

September 24, 2019 Paul Brigandi

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Agenda

- 1. Major Updates
- 2. "Significant" Editorial Changes

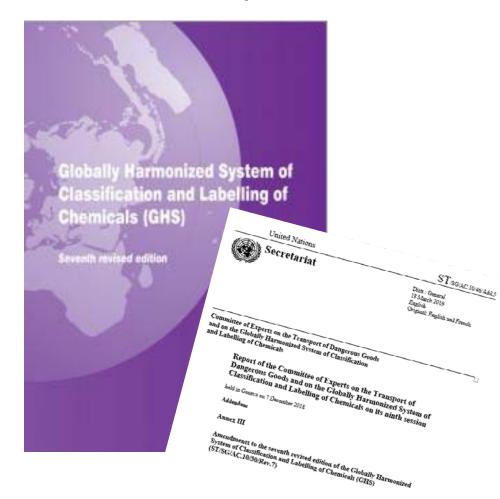




Amendments to the 7th Revised Edition of the Purple Book

ECOSOC Committee of Experts on the TDG and on the GHS Report ST/SG/AC.10/46/Add.3 – Annex III

Amendments to the seventh revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals GHS: https://www.unece.org/trans/main/dgdb/dgcomm/ac10rep.html





Major Updates in Revision 8

Chemicals Under Pressure	New hazard class to fill a gap in coverage
Skin Corrosion/Irritation Non-animal Methods	2 Significant Updates to the Tiered Approach Greater enumeration of non-animal methods and more guidance
Precautionary Statements	New Prevention Statement - P203 New Medical Response Statements Updated guidance on combinations of medical P-Statements
Labeling of Small Packaging	Annex 7: New examples covering Sets/Kits
Dust Explosion Hazard	New Annex 11: Guidance on Other Hazards Not Resulting in Classification

Chemicals Under Pressure

New hazard class to fill a gap in coverage



Aerosols vs. Chemicals Under Pressure (CUP)

Aerosols



Non-refillable receptacles which are fitted with a release device

Generally have lower internal pressure than CUP

"Limited" capacity

Chemicals Under Pressure



In a pressure receptacle other than aerosol dispensers and can be refillable

At a pressure of 200 kPa (gauge) or more at 20°C

Capacity can be much larger than aerosols

Chemicals Under Pressure

Chemicals under pressure are liquids or solids (e.g., pastes or powders), pressurized with a gas at a pressure of 200 kPa (gauge) or more at 20 °C in pressure receptacles other than aerosol dispensers and which are not classified as gases under pressure.

Category	Criteria
	Any chemical under pressure that:
1	(a) contains ≥ 85% flammable components (by mass); and
	(b) has a heat of combustion of ≥ 20 kJ/g.
	Any chemical under pressure that:
	(a) contains > 1 % flammable components (by mass); and
	(b) has a heat of combustion < 20 kJ/g;
2	or that:
	(a) contains < 85 % flammable components (by mass); and
	(b) has a heat of combustion ≥ 20 kJ/g.
	Any chemical under pressure that:
3	(a) contains ≤ 1% flammable components (by mass); and
	(b) has a heat of combustion of < 20 kJ/g.



Hazard Communication Elements

Aerosols

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

Chemicals Under Pressure

Hazard Category	Pictogram	Signal Word	Hazard Statement
1		Danger	Extremely flammable chemical under pressure: May explode if heated
2		Warning	Flammable chemical under pressure: May explode if heated
3		Warning	Chemical under pressure: May explode if heated





