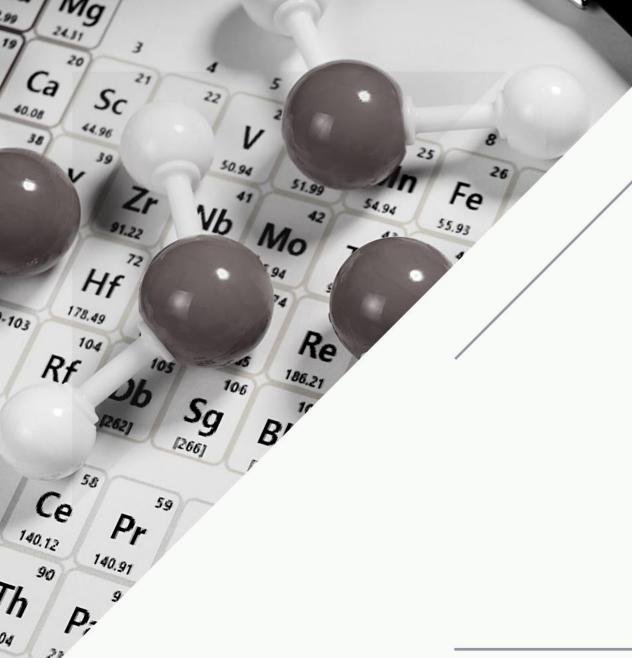
Korea Material Safety Data Sheet

Ashley Min Regulatory researcher GPC Korea





Summary of Topics

- 1. Updates on MSDS
- 2. Approval for non-disclosure
- 3. Procedures
- 4. Deadline
- 5. GPC services



Material Safety Data Sheet (MSDS) (1)

MSDS

- A manual of a chemical product (substances or mixtures) for the safe use in workplace
- KOSHA (Korea Occupational Safety and Health Act)
- K-OSHA (Korean Occupational Safety and Health Agency)

A person who prepare MSDS

- A manufacturer or importer of materials controlled under the MSDS regulation
- A person appointed by an overseas manufacturer (OR)



Material Safety Data Sheet (MSDS) (2)

Substances subject to prepare MSDS

- A chemical substance or mixture that causes health disorders to employees
- Such as hazardous chemicals etc

Exception

- specified in other Acts
- provided mainly to general consumers for daily life
- with low toxicity and explosiveness risk
- for R&D



Material Safety Data Sheet (MSDS) (3)

- 1. Information about the chemical product and company
- Hazard and risk assessment
- 3. Name and content of ingredients
- 4. First Aid Measures
- 5. How to deal with explosions and fires
- 6. Measures for leakage accidents
- 7. Handling and storage
- 8. Exposure prevention and personal protection
- 9. Physicochemical properties
- 10. Stability and Reactivity
- 11. Toxicological information
- 12. Environmental Impact
- 13. Disposal precautions
- 14. Information required for transportation
- 15. Legal Regulatory Status
- 16. Other notes

Warning labels including precautionary statements

- GHS pictograms
- Signal words
- Hazard statements (H codes)
- Precautionary statements (P codes)

1.2.11. 흡인 유해성(aspiration harzard)

구분		1	2
GHS 그림문자		&	\$
RTDG 그림문자		요구되지 않음	요구되지 않음
신호어		위험	경고
유해·위험 문구		H304	H305
예방조치 문구	예방	없음	없음
	대응	P301+P310 P331	P301+P310 P331
	저장	P405	P405
	폐기	P501	P501



Approval for non-disclosure

- To write the alternative information (alternative names and alternative contents) in MSDS instead of information that are trade secrets
- The validity period of approval is 5 years from the date of approval

Alternative name

 Apply <Regulations on the Preparation of Data Protection Application and the Management of Protected Data, etc>

Alternative content

- If the content of the ingredient is 25% or more, +/- 20%P
- If the content of the ingredient is less than 25%, +/- 10%P



Procedures

OR appointment

Prepare MSDS

(Approval for non-disclosure)

Submit MSDS Reflect MSDS number Transfer and provision MSDS

Regional
Employment and
Labor
Administration
OR appointment
letter

5yrs max unless specified differently

K-OSHA

Alternative information etc

Takes max 1month to get approval (might take longer if additional information is required)

