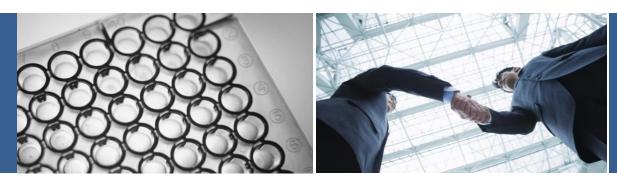


## Webinar Series Opening & Latest Updates of EU & GB CLP



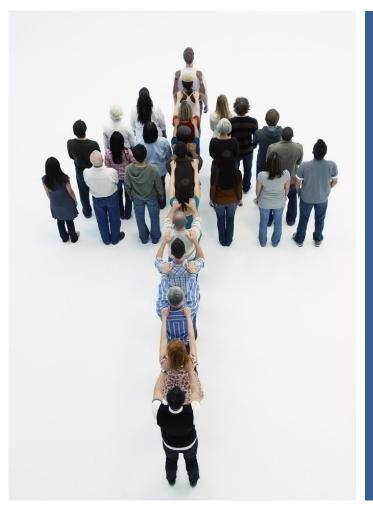
*Global Chemical Regulatory Compliance* 



Dean Winder Regulatory Consultant CIRS Europe Dean.winder@cirs-reach.com







- 1. Introduction to Webinar Series
- 2. Regulations governing EU CLP
- 3. SDS Requirements
- 4. Label Requirements
- 5. GB CLP
- 6. Q&A

## Who is CIRS?





• CIRS is an individual consulting firm founded in 2007 and headquartered in China;

- Has 350+ employees and annual revenue approximately 30 M USD;
- Has branch offices in Dublin(Ireland), London (UK), Arlington(US), Seoul (Korea), Nanjing(China), Beijing(China), Hangzhou(China);
- CIRS provides regulatory compliance consulting, testing and training services.
- CIRS shares more than 70% Chinese consulting markets;
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## **2020 CIRS Training Courses: Global GHS**





Covered **12+** Topics

600+ Participants

Attendees from **30+** Countries

80+ post webinar Q&A

# **Series Introduction**



- Why are we hosting this free series?
  - Follow on from 2020
  - Keeping our Clients up to date
- What to expect in the coming weeks?
  - Recent Global GHS Updates
  - FAQ Documents
- Guest Presenters
  - Mrs. Elif Koç

# Making the most of the Series



- Send us your questions
- Request the Presentations
- Keep up to date with our Advanced Articles
- Consult our FAQ Documents





- 1. Serial Webinar Opening & Latest Updates of EU & GB CLP Mr. Dean Winder
- 2. CLP Compliance in retail supply chain Mr. Bryan Zhou
- 3. Introduction of Turkey GHS and KKDIK Updates Mrs. Elif Koç
- 4. Latest Updates of the South Korean OSHA amendment Julie Harrington.
- 5. Interpretation and FAQ on China SDS and Labelling Mr. Li Xiang

Every Wednesday from 23<sup>rd</sup> of June to 21<sup>st</sup> of July 2021 14:00 (GMT+1)/9:00am (PST)







# REGULATION (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures

- 1. Classification
- 2. Labelling
- 3. SDS
- 4. C&L notification
- \* Guidance available on ECHA

\*\* https://echa.europa.eu/regulations/clp/understanding-clp



#### **CLP Annex VI**

- Annex VI of CLP gives a list of harmonized classification and labelling for hazardous substances.
- For listed substances, the Annex VI classifications are mandatory.

Summary of Classification and Labelling							
Harmonised o	lassification	- Annex VI	of Regu	ulation (EC) No 1272/	2008 (CLP Regula	ation)	
General Information							
Index Number	EC / List no.	CAS Number	International Chemical Identification				
603-002-00-5	200-578-6	64-17-5	ethanol ethyl alcohol				
ATP Inserted / Updated: CLP00 @ CLP Classification (Table 3)							
Classification			Labelling	ling Specific Concentration limits, M-Fa		Notes	
Hazard Class ar Category Code(	Statem	ent State	ard ment e(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)	Acute Toxicity Estimates (ATE)	
Flam. Liq. 2	H225	H225			GHS02 Dgr		

https://echa.europa.eu/brief-profile/-/briefprofile/100.000.526 https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/49769