Skin Corrosion/Irritation

Significant Updates to the Tiered Approach

Greater enumeration of non-animal methods and more guidance



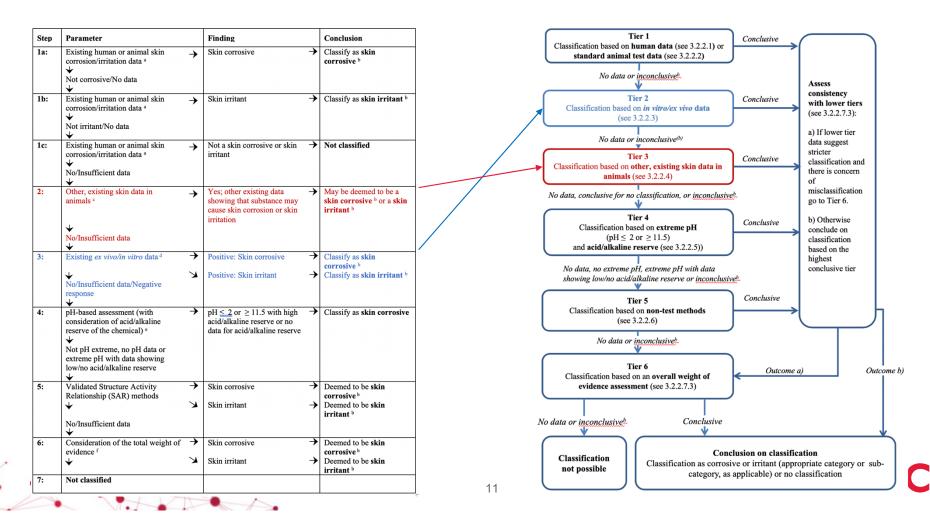
Highlights of Major Changes

- Tiered Approach
 - The Tiered Approach was retained vs. an Integrated Approach but with the modification to apply a
 weight of evidence assessment where information at a lower tier suggests a stricter classification
 and there is concern of misclassification
 - The relative order of the *in-vitro/ex-vivo* and "other animal skin data" tiers are switched
 - There is a new more conceptual flow diagram illustrating the Tiered Approach with less detail compared to the old Figure 3.2.1



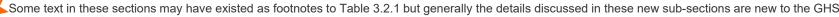


Modification to the Tiered Approach (i.e. Figure 3.2.1)



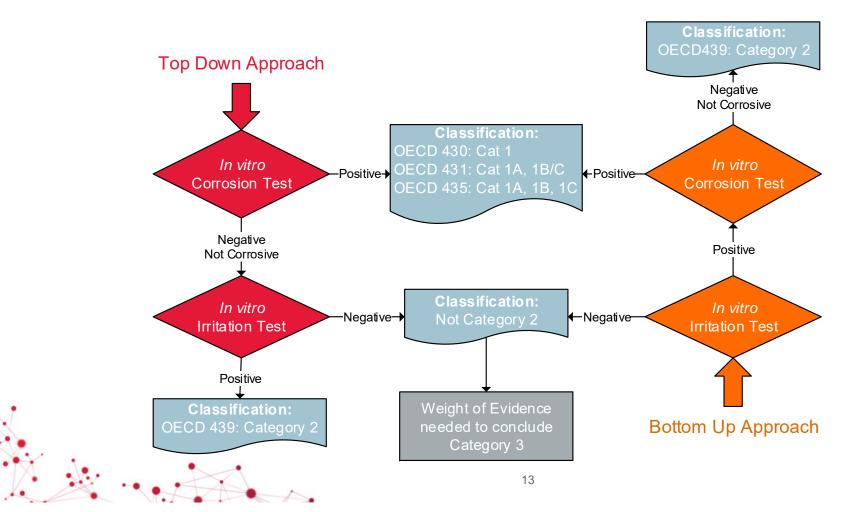
Highlights of Major Changes

- Significant re-organization of the chapter to align with the Tiered Approach
 - Now have sub-headings with discussion of classification based on:
 - Human Data
 - Standard Animal Data
 - In vitro/ex vivo Data
 - · Other, Existing Skin Data in Animals
 - Chemical Properties
 - Non-animal Methods
- No new methods with respect to classification, however, there is increased emphasis on using non-animal data (i.e. in vitro/ex vivo and non-animal methods). For example:
 - In vitro/ex vivo methods have their own sub-section, have been moved up to Tier 2 and specific examples of validated methods with criteria are provided in Guidance Section 3.2.5.3.4
 - Consideration of specific non-animal methods are now described in the chapter (e.g. computer models predicting structure-activity relationships (e.g. structural alerts SAR and QSAR) and readacross using analogue and category approaches)