Governmental fee:

70USD as basic fee + 40USD per ingredients K-OSHA

MSDS + names and contents of nonhazardous ingredients in materials



Deadline

Existing MSDS

(imported and have MSDS before Jan 16th, 2021)

 A grace period based on tonnage band

Deadline	Tonnage band		
Jan 16th, 2022	Over 1000 tpa		
Jan 16th, 2023	100-1000 tpa		
Jan 16th, 2024	10-100 tpa		
Jan 16th, 2025	1-10 tpa		
Jan 16th, 2026	Below 1 tpa		

*Tonnage band: actual importing volume

New MSDS

(newly imported after Jan 16th, 2021)

- No grace period
- Need to submit MSDS prior to manufacture or import



Re-submission

If any of the following changes occur, need to resubmit MSDS reflecting the changes

- Product name (no change in the ingredient name and content)
- Name and content of hazardous ingredients
- Hazard to health and the environment, physical risks



GPC services

Check (Approval for Reflect **Submit** Post **Prepare** Share MSDS MSDS MSDS non-MSDS MSDS management disclosure) exemption number Local language Communication Local language Communication Local language (Korean) support (Korean) support with the authority (Korean) support with the authority, importers etc Provide services Provide services Response to based on updated based on updated Regulatory requirement requirement updates Re-submission



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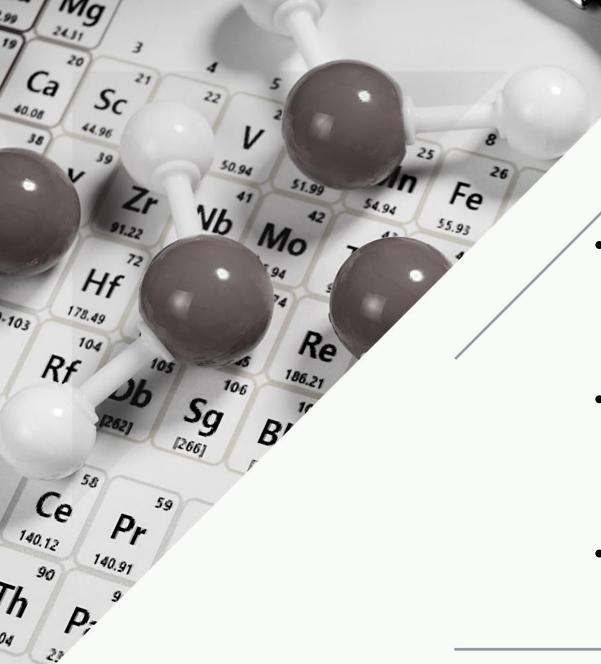
SDS Compliance in Turkey

Related regulations & updates



Miraç Mert Pelister GPC Turkey Business Coordinator & Regulatory Researcher





Summary of Topics

- Regulation Information
 - Changes in regulation
 - KKDIK
 - Differences
- SDS Requirements
 - Standards
 - Technical
 - Author
- Summary & Role of GPC



Which regulation to follow?

- 2009->2016 Bylaw on Preparation & Distribution of SDS of Hazardous Substances and Preparations
- Since 2014 -> «Bylaw on Safety Data Sheets of Hazardous Substances and Mixtures»
- Turkey-REACH / KKDIK -> Transition
- Both can be followed until 31st Dec 2023
- KKDIK is recommended



What are the main differences?

SDS Regulation (2014)

- PPP under scope
- Biocidal not included
- Only exam needed for authors to be certified
 - 120 minutes exam

KKDIK (2017)

- PPP & Biocidals included
- Authors are Chemical Safety Assessors
 - 64 hour education needed
 - 180 minutes exam



Important to know



 Based on CLP Regulation (13th ATP)



Standard 16
 Headings



In Turkish & by certified author



Standard Headings

- Substance & Company Info
- Hazard identification
- Composition
- First aid measures
- Firefighting measures
- Accidental release measures
- Handling & storage

- Exposure controls/personal protection
- Physicochemical properties
- Stability & reactivity
- Toxicological information
- Ecotoxicological information
- Disposal information
- Transportation
- Other (including author certificate info)



