

Global GHS Training Course

No.6 - CLP and the SCIP Database



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EU REACH







Substances of Very High Concern (SVHC)



SCIP Database





EU REACH



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EU REACH

- Registration,
- Evaluation,
- Authorisation and Restriction of
- Chemicals



Managed by ECHA (European Chemicals Agency)











There is no timeline of Non Phase-in Substance.

-Substance imported or manufactured > 1 ton per year.



EU REACH





EU CLP



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Introduction of GHS



Globally Harmonized **S**ystem of Classification and Labelling of Chemicals



8th Revised Edition

http://www.unece.org/trans/danger/publi/ghs/ghs_rev08/08files_e.html

Introduction of GHS





GHS: hazard classifications



Physical Hazards	 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
Health Hazards	 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
Environment al Hazards	• Aquatic Toxicity (Acute, Chronic); Hazardous For The Ozone Layer

How to classify



1. Experimental data

Table 2.6.1: Criteria for flammable liquids					
Category	Criteria				
1	Flash point < 23 °C and initial boiling point \leq 35 °C				
2	Flash point < 23 °C and initial boiling point > 35 °C				
3	Flash point $\ge 23 \text{ °C}$ and $\le 60 \text{ °C}$				
4	Flash point > 60 °C and \leq 93 °C				

2. Calculation

Table 3.3.3: Concentration of ingredients of a mixture classified as skin Category 1 and/or eye Category 1 or 2 that would trigger classification of the mixtures as hazardous to the eye (Category 1 or 2)

Sum of ingredients classified as	Concentration triggering classification of a mixture as			
	Irreversible eye effects	Reversible eye effects Category 2		
	Category 1			
Eye or skin Category 1	≥ 3%	\geq 1% but < 3%		
Eye Category 2/2A		≥ 10%		

GHS: SDS



1. Identification of the substance/mixture and of the company/undertaking	9. Physical and chemical properties
2. Hazard identification	10. Stability and reactivity
 Composition/information on ingredients 	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

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





GHS in different countries/areas



EU	Regulation EC 1272/2008 (CLP)
USA	HCS 2012 / HazCom 2012
China	GB 30000, GB/T 16483-2008, GB/T 17519-2013
Japan	JIS Z 7253, JIS Z 7254
Korea	MOEL 2016-19
Thailand	B.E.2555
Malaysia	CLASS 2013, ICOP 2014
Taiwan	CNS 15030
Brazil	NBR 14725:2012
Singapore	SS 586:2014

Note: each country/area updates the local requirements (regularly or irregularly).

The CLP Regulation



- 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 classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)								
General Inform	ation							
Index Number	Index Number CAS Number CAS Number International Chemical Identification							
603-002-00-5	200-578-6	64-17-5 ethanol ethyl alcohol						
ATP Inserted / Updated: CLP00 Ø								
Class	ification			Labelling		Specific Concentration limits, M-Factors,	Notes	
Hazard Class and Category Code(s) Hazard Hazard Statement Code(s) Hazard Statement Code(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

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 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 H224 Extremely flammable liquid and vapour. 1 Danger 2 Highly flammable liquid and vapour. Danger H225 3 Warning H226 Flammable liquid and vapour. **Precautionary Statements** Prevention Response Storage Disposal P210 P303 + P361 + P353 P403 + P235 P501 heat/sparks/open IF ON SKIN (or hair): Remove/Take off Store in a well-ventilated Dispose of contents/container to ... Keep away from flames/hot surfaces. - No smoking. immediately all contaminated clothing. place. Keep cool. ... in accordance with local/regional/ Rinse skin with water/shower. Manufacturer/supplier to specify applicable Highly recommended national/international regulations (to be * Optional unless deemed necessary, ignition source(s). for flammable liquids specified). e.g. due to the risk of generating a category 1 and other Highly recommended Highly recommended for the general potentially explosive atmosphere liquids that are volatile public if the substance / mixture is so as to generate a P233 subject to legislation on hazardous potentially explosive P370 + P378 waste. It is recommended to specify Keep container tightly closed. atmosphere In case of fire: Use ... for extinction. the site of disposal while a reference to the applicable legislation is not Highly recommended for category 1. Manufacturer/supplier to specify necessary. unless P404 has already been assigned appropriate media. Recommended for industrial / Recommended for category 2, unless if water increases risk. professional users if there are specific P404 has already been assigned disposal requirements above the Highly recommended if specific Optional for category 3 normal expectation for the disposal of extinction media are required or appropriate, e.g. if water is ineffective chemicals. . It is recommended to Recommended if product is volatile so as specify the site of disposal while a to generate a potentially explosive or if water increases risk reference to the applicable legislation atmosphere, unless P404 has already is not necessary. been assigned

Source: http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf

Label Example





Language requirements





Languages required for labels and safety data sheets

Country	Language 1	Language 2	Language 3
Austria	German		
Belgium 1)	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		

Information required for SDS authoring



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.

