



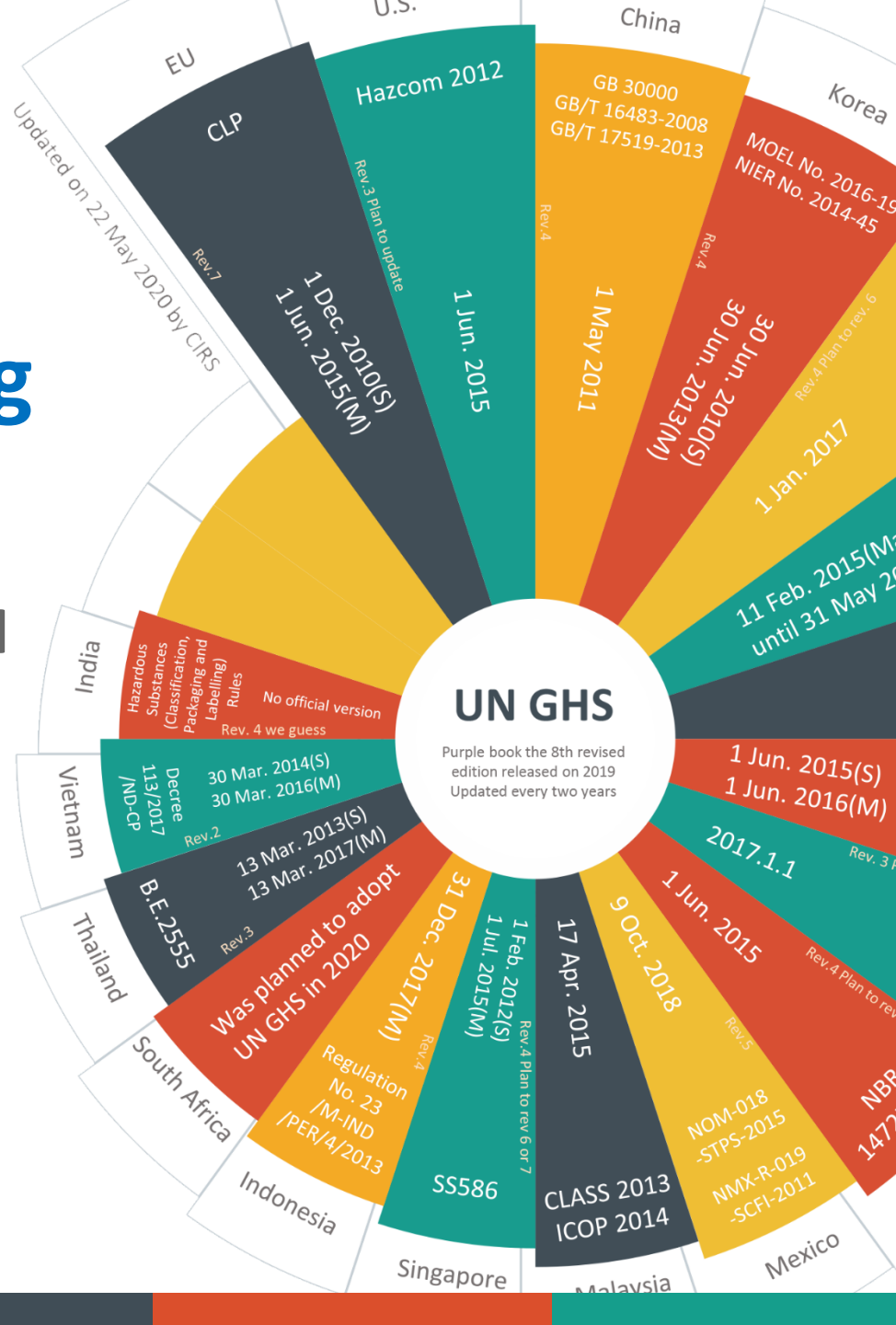
Global GHS Training Course

No. 8 How to keep your CBI in secret during hazard communication



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- Has 350+ employees and annual revenue approximately 50 M USD;
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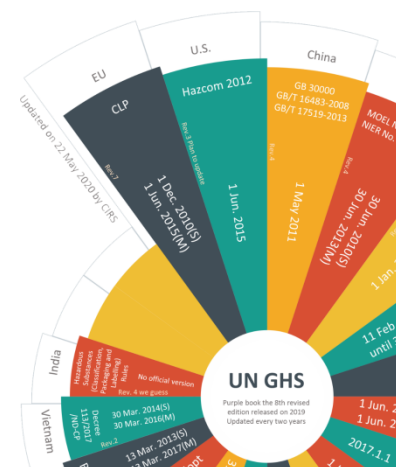
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CBI in UN SDS

GHS has given different competent authorities capabilities to make their own provisions to protect confidential business info in SDSs or on labels as long as such provisions do not compromise the health and the safety of workers and consumers. In some region or countries, withholding confidential business info in SDSs or labels even requires prior approval from local competent authorities.