### **GHS: hazard classifications**

Physical Hazards	<ul> <li>Explosives; Flammable Gases; Chemically Unstable Gas; Aerosols; Oxidizing Gases; Gases Under Pressure; Flammable Liquids; Flammable Solids; Self-reactive Substances; Pyrophoric Liquids; Pyrophoric Solids; Self-heating Substances; Substances, Which In Contact With Water, Emit Flammable Gases; Oxidizing Liquids; Oxidizing Solids; Organic Peroxides; Corrosive To Metals; Desensitized Explosives</li> </ul>
Health Hazards	<ul> <li>Acute Toxicity; Skin Corrosion / Irritation; Serious Eye Damage / Eye Irritation; Respiratory Sensitization; Skin Sensitization; Germ Cell Mutagenicity; Carcinogenicity; Toxic To Reproduction; Effects On Or Via Lactation; Specific Target Organ Systemic Toxicity (Single Exposure); Specific Target Organ Systemic Toxicity (Repeated Exposure); Aspiration Hazard</li> </ul>
Environment al Hazards	• Aquatic Toxicity (Acute, Chronic); Hazardous For The Ozone Layer





# **SDS Requirements**



1. Identification of the substance/mixture and of the company/undertaking	9. Physical and chemical properties
2. Hazard identification	10. Stability and reactivity
<ol><li>Composition/information on ingredients</li></ol>	11. Toxicological information
4. First-aid measures	12. Ecological information
5. Fire-fighting measures	13. Disposal consideration
6. Accidental release measures	14. Transport information
7. Handling and storage	15. Regulatory information
8. Exposure controls/personal protection	16. Other information



### Language requirements



#### Languages required for labels and safety data sheets

Country	Language 1	Language 2	Language 3
Austria	German		
Belgium <sup>1)</sup>	French	Dutch	German
Bulgaria	Bulgarian		
Croatia	Croatian		
Cyprus	Greek		
Czech Republic	Czech		
Denmark	Danish		
Estonia	Estonian		
Finland	Finnish	Swedish	
France	French		
Germany	German		
Greece	Greek		



- ≻Company Info name, address, contact, emergency contact.
- Destination (standard, language); For CLP SDS, indicate if CIRS is the OR of the substance or any substance in the product.
- Product info product name, usage, component (CAS number and
- concentration/ concentration range)
- > Physical info physical state, color, odor, etc.
- > Transportation information (if available) UN number, proper shipping name
- > Any other implementation SDS, registration number, toxic/eco-toxic data, etc



#### **Precautionary Statement Guidance**

- The P-statements should be selected based on the rules in CLP Article 28 and Part 1 of Annex IV to CLP
- The selection of P-statements should take into account the underlying hazards and identified or foreseen uses of the substance
- If the content of two P-statements are the same, choose the most relevant statement
- The P-statements assignment follows a "traffic light" system. They are "highly recommended", "recommended", "optional" and "not to be used" for the hazard label
- A particular recommendation should be seen in the light of the original CLP conditions for use specified under the relevant precautionary statement in the selection tables
- Two target groups under the CLP Regulations. Where there is no explicit mention of the target group, the conditions for use apply to both the general public and industrial/professional users
- Where the use of a particular precautionary statement is (highly) recommended but some exemptions are indicated ("unless" condition), it should not be used where the conditions specified in the "unless" clause apply:

CLP Update	Noteworthy Points			
The update to the REACH annex II applies from beginning 2021.	<ul> <li>Nanoforms information must be included in the SDS.</li> <li>If available, the specific concentration limits, the multiplying factors and acute toxicity estimates set in accordance with CLP should be provided in the SDS.</li> <li>the unique formulation identifier (UFI) is indicated in the SDS only with regard to the dangerous mixtures</li> </ul>			
The 12 <sup>th</sup> ATP applied from October this 2020	<ul> <li>Annex II: Deleted phrase EUH001; renumbering of sections.</li> <li>Annex III: Added hazard statements H206, H207, H208 and H232.</li> <li>Annex IV: Corrected and revised P phrases.</li> <li>Annex IV: Added a new hazard category, i.e., desensitised explosives.</li> <li>Annex VI: Added a new hazard category for flammable gases and new hazard class desensitised explosives in table 1.1.</li> </ul>			
The 13th ATP applies from May 2020.	<ul> <li>The preservatives MIT, CMIT/MIT and the bleaching agent Sodium hypochlorite, had their classifications either added to Annex VI or updated.</li> <li>MIT has been assigned a 15 ppm specific concentration limit which is significantly lower than the 0.1% concentration limit used for general category 1A skin sensitisers.</li> <li>The addition of oral and inhalation Acute Toxicity Estimates (ATEs) for Pinoxaden (CAS number 243973-20-8).</li> </ul>			
The 14th ATP will apply from October 1 <sup>st</sup> 2021.	<ul> <li>The label of liquid mixtures containing 1% or more of titanium dioxide particles with aerodynamic diameter equal to or below 10 μm will bear the EUH211 statement: "Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist."</li> <li>The label of solid mixtures containing 1% or more of titanium dioxide will bear the EUH212 statement: "Warning! Hazardous respirable dust may be formed when used. Do not breathe dust."</li> <li>Note V: If the substance is to be placed on the market as fibres (with diameter &lt; 3 μm, length &gt; 5 μm and aspect ratio ≥ 3:1) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry, their hazardous properties must be evaluated in accordance with Title II of this Regulation, to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied."</li> <li>"Note W: It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung."</li> <li>"Note 10: The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 μm."</li> </ul>			

