月 12 日原国家环境保护总局发布的《新化学物质环境管理办法》同时废止。

环境保护部部长 周生贤

NCS are chemical substances that are not listed in 'Inventory of Existing Chemical Substances in China' (IECSC).