UN GHS purple book has set a few general principles for the disclosure of confidential business info (CBI) in SDSs and on labels:

- CBI claims should be limited to the names of substances and their concentrations in mixtures;
- Where CBI has been withheld, the SDS and the label shall indicate;
- CBI should be disclosed to competent authority upon request.



EU GHS

- In EU, essentially all hazardous substances must be declared in the safety data sheets (SDSs) if their concentrations exceed certain cut-off value. Usually non-hazardous constituents do not need to be disclosed. However, non-hazardous substances must also be disclosed if there are union workplace exposure limits or if they belong to PBT substances. When disclosing composition info in SDSs, substance identifiers (CAS number or EC number), substance names as well as concentration or concentration ranges must be provided. If the concentration range is used, the classification derived for the particular concentration range should be based on the highest concentration in the range quoted.
- Companies who are concerned about disclosing the full composition of a mixture in SDS or on product labels can request the use of an alternative chemical name for a hazardous substance to protect their trade secrets. The request must be submitted to European Chemicals Agency (ECHA). A fee also needs to be paid in accordance with EU CLP regulation.

Section 3 Composition/Information on Ingredients

Section 3 Composition/information on ingredients

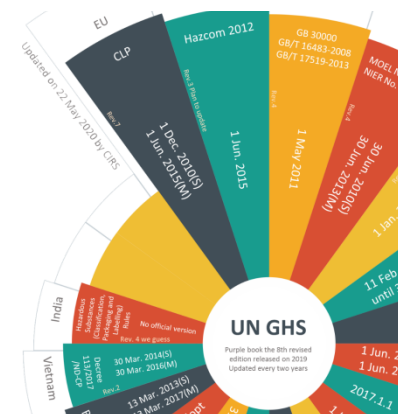
Substance/Mixture:

Mixture

Ingredient(s):

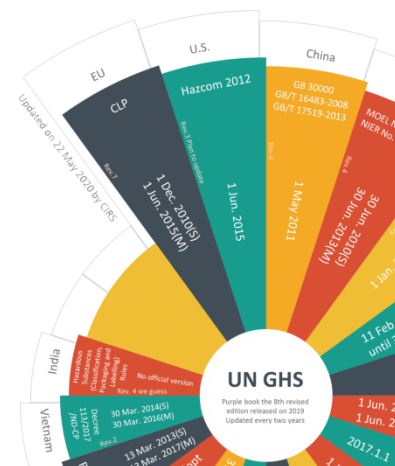
Chemical Name	Registration No.	CAS No.	EC No.	Concentration	Classification
Inorganic bases-1	N/A	Trade secret	Trade secret	5-20%	H314 1A; (H319: 0,5 % ≤ C < 2 % H315: 0,5 % ≤ C < 2 % H314 1A: C ≥ 5 % H314 1B: 2 % ≤ C < 5 %)
Inorganic bases-2	N/A	Trade secret	Trade secret	5-10%	H302; H314 1A;

2% of the mixture consists of component (s) of unknown toxicity.



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USA GHS



According to OSHA's hazard communication standards, the following info must be disclosed in SDSs and on labels:

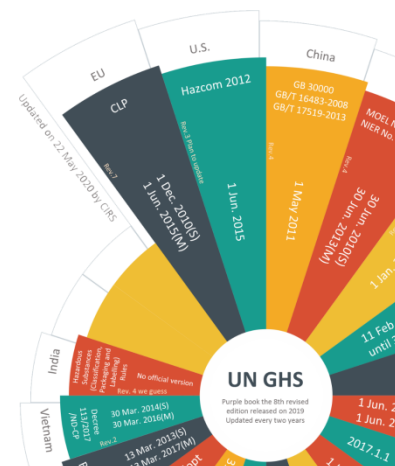
- The chemical and common names of all ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except that chemicals identified as carcinogens shall be listed if the concentrations are 0.1% or greater;
- The chemical and common names of all ingredients which have been determined to be health hazards, and which comprise less than 1% (0.1% for carcinogens) of the mixture, if there is evidence that the ingredients could be released from the mixture in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health risk to employees; and,
- The chemical and common names of all ingredients which have been determined to present a physical hazard when present in the mixture;
- Chemical name, substance identification number and exact weight percentage belong to trade secrets if the claim that the information withheld is a trade secret can be supported. Prior approval from OSHA is not required. All hazards must be disclosed. If confidential business info is claimed and withheld from SDSs, they must be indicated as trade secrets in SDSs.

Canada GHS

- According to Canada WHIMS 2015, for ingredients that present a health hazard, the chemical name, synonyms, CAS No. and exact concentration or specified concentration range must be given in SDSs. Very broad concentration ranges are not allowed.
- When a supplier or employer wants to be exempt from having to disclose confidential business information (CBI), such as the chemical identity of one or more trade-secret hazardous ingredients, they must file a claim for exemption with Health Canada. Once a complete application is received, a Hazardous Materials Information Review Act (HMIRA) Registry Number is assigned to the claim by Health Canada. The HMIRA Registry Number is required to be shown on the (material) safety data sheets ((M)SDSs) and for certain claims, on the label, for that product to be sold on the Canadian market or imported into Canada without disclosure of the CBI.

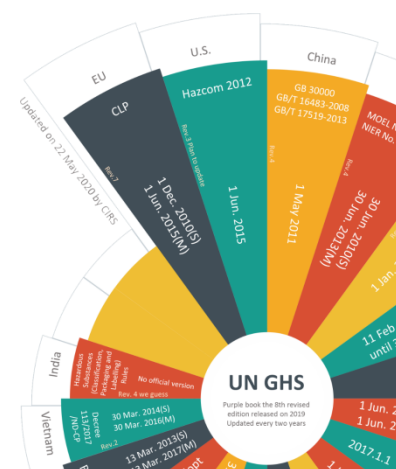
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Asian GHS



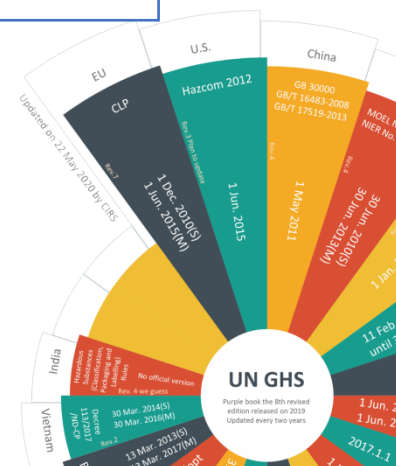
Asian GHS - China

- Both GB 15258-2009 and GB/T 17519-2013 have given clear guidance on information disclosure on labels and in SDSs. Hazardous ingredients contributing to the classification of a substance or mixture and their concentration or concentration ranges shall be disclosed. Generic names are acceptable.
- For trade secret ingredients, real substance names and CAS numbers can be hidden. However, hazards shall be fully disclosed.



Section 3. Composition/information on ingredients

- ✓ This section should specify that the chemical product is a substance or mixture.
- ✓ If it is a substance, the chemical name or generic name, the U.S. Chemical Abstracts Service registration number (CAS#) and other identifiers should be provided.
- ✓ Chemical name or generic name of all hazardous ingredients as well as the concentration or concentration scope should be provided.



Section 3 Composition/Information on Ingredients

3. 成分/组成信息			
物质或混合物:		混合物	Mixture
成分:	Chemical Name	CAS No.	Concentration
化学名称	CAS 号		含量 (%)
顺丁橡胶	butadiene rubber	9003-17-2	60-100%
抗氧化剂	antioxidant	保密	<1%