CLP Update	Noteworthy Points		
The 15 <sup>th</sup> ATP applies from March 2022 (update to Annex VI)	<ul> <li>The substance lead (CAS number 7439-92-1 and index numbers 082-013-00-1 (lead powder; [particle diameter &lt; 1 mm];) and 082-014-00-7 (lead massive; [particle diameter ≥ 1 mm];))</li> <li>The environmental classification for the massive form will not be included in Annex VI</li> <li>With regard to the substance 2-butoxyethanol; ethylene glycol monobutyl ether; (CAS number 111-76-2</li> <li>The hazard class 'acute toxicity (inhalation) this hazard class should not be modified in Annex VI</li> </ul>		
The 16 <sup>th</sup> ATP applied from February 2021 (update to Annex VI)	<ul> <li>This relates to the updates to information surrounding carcinogen and mutagens.</li> <li>Substances that have been updated include, benzene, 1,3- butadiene, dimethyl sulphoxide extract, benzo[a]-pyren.</li> </ul>		
The 17th ATP applies from December 2022 (update to Annex VI)	<ul> <li>Updates to the Acute Toxicity Estimates (ATE)</li> <li>ATE values have been derived by the Agency for dicopper oxide, dicopper chloride trihydroxide, tetracopper hexahydroxide sulphate and tetracopper hexahydroxide sulphate hydrate, copper flakes (coated with aliphatic acid), copper(II) carbonate–copper(II) hydroxide (1:1), copper dihydroxide; copper(II) hydroxide, bordeaux mixture; reaction products of copper sulphate with calcium dihydroxide and copper sulphate pentahydrate.</li> </ul>		

## **Important Updates**



- The REACH Annex II updated from 2015/830 to 2020/878.
- The formats of the EU SDS should be updated before the end of 2022.
- The plan is for the EU CLP to be updated again before 2024
- It has caused much discussion surrounding the addition of nanomaterials and the endocrine disruptors to CLP





#### **GHS: label element**



1. Pictograms



• 2. Signal words

Danger or Warning

• 3. Hazard statements

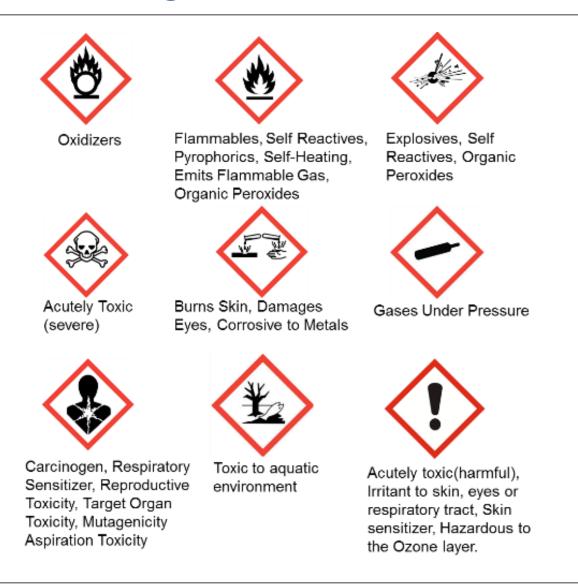
May damage fertility or the unborn child; Very toxic to aquatic life with long lasting effects.

• 4. Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection; Avoid release to the environment; If exposed or concerned: Get medical advise/attention;