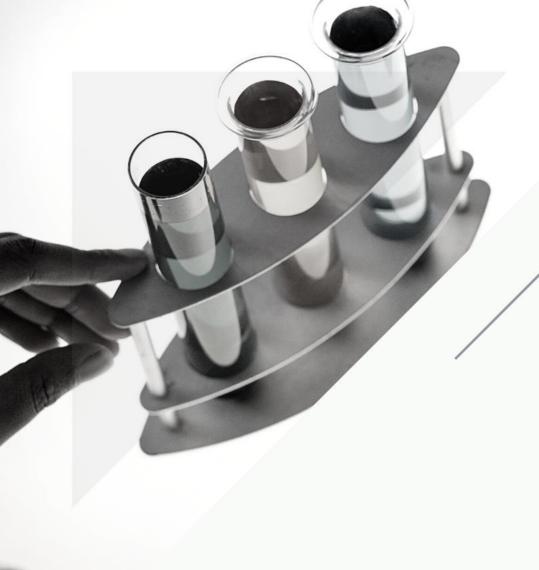
When is SDS required?

 Substance classified as hazardous according to CLP PBT/vPvB substances

 In "candidate for authorization" list for other reasons

- In case of mixtures:
 - Gas: >0.2% harmful
 - Non-gas: >1% harmful or >0.1% CMR/PBT
 - OEL substance





When is SDS provided?

- If it meets the criteria:
 - Either physically or digitally
 - Free of charge
 - In Turkish

Provided to the buyer!



What if SDS is NOT required?

 Registration numbers If the substance is restricted; details

 If the substance is subject to authorization; details Any valid information on substance (including specific conditions as a result Annex 11 section 3) to apply risk management measures

Provided down the supply chain latest by the first delivery!



Registration Dossier

- SDS is provided as an attachment if:
 - Chemical Safety Report (CSR) is required for the registration dossier
 - Downstream users need to add exposure scenarios from previous actor in the supply chain to their SDS
 - Distributors pass on the information and exposure scenarios down the supply chain





Updating SDS



When to update

- If new information is present:
 - Affecting risk management measures
 - Hazard classification
- Subject to authorization
 - Permit is given or rejected
- Subject to restriction

Must be distributed to buyers of past 12 months, free of charge

Including registration number if update is post-registration



Responsibility

- Manufacturers, importers, downstream users, distributers must keep SDS for 10 years after:
 - Last production
 - Last import
 - Last purchase
 - Last usage



Summary

- Currently two regulations are effective regarding SDS
 - To be compliant with KKDIK now is recommended
- Substances classified as hazardous must prepare SDS
- SDS will be included in the registration dossier if CSR is needed
- SDS must be in Turkish language and authored by a certified author
- SDS is compliant with GHS



What GPC can do for you

- Certified authors according to KKDIK Annex 18
- Fully compliant SDS in Turkish
- Free update within initial 6 months
- Competitive prices



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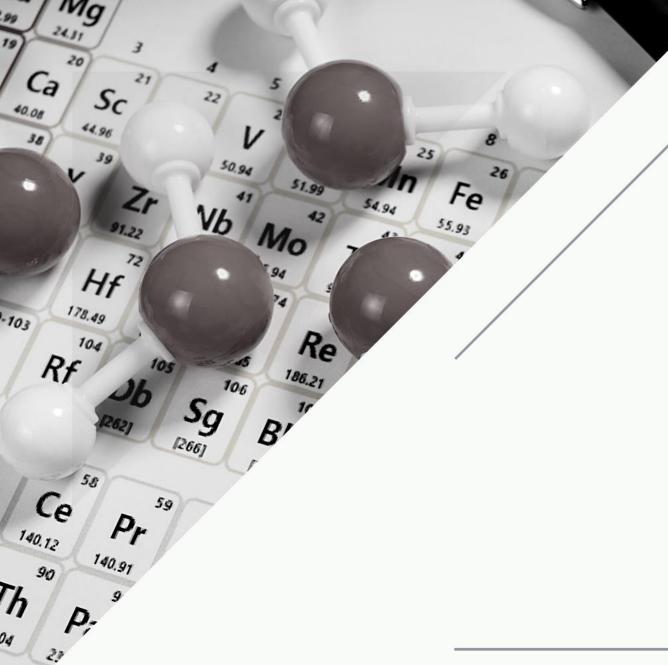


Updates on Safety Data Sheet (SDS) — it's impact on Australian introduce

Speaker

Dr. Yashwanth Bomma Team Lead Ecotoxicology Global Product Compliance Europe AB





Summary of Topics

- GHS overview
- Responsible Persons
- Time line of transition
- Transition and Adaptation
- Changes under GHS7
- Comparison between GHS 3 and GHS 7
- Take home message
- How GPC can help you?