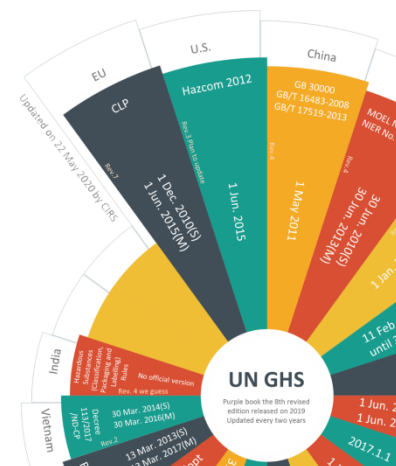
Confidential

Hazard Category		Cut-Off Value (%)
Acute Toxicity		≥1.0
Skin Corrosion/Irritation		≥1.0
Serious Eye Damage/Eye Irritation		≥1.0
Respiratory or Skin Sensitization		≥0.1
Germ Cell Mutagenicity	Category 1	≥0.1
	Category 2	≥1.0
Carcinogenicity		≥0.1
Reproductive Toxicity		≥0.1
STOT- Single Exposure		≥1.0
STOT – Repeated Exposure		≥1.0
Aspiration Hazard	Category 1	≥10 and dynamic viscosity ≤20.5 mm ² /s (40°C)
	Category 2	≥10 and dynamic viscosity ≤14 mm ² /s (40°C)
Hazardous to the aquatic environment		≥1.0

Asian GHS – Korea

- The 2019 OSHA amendment requires companies to prepare safety data sheets for chemicals meet GHS hazard criteria, **disclose full composition info** and **submit the safety data sheets to the MoEL** prior to production or import. The SDS submission requirement will be enforced from **15 Jan 2021**.
- Hazardous substances must be fully disclosed in SDSs. If a company wishes to protect trade secret info and hide the real name of a hazardous ingredient, it must apply for prior approval from MoEL. If the application is granted, the company can then use a generic name instead of full name.

- Preparation SDS according to K-OSHA standards and providing SDS to chemical buyers/handlers when they deliver chemical
- Any changes in SDS must be informed by providing revised SDS to chemical buyers/handlers immediately
- Submission SDS to MoEL with details of use information via IT system before manufacture or import
- Submission revised SDS to MoEL in case there is changes in SDS (product name/components/content(%)/hazards) via IT system immediately
- Manufacturers or importers don't need to submit SDS
 - When they disclose full composition(100%) in Section 3
 - or once they confirm some hidden substances in Section 3 are not hazardous by using form no. 62 of enforcement rule of K-OSHA (Letter of Confirmation from overseas manufacturers or producers) – but via IT system



Asian GHS – Korea

- Manufacturers or importers can hide chemical name or content(%) in SDS, in case the information is applicable for confidential business information via authorization procedure
(except for high toxic chemical notified by MoEL)
- Manufacturers or importers should get authorization about the CBI claim from MoEL by submitting form no. 63 of enforcement rule of K-OSHA* – but via IT system
- MoEL will give authorization number and expiry date
- Initial expiry duration of the authorization is 5 years, they can apply for extension of the date every 5 years (at least 1 month before the expiration date) via IT system

Asian GHS – Korea

Form no. 63 (via IT System) of enforcement rule of K-OSHA

- Reasonable reason for CBI Claim
- Substitute data (Generic name/content range(%)/etc.)
- Original full composition information (chemical name/content(%)) and hazards of the substances
- SDS

Form no. 63 CBI		<input type="checkbox"/> Approval <input type="checkbox"/> Extension approval		Claim		
* 색상이 어두운 칸은 신청인이 적지 않으며, []에는 해당되는 곳에 √ 표를 합니다. (양쪽)						
접수번호	접수일시	처리일	처리기간	1개월(2주)		
Applicant	<input type="checkbox"/> Only representative <input type="checkbox"/> JO - OR appointment number () <input type="checkbox"/> X					
	Company name	CEO	② Industry			
	Business registration number	Number of Staff				
	Address					
	(E-mail:)					
	Tel.	Fax				
③ Category	<input type="checkbox"/> Manufacture <input type="checkbox"/> Import		<input type="checkbox"/> R&D <input type="checkbox"/> non-R&D			
④ Product name						
⑤ Full composition	Classified or not	Chemical name (CAS No.)	CBI claim	Content (%)	CBI claim	Hazards information
	<input type="checkbox"/> O <input type="checkbox"/> X- []not applicable []not available	1.	[]O []X		[]O []X	
	<input type="checkbox"/> O <input type="checkbox"/> X- []not applicable []not available	2.	[]O []X		[]O []X	
	<input type="checkbox"/> O <input type="checkbox"/> X- []not applicable []not available	3.	[]O []X		[]O []X	
	<input type="checkbox"/> O <input type="checkbox"/> X- []not applicable []not available	4.	[]O []X		[]O []X	
- Number of all composition: - Number of classified chemicals: - Number of CBI chemicals:						
⑥ Substitute data	Substitute chemical name		Substitute content(%)			
	1.					
	2.					
	3.					
* only chemical information which you would like to hide						
⑦ Hazards information						
⑧ Approval number	* If you have gotten approval from government, describe approval number and expiry duration					

Asian GHS - Japan



According to JIS 7253, substance name and its concentration or concentration range shall be indicated in SDSs if it is present above concentration limit and contributes to the classification of a product.