CLP Update	Noteworthy Points
The update to the REACH annex II will apply from the next year.	 Nanoforms information must be included in the SDS. If available, the specific concentration limits, the multiplying factors and acute toxicity estimates set in accordance with CLP should be provided in the SDS. the unique formulation identifier (UFI) is indicated in the SDS only with regard to the dangerous mixtures
The 12 th ATP will apply from October this year	 Annex II: Deleted phrase EUH001; renumbering of sections. Annex III: Added hazard statements H206, H207, H208 and H232. Annex IV: Corrected and revised P phrases. Annex IV: Added a new hazard category, i.e., desensitised explosives. Annex VI: Added a new hazard category for flammable gases and new hazard class desensitised explosives in table 1.1.
The 13th ATP applies from May this year.	 The preservatives MIT, CMIT/MIT and the bleaching agent Sodium hypochlorite, had their classifications either added to Annex VI or updated. 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. The addition of oral and inhalation Acute Toxicity Estimates (ATEs) for Pinoxaden (CAS number 243973-20-8).
The 14th ATP will apply from October 1 st 2021.	 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." 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." Note V: If the substance is to be placed on the market as fibres (with diameter < 3 µm, length > 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." "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." "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."



Substances of Very High Concern (SVHC)



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Introduction



Obligations	Notification of Substances in Articles	Communication of information on substances in Articles	Notification of Articles to SCIP Database	
Legal Basis	Article 7(2) REACH	Article 33 of REACH	Article 9(1)(i) WFD	
Concerned parties	Article producers and Supplier	Article Suppliers		
Substances Concerned	Substances included in the candidate list of SVHCs for Authorisation			
Possible Exemptions	If the substance is already registered for that use or if exposure can be excluded	No	For suppliers that are retailers only selling to consumers	
Tonnage Threshold	1 tonne per year			
Concentration threshold in the Article	0.1% (w/w)			
Information to be Provided	ECHA	Article recipient and consumers upon request	ECHA	

What is an SVHC?



Notification of these substances are required)

Carcinogenic, mutagenic or toxic to reproduction (CMRs) Persistent, bioaccumulative and toxic (PBTs)

Seriously and / or irreversibly damaging the environment or human health

Very persistent and bio-accumulative (vPvBs);



How can I achieve SVHC compliance?

SVHC in greater than 0.1 % w/w total amount of the SVHC exceeds 1 ton/year **Notification:** if any SVHC on candidate list present in an article

Communication: inform the recipients of the article along the supply chain

Restriction: ensure that their products do not contain other REACH restricted substances.

Authorization: Those SVHCs will not be allowed to be used unless the company is granted an authorization.



SCIP Database



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Background



In 2015 the waste framework directive was created

Mandatory from the 5th of January 2021 2018 the revised waste framework directive came into effect

Information Substances of Concern In articles

SCIP Database was established



Who Needs to Submit a Notification?





How to identify the SVHCs in your articles?

Testing is the	Collecting hazardous data from other members in your supply chain, this would include the testing reports. Some companies employ the use of various software in order to streamline this process including IMDS, Bomcheck, chemSHERPA and ECBOS [®] GPM.
most direct method	Searching the hazardous material database, which contains data on many hazardous substances, the assessment report will provide you with a risk profile of your allowing you to more accurately determine what SVHCs could be present.
but	Carrying out preliminary laboratory screening to rule out any unnecessary testing would therefore lower the cost of testing for the presence of SVHCs in your article.

The Database



Submit information on articles to the SCIP database

Data preparation in IUCLID.

Data submission in the ECHA Submission portal.

Material for system-to-system submission of data A prototype of this database has been launched on the ECHA website This test data will be considered as such and deleted prior to the end of October 2020

Information to be submitted



Component information

*Cor r	nponent name	*Amount	*Article category	*Primary article identifier type	*Primary article identifier value	*Production in European Union	Other article identifier type	Other article identifier value	
Unit V	Veight (g)	Picture	Height (m)	Length (m)	Width (m)	Diameter (m)	Density (kg/m³)	Volume (m³)	
	*Material information								
	*Mate	rial name	*Material/ Mixture	e category	Description	Unit Weight (g) Other chara	acteristic	
	SVHC Substances								
*Substance name *CAS *% (w/v					*% (w/w)				

CIRS Advantages



Experienced REACH Regulation Team



- One of the largest Only Representative in the world (EU REACH, China REACH, K-REACH)
- Act as Only Representative for over 3,000 non-EU companies
- Registered over 2,000 substances
- Served clients in more than 25 countries
- Partner of BCF (British Coating Federation)

Globally Available Network of Consultants



- We have office in Europe, China, South Korea, USA
- We are going to set office in Germany, Japan, Singapore...





Reliable IT Software Developed and maintained for Over 10+ Years

- Designated Hazardous substance control and chemical compliance management platform
- Abundant Big Data and database of different chemical products properties for preliminary analysis
- Customized software service
- Used by international companies



Accredited laboratory with 10+ years experience

- Focus on hazardous substance testing especially for **SVHC** since 2008
- Qualified lab with global accreditation
- Internationally accepted testing reports
- Served more than 10,000 global clients



Q&A Session

Following our event, please always click

http://www.cirs-reach.com/news-and-articles/2020-CIRS-Training-Courses-Global-GHS.html

to find further updates

Contact Email: <u>service@cirs-reach.com</u> For our Consultation

Next Webinar: Does article need to comply with GHS **Time & Date:** (GMT+1) 15:00, August 12th Registration still Available



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GB 30000 GB/T 16483-2008 GB/T 17519-2013



Thank you for your attention