GHS (Global Harmonisation System) overview

- UN GHS Purple book is an international global method of classifying chemicals and preparing labels and safety data sheets.
- GHS version 1 (2005)
- GHS version 8 (2019)
- Essential requirements of Safety data sheet.

- Section 1 Identification of the substance or mixture and of the supplier;
- Section 2 Hazard identification;
- Section 3 Composition/information on ingredients;
- Section 4 First-aid measures;
- Section 5 Fire-fighting measures;
- Section 6 Accidental release measures;
- Section 7 Handling and storage;
- Section 8 Exposure controls/personal protection;
- Section 9 Physical and chemical properties;
- Section 10 Stability and reactivity;
- Section 11 Toxicological information;
- Section 12 Ecological information;
- Section 13 Disposal consideration;
- Section 14 Transport information;
- Section 15 Regulatory information;
- Section 16 Other information.



Responsible Persons

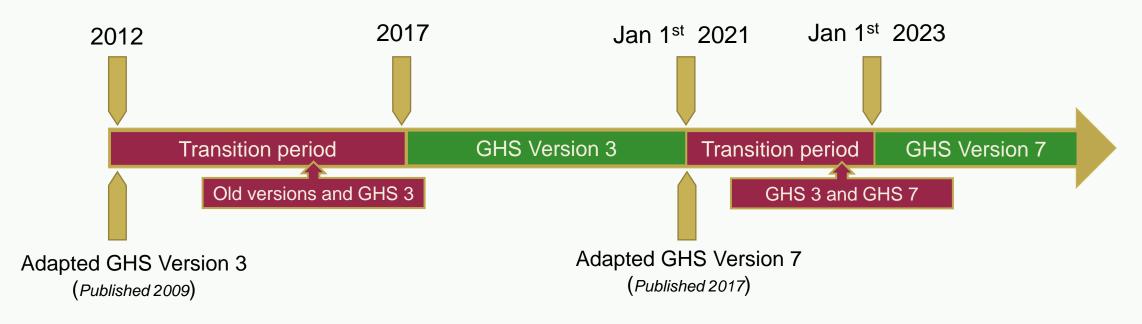
- Manufacturers
- Importers
- Suppliers
- Chemical Users

Correctly classify the chemicals that they import or manufacture and prepare correct labels and SDS for those chemicals

- Provide SDS with hazardous chemicals.
- Chemicals using, handling and storing hazardous chemicals labelled in accordance with adapted GHS



Time-Line of Transition



 Chemicals manufactured or imported before 1 January 2023 can continue to be supplied indefinitely without needing to reclassified or relabelled in accordance with GHS 7.



Transition and Adaptation

States/Territories updated law for adopting GHS 7					
Commonwealth	Work Health and Safety Regulations 2011				
New South Wales	Work Health and Safety Regulation 2017				
Northern Territory	Work Health and Safety (National Uniform Legislation) Regulations 2011				
Victoria	Occupational Health and Safety Regulations 2017 and the Dangerous Goods (Storage and Handling) Regulations 2012				

States/Territories yet to update law for adopting GHS 7						
Australian Capital Territory	Work Health and Safety Regulation 2011					
Queensland	Work Health and Safety Regulation 2011					
Tasmania	Work Health and Safety Regulation 2012					
Western Australia	New WHS Regulations, GHS 7 will be considered in the updated					