If substance name belongs to trade secrets, a generic substance name can be used. However, the following substances must be disclosed and cannot be claimed as confidential:

- Respiratory sensitizing or skin sensitizing substance $>0.1\%w/w$;
- Carcinogenic cate. 2 substance $>0.1\%w/w$;
- Reproductive toxicant cate. 1 or cate. 2 $>0.1\%w/w$;
- STOT Cate. 2 substance $>1\%w/w$;

Asian GHS – Taiwan

In Taiwan, hazardous ingredients contributing to the classification of a substance or mixture and their concentration shall be disclosed.

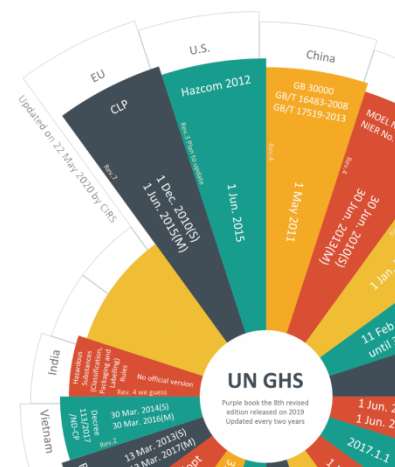
Companies who do not wish to disclose the name or concentration of hazardous chemicals or suppliers' names in SDSs for the necessity of national security or trade secret protection shall provide a written document to Taiwan OSHA and obtain an approval.

However, chemical substances with the following hazard classifications are not allowed to be withheld in safety data sheets (SDSs) and on labels:

- Acute toxicity cate. 1, 2 & 3;
- Skin corrosion and irritation cate. 1;
- Serious eye damage/irritation cate. 1;
- Respiratory or skin sensitisation;
- Carcinogenic, Mutagenic or Reproductive Toxicant;
- STOT single exposure or repeated exposure - cate. 1.

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Summary



Summary

- **EU CLP:** Hiding composition info: A request for the use of an alternative chemical name shall be submitted to ECHA and approved by ECHA;
- **US:** A manufacturer may provide an ingredient concentration range on its safety data sheet (SDS) in lieu of an exact concentration. However, it must include a statement that the exact concentration has been withheld as a trade secret.
- **Canada:** Must file a claim of exemption
- **China:** For trade secret ingredients, the exact substance names and CAS numbers can be hidden. However, hazards shall be fully disclosed.
- **Korea:** Substance name, CAS or content can be hidden. Hazards must be fully disclosed.
- **Japan:** The generic name may be printed in cases where component information concerning chemical substances other than the designated chemical substance relates to trade secrets.
- **Taiwan:** Chemicals with certain hazard classifications are not allowed to be withheld. Name, concentration of hazardous chemicals or suppliers' names can be protected as secret after a written document is submitted to authority and an approval is obtained.

GHS Regulations in different countries/areas



EU	Regulation EC 1272/2008 (CLP)
USA	HCS 2012 / HazCom 2012
Canada	WHIMS 2015
China	GB 15258-2009, GB/T 17519-2013
Korea	MOEL 2016-19
Japan	JIS Z 7253, JIS Z 7254
Taiwan	CNS 15030
Thailand	B.E.2555
Malaysia	CLASS 2013, ICOP 2014
Singapore	SS 586:2014

Useful Links

1. Asia-Pacific Chemical Inventory Search System (APCISS):

<http://apciss.cirs-group.com/?l=en-us>

2. Regulatory Related Materials Download:

<http://freedoc.cirs-group.com/en>

3. Free Webinar Information:

<http://www.cirs-reach.com/events>

4. Regulatory News Updates:

<http://www.cirs-reach.com/>



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Contact Email: service@cirs-reach.com

For our Consultation

Next Webinar: The emergency contact number required in Global GHS SDSs

Time & Date: (GMT+1) 15:00, 26th Aug 2020

Registration still Available