Evaluation of In Vitro Data for Skin Corrosion/Irritation Classification





Highlights of Major Changes

- **Extensive** updates to Section 3.2.5.3 Background Guidance. New sub-sections for classification based on:
 - Human Data
 - In-vitro/ex vivo Data
 - Summary of OECD Methods 430, 431, 435, and 439 including criteria per category/sub-category
 - Other existing skin data in animals
 - Acute Dermal Toxicity: OECD 404
 - Repeated Dose Dermal: OECD 410 and 412
 - Skin Sensitization: OECD 406
 - Irritation data from Local Lymph Node Assay: OECD 429, 442A and 442B
 - Skin Absorption studies: OECD 427





Precautionary Statements

New prevention statement - P203

New medical response statements

Updated guidance on combinations of medical P-Statements



Old Prevention Statements P201 & P202

Code	Prevention Statement	Hazard Class	Hazard Category	Conditions for use
P201	Obtain special instructions before	Explosives (chapter 2.1)	Unstable explosive	
	use.	Germ cell mutagenicity (chapter 3.5)	1, 1A, 1B, 2	
		Carcinogenicity (chapter 3.6)	1, 1A, 1B, 2	
		Reproductive toxicity (chapter 3.7)	1, 1A, 1B, 2	
		Reproductive toxicity, effects on or via lactation (chapter 3.7)	Additional category	
P202	Do not handle until all safety	Flammable gases (chapter 2.2)	A, B	
	precautions have been read and		(chemically unstable	
	understood.		gases)	
		Germ cell mutagenicity (chapter 3.5)	1, 1A, 1B, 2	
		Carcinogenicity (chapter 3.6)	1, 1A, 1B, 2	
		Reproductive toxicity (chapter 3.7)	1, 1A, 1B, 2	
		Reproductive toxicity, effects on or via lactation (chapter 3.7)	Additional category	

New Prevention Statement P203

Code	Prevention Statement	Hazard Class	Hazard Category	Conditions for use
P201 Deleted				
P202 Deleted				
P203	Obtain, read and follow all safety	Explosives (chapter 2.1)	Unstable explosive	
	instructions before use.	Flammable gases (chapter 2.2)	A, B (chemically unstable	
			gases)	
		Germ cell mutagenicity (chapter 3.5)	1, 1A, 1B, 2	
		Carcinogenicity (chapter 3.6)	1, 1A, 1B, 2	
		Reproductive toxicity (chapter 3.7)	1, 1A, 1B, 2	
		Reproductive toxicity, effects on or via lactation (chapter 3.7)	Additional category	