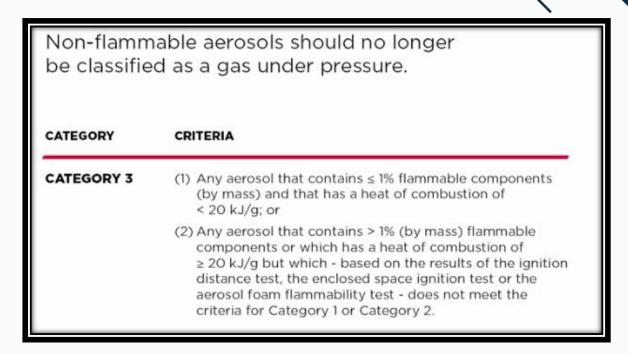
Key Changes under GHS 7

- 1. Changes in classification and labelling requirements for
 - a) Aerosols,
 - b) Flammable gases,
 - c) Desensitised explosives and
 - d) Eye irritants.
- 2. Changes in Precautionary statements



Aerosols

- Flammable aerosol hazard class is renamed to "AEROSOLS".
- Included new "Category 3" for Non-flammable chemicals.
- No Changes in the Category 1 and 2 aerosols (flammable aerosols).





Aerosol Hazard Communication

	Category 1	Category 2	Category 3
Symbol			No Symbol
Signal Word	Danger	Warning	Warning
Hazard Statement	 Extremely flammable aerosol Pressurized container: may burst if heated 	 Flammable aerosol Pressurized container: may burst if heated 	Pressurized container: may burst if heated



Flammable Gases

Category			Criteria		
	Flammable gas		Gases, which at 20 °C and a standard pressure of 101.3 kPa: (a) are ignitable when in a mixture of 13% or less by volume in air; or (b) have a flammable range with air of at least 12 percentage points regardless o the lower flammability limit unless data show they meet the criteria for Category 1B		
1A	Pyrophoric gas		Flammable gases that ignite spontaneously in air at a temperature of 54 °C or below		
	Chemically unstable gas	A	Flammable gases which are chemically unstable at 20°C and a standard pressure of 101.3 kPa		
		В	Flammable gases which are chemically unstable at a temperature greater than 20°C and/or a pressure greater than 101.3 kPa		
1B	1B Flammable gas		Gases which meet the flammability criteria for Category 1A, but which are not pyrophoric, nor chemically unstable, and which have at least either: (a) a lower flammability limit of more than 6% by volume in air; or (b) a fundamental burning velocity of less than 10 cm/s;		
2	2 Flammable gas		Gases, other than those of Category 1A or 1B, which, at 20 °C and a standard pressure of 101.3 kPa, have a flammable range while mixed in air		



Flammable Gas Hazard Communication

	Category	Gases categorized as 1A by meeting pyrophoric or unstable gas A/B criteria			_	
	1A	Pyrophoric Gas	ric Gas Chemically unstable		Category 1B	Category 2
			Category A	Category B		
Symbol						No Symbol
Signal Word	Danger	Danger	Danger	Danger	Danger	Warning
Hazard Statement	• Extremely flammable gas	Extremely flammable gas May ignite spontaneously if exposed to air	 Extremely flammable gas May react explosively even in the absence of air 	Extremely flammable gas May react explosively even in the absence of air at elevated pressure and/or temperature	• Flammable Gas	• Flammable Gas



Desensitized Explosives

 New Hazard Class under GHS 7, which are solid or liquid explosives which are phlegmatized to suppress their explosive properties

Category	Criteria
1	Desensitized explosives with a corrected burning rate (A _C) equal to or greater than 300 kg/min but not more than 1200 kg/min
2	Desensitized explosives with a corrected burning rate (A _C) equal to or greater than 140 kg/min but less than 300 kg/min
3	Desensitized explosives with a corrected burning rate (A _C) equal to or greater than 60 kg/min but less than 140 kg/min
4	Desensitized explosives with a corrected burning rate (A _C) less than 60 kg/min



Desensitized Explosives Hazard Communication

	Category 1	Category 2	Category 3	Category 4
Symbol				
Signal Word	Danger	Danger	Warning	Warning
Hazard Statement	Fire blast or projection hazard; increased risk of explosion if desensitizing agent is reduced	Fire or projection hazard; increased risk of explosion if desensitizing agent is reduced	Fire or projection hazard; increased risk of explosion if desensitizing agent is reduced	Fire or projection hazard; increased risk of explosion if desensitizing agent is reduced



Eye Irritants and hazard communications

 The model Work health and safety laws, ensured to capture all Category 2 eye irritants including those that fall under Category 2B.