#### **The 9 Standard Pictograms**





## **CLP** labelling

#### How to Find Signal Words, Pictogram, H and P Phrases for Flammable Liquids in Various Categories

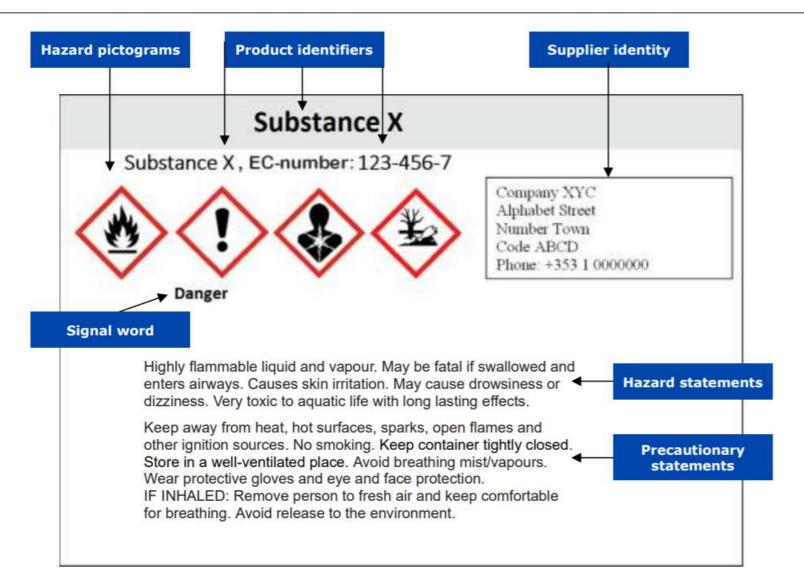
#### 7.3.2.6 Flammable Liquids

Hazard category	Signal word	Hazard statement			
1 Danger		H224 Extremely flamma	( ( )		
2	Danger	H225 Highly flammable liquid and vapour.			
3 Warning		H226 Flammable liquid	•		
		Precautionary Stateme	ents		
Prevention	n	Response	Storage	Disposal	
P210		P303 + P361 + P353	P403 + P235	P501	
Keep away from I flames/hot surfaces. – No Manufacturer/supplier to s ignition source(s).	specify applicable sed. category 1, y been assigned ory 2, unless assigned t is volatile so as y explosive	<ul> <li>IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.</li> <li>* Optional unless deemed necessary, e.g. due to the risk of generating a potentially explosive atmosphere</li> <li>P370 + P378</li> <li>In case of fire: Use for extinction.</li> <li> Manufacturer/supplier to specify appropriate media.</li> <li>- if water increases risk.</li> <li>* Highly recommended if specific extinction media are required or appropriate, e.g. if water is ineffective or if water increases risk</li> </ul>	<ul> <li>Store in a well-ventilated place. Keep cool.</li> <li>* Highly recommended for flammable liquids category 1 and other liquids that are volatile so as to generate a potentially explosive atmosphere</li> </ul>	<ul> <li>Dispose of contents/container to</li> <li> in accordance with local/regional/ national/international regulations (to be specified).</li> <li>Highly recommended for the general public if the substance / mixture is subject to legislation on hazardous waste. It is recommended to specify the site of disposal while a reference to the applicable legislation is not necessary.</li> <li>Recommended for industrial / professional users if there are specific disposal requirements above the normal expectation for the disposal of chemicals. It is recommended to specify the site of disposal while a reference to the applicable legislation is not necessary.</li> </ul>	

Source: http://echa.europa.eu/documents/10162/13562/clp\_labelling\_en.pdf



## Label Example









• The Northern Ireland Agreement makes EU Law applicable in NI

• Therefore, the GB CLP Regulations only apply to Scotland England and Wales

• The information on GB CLP is very limited now as there isn't regulatory documents published for classification & labelling.

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- The GB CLP is expected to be similar to EU CLP
- The classification criteria is the same.
- There is a mandatory classification list (GB MCL) on the HSE website.
- When providing products within GB a GB CLP compliant SDS and Label will be required
- When exporting products to NI or EU an EU CLP compliant SDS and Label will be required



#### What We Know So Far

- Mandatory classification is a classification that is equivalent to the 'harmonised classifications' that exist under EU CLP.
- Where a substance has an MCL for some or all hazard classes, suppliers to the GB market must apply it
- The GB mandatory classification and labelling system will be hosted, managed and operated by HSE (as the GB CLP Agency)
- Self-classification is where the supplier gathers and evaluates all of the available information, then compares it to the classification criteria
- Substances which do have a mandatory classification must be self-classified for any hazard classes not covered by that mandatory classification



### **GB CLP substance notification**

- GB-based manufacturer or importer placing chemicals on the GB market
- NI-based manufacturer, downstream user or distributor supplying qualifying NI goods (QNIG) directly to the GB market
- You must submit your notification to HSE within one month of placing new substances on the GB market.
- Notifications already made to ECHA and which are included in the ECHA Classification and Labelling Inventory on 31 December 2020, do not need to be re-notified.
- If the classification of the substance changes, then you will need to submit a notification to HSE.
- Otherwise, notification will only be needed where a substance is placed on the GB market for the first time after 31 December 2020.



# Q & A

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