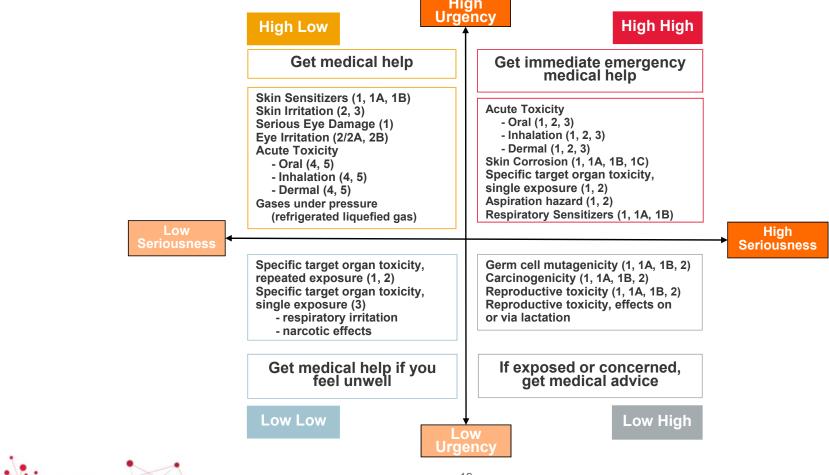


Rationalization of Medical Response Statements

- Reduced the number of statements to avoid redundancy and conflicting advice
 - All Revision 7 medical response statements were deleted
 - P310: Immediately call a POISON CENTER/doctor/...
 - P311: Call a POISON CENTER/doctor/...
 - P312: Call a POISON CENTER/doctor/...if you feel unwell.
 - P313: Get medical advice/attention.
 - P314: Get medical advice/attention if you feel unwell.
 - P315: Get immediate medical advice/attention.
- Removed the "/" and "..." options since the Sub-committed observed that these notations often appear on labels
- The new statements avoid reference to Poison Centers given that access varies by jurisdiction (e.g. in the UK the general public does not have access to poison centers) and they do not exist in some jurisdictions
- · Aim for simple, succinct, translatable and universally understood statements



New Statements are Based on Urgency and Seriousness





New Medical Response Statements

Code	Prevention Statement	Hazard Class	Hazard Category	Conditions for use
P316 Get emergency medical help immediately.	Acute toxicity, oral (chapter 3.1)	1, 2, 3	Competent Authority or manufacturer / supplier	
	Acute toxicity, dermal (chapter 3.1)	1, 2, 3	may add, 'Call' followed	
	Acute toxicity, inhalation (chapter 3.1)	1, 2, 3	by the appropriate emergency telephone number, or the appropriate emergency	
	Skin corrosion (chapter 3.2)	1, 1A, 1B, 1C		
		Respiratory sensitization (chapter 3.4)	1, 1A, 1B	medical help provider,
	Specific target organ toxicity, single exposure; (chapter 3.8)	1, 2	for example, a Poison Centre, Emergency	
	Aspiration hazard (chapter 3.10)	1, 2	Centre or Doctor.	





New Medical Response Statements

Code	Prevention Statement	Hazard Class	Hazard Category	Conditions for use
P317	Get medical help.	Gases under pressure (chapter 2.5)	Refrigerated liquefied gas	
		Acute toxicity, oral (chapter 3.1)	4, 5	
		Acute toxicity, dermal (chapter 3.1)	4, 5	
		Acute toxicity, inhalation (chapter 3.1)	4, 5	
		Skin irritation (chapter 3.2)	2, 3	
		Serious eye damage (chapter 3.3)	1	
		Eye irritation (chapter 3.3)	2/2A, 2B	
		Skin sensitization (chapter 3.4)	1, 1A, 1B	





New Medical Response Statements

Code	Prevention Statement	Hazard Class	Hazard Category	Conditions for use
P318	IF exposed or concerned, get medical	Germ cell mutagenicity (chapter 3.5)	1, 1A, 1B, 2	
	advice.	Carcinogenicity (chapter 3.6)	1, 1A, 1B, 2	
		Reproductive toxicity (chapter 3.7)	1, 1A, 1B, 2	
		Reproductive toxicity, effects on or via lactation (chapter 3.7)	Additional category	
P319	Get medical help if you feel unwell.	Specific target organ toxicity, single exposure; respiratory tract irritation (chapter 3.8)	3	
		Specific target organ toxicity, single exposure; narcotic effects (chapter 3.8)	3	
		Specific target organ toxicity, repeated exposure (chapter 3.9)	1, 2	





Always combine medical response statements with at least one route of exposure or symptom ("IF" statement). However, this does not apply to P319 "**Get medical help if you feel unwell**" for specific target organ toxicity repeated exposure, or to P317 "**Get medical help**" for gases under pressure (refrigerated liquefied gas) which are not combined with a separate "IF" statement. Relevant "IF" statements describing symptoms (e.g. P332, P333, P337, P342) should be included in full;

For Example:

Classification	If Statement	Medical Statement
Acute Dermal Toxicity; Cat 2	IF ON SKIN:	Get emergency medical help immediately.
Severe Eye Damage/Eye Irritation; Cat 2	If eye irritation persists:	Get medical help.
Target Organ – Repeated Exposure; Cat 1	Not applicable	Get medical help if you feel unwell.

Then use:

IF ON SKIN: Get emergency medical help immediately. If eye irritation persists: Get medical help. Get medical help if you feel unwell.



Where the same medical response statement is triggered for different routes of exposure, then the exposure routes should be combined. If the same response statement is triggered with three or more routes of exposure then P308, "**IF exposed or concerned:**", may be used instead. If a route of exposure is triggered multiple times it should only be included once;

For Example:

Classification	If Statement	Medical Statement
Acute Oral Toxicity; Cat 2	IF SWALLOWED:	Get emergency medical help immediately.
Acute Inhalation Toxicity; Cat 1	IF INHALED:	Get emergency medical help immediately.
Skin Corrosion/Irritation; Cat 1A	IF ON SKIN:	Get emergency medical help immediately.

Then use:

IF SWALLOWED, INHALED OR ON SKIN: Get emergency medical help immediately.

Or

If exposed or concerned: Get emergency medical help immediately.



Where different medical response statements are triggered for the same route of exposure, then P316 "Get emergency medical help immediately" should have priority over P317 "Get medical help"; and P317 should have priority over P319 "Get medical help if you feel unwell". P318, "If exposed or concerned get medical advice", should always appear if triggered. To improve clarity and readability when more than one medical statement appears, supplemental text such as 'additionally' or 'also' should be inserted;

For Example:

Classification	If Statement	Medical Statement
Acute Oral Toxicity; Cat 4	IF SWALLOWED:	Get medical help.
Aspiration Hazard; Cat 1	IF SWALLOWED:	Get emergency medical help immediately.

Then use:

IF SWALLOWED: Get emergency medical help immediately.





Where different medical response statements are triggered for the same route of exposure, then P316 "Get emergency medical help immediately" should have priority over P317 "Get medical help"; and P317 should have priority over P319 "Get medical help if you feel unwell". P318, "If exposed or concerned get medical advice", should always appear if triggered. To improve clarity and readability when more than one medical statement appears, supplemental text such as 'additionally' or 'also' should be inserted;

For Example:

Classification	If Statement	Medical Statement
Acute Oral Toxicity; Cat 4	IF SWALLOWED:	Get medical help.
Aspiration Hazard; Cat 1	IF SWALLOWED:	Get emergency medical help immediately.
Carcinogenicity; Cat 2	Not applicable	IF exposed or concerned, get medical advice.

Then use:

IF SWALLOWED: Get emergency medical help immediately.



Where different medical response statements are triggered for the same route of exposure, then P316 "Get emergency medical help immediately" should have priority over P317 "Get medical help"; and P317 should have priority over P319 "Get medical help if you feel unwell". P318, "If exposed or concerned get medical advice", should always appear if triggered. To improve clarity and readability when more than one medical statement appears, supplemental text such as 'additionally' or 'also' should be inserted;

For Example:

Classification	If Statement	Medical Statement
Acute Oral Toxicity; Cat 4	IF SWALLOWED:	Get medical help.
Aspiration Hazard; Cat 1	IF SWALLOWED:	Get emergency medical help immediately.
Carcinogenicity; Cat 2	Not applicable	IF exposed or concerned, get medical advice.

Then use:

IF SWALLOWED: Get emergency medical help immediately. Also, if exposed or concerned, get medical advice.



Where different medical response statements are triggered for different routes of exposure, all the relevant precautionary statements for medical response should appear.

For Example:

Classification	If Statement	Medical Statement
Acute Oral Toxicity; Cat 4	IF SWALLOWED:	Get medical help.
Acute Inhalation Toxicity; Cat 2	IF INHALED:	Get emergency medical help immediately.
Skin Sensitization; Cat 1A	If skin irritation or rash occurs:	Get medical help.

Then use:

IF INHALED: Get emergency medical help immediately. IF SWALLOWED or if skin irritation or rash occurs: Get medical help.





Labeling of Small Packagings

Annex 7: New examples covering Sets/Kits