	Category 1	Category 2A	Category 2B
Symbol		\	No symbol
Signal Word	Danger	Warning	Warning
Hazard Statement	Causes serious eye damage	Causes serious eye irritation	Causes eye irritation



Precautionary Statement

Precautionary Statement	GHS version 7
P212	Avoid heating under confinement or reduction of desensitizing agent.
P210	Keep away from heat and hot surfaces sparks or open flames and other ignition sources. No smoking.
P233	Keep containers tightly closed



Comparison between GHS 3 and GHS 7

	GHS 3	GHS 7	Changes
Aerosols	Category 1; Category 2	Category 3	New category has been added
Flammable Gases	Category 1; Category 2	Category 1A and Category 1B	New category has been added
Desensitization explosives	Not available	Category 1, Category 2 Category 3 and Category 4	New hazard classification
Eye Irritant	Category 1; Category 2/2A and Category 2B	Category 2B	This is also new requirement
P212	Not available	Avoid heating under confinement or reduction of desensitizing agent.	New Precautionary statement
P210	Keep away from heat/hot surfaces/sparks/open flames. No smoking.	Keep away from heat and hot surfaces sparks or open flames and other ignition sources. No smoking.	Minor changes in statement



Take Home Message

- Start using GHS version 7 for labels and SDS on products placed from 1 January 2021
- Chemicals manufactured or imported before 1 January 2023 can continue to be supplied indefinitely without needing to reclassified or relabelled in accordance with GHS 7
- From 1 January 2023, Chemicals should only be classified and labelled in accordance with GHS 7 and has SDS prepared in accordance with GHS 7.



How GPC can help

- GPC has a legal entity in Australia
- Authorized Representative services
- GPC has authored more than 4000+ SDS, we have clear understanding about UN-GHS



Write to us for AICIS related services: compliance@au.gpcregulatory.com



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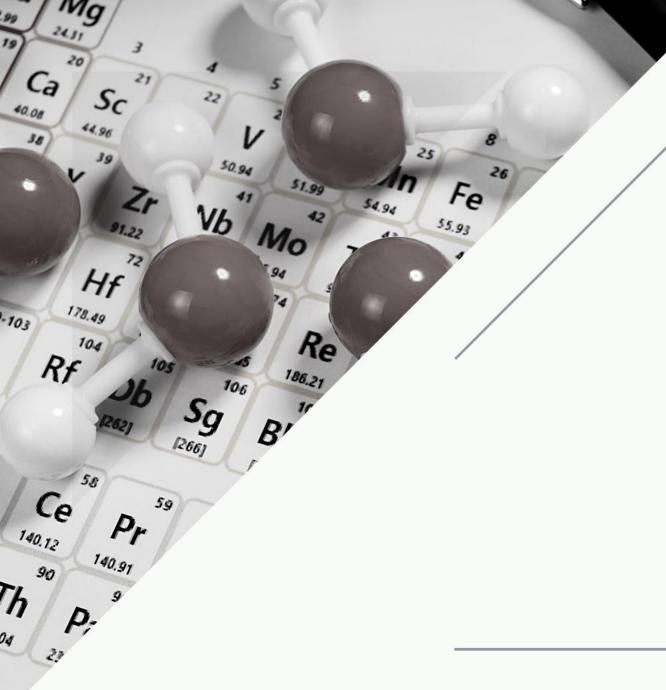


Updates in Safety Data Sheets – EU & UK



Shrirang Bhoot,
Chief Technical Officer (CTO),
Global Product Compliance Group





Summary of Topics

- Introduction
- 16 sections of SDS
- When SDS is applicable
- What about Mixtures
- EU SDS Obligations
- Timeline and transition provisions
- Need to update SDS
- UK REACH & SDS
- Stepwise actionable points



Introduction

- Safety data sheets are intended to provide the users of chemicals with the necessary information to help them protect human health and the environment.
- Users of chemicals are companies or individuals within the European Union/European Economic Area who use a substance, either on its own or in a mixture, in their industrial or professional activities.
- Safety data sheets are intended both for the workers who handle the chemicals and for those responsible for safety.
- The format of the safety data sheet is defined in the REACH Regulation. It is divided into 16 sections



16 Sections of SDS

Section 1
Identification of the substance / mixture and of the company / undertaking

Section 2
Hazard identification

Section 3
Composition / information
on ingredients

Section 4
First aid measures

Section 5
Firefighting measures

Section 6
Accidental release measures

Section 7
Handling and storage

Section 8
Exposure controls / personal protection

Section 9
Physical and chemical properties

Section 10
Stability and reactivity

Section 11
Toxicological information

Section 12 Ecological information

Section 13
Disposal considerations

Section 14
Transport information

Section 15 Regulatory information

Section 16
Other information



When SDS is applicable

You should receive a safety data sheet for:

- A substance or mixture that is classified as hazardous according to CLP; or
- A substance that is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or
- A substance that is included in the Candidate List of substances of very high concern (SVHCs)1.



What about Mixtures

- Suppliers of hazardous mixtures should communicate the relevant information from the exposure scenarios of the ingredient substances with the safety data sheet for the mixture.
- This information can be provided in a numbers of ways:
 - Provide consolidated safe use information for the mixture as an annex to the safety data sheet; or
 - Incorporate consolidated safe use information for the mixture in the main body of the safety data sheet, mainly in Section 8; or
 - Attach relevant exposure scenarios for the ingredient substances as an annex to the safety data sheet.



EU SDS Obligations

- Industry needs to understand which tasks and requirements under Article 31 of REACH (Requirements for safety data sheets) and Annex II of REACH as Regulation (EU) 2015/830, has been replaced by:
- Commission Regulation (EU) 2020/878: amending Annex II by introducing
 - specific requirements regarding nanoforms of substances,
 - adapting to the 6th and 7th revision of the GHS,
 - and adding requirements regarding the Unique Formula Identifier (as set by Annex VIII to Regulation (EC) 1272/2008),
 - endocrine disrupting properties,
 - specific concentration limits, M-factors and acute toxicity estimates.



Timeline



Any new SDS has to be as per Regulation (EU) 2020/878 As per Regulation (EU) 2015/830 or as per Regulation (EU) 2020/878

Everything as per Regulation (EU) 2020/878



Transitional provision to implement the latest version of Annex II to REACH

All safety data sheets provided after 1st January 2021, including new and updated safety data sheets, can be provided in the current format according to Regulation (EU) 2015/830 or in the new format according to Regulation (EU) 2020/878 till 31st Dec 2022, including the following scenarios:

- No change to safety data sheet
- Small change to safety data sheets not within scope of Article 31(9)
- Update to safety data sheets within the scope of Article 31(9) or introducing the UFI
- New safety data sheets authored for the first time after 1st January 2021



Need to update SDSs

SDS must be updated and re-issued are given in Article 31(9)

Suppliers shall update the safety data sheet without delay on the following occasions:

- (a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
- (b) once an authorisation has been granted or refused;
- (c) once a restriction has been imposed.



UK REACH & SDS

- Safety Data Sheets (SDS) are required by the UK REACH Regulation.
- The SDS will contain the information necessary to allow employers to do a risk assessment as required by the Control of Substances Hazardous to Health Regulations (COSHH). The SDS itself is not an assessment.
- However, it will describe the hazards helping employers assess the probability of those hazards arising in the workplace.
- SDS are a must if a chemical is hazardous and is being supplied for use at work, whether
 in packages or not. SDS are also needed if your chemical is not classified as hazardous
 but contains small amounts of a hazardous substance.
- Defra has the lead responsibility for UK REACH and the SDS requirements.



Stepwise Actionable Points

Step 1

Identify the competent person/consultant to do the activities for SDS compliance

Step 2

Identify & verify if you are manufacturing / exporting Substance, Mixtures or Mixtures in Mixtures (MiM's)

Step 3

Prepare inventory of the SDS for substances and mixtures along with its ingredients manufactured and exported to EU

Step 4

Verify & compile the classification of the substance and mixtures as per CLP requirements and verify available SDS

GPC can:

- Do the pre-assessment of your available SDS
- Compile the data required for SDS updation
- Prepare the SDS as per the latest requirements



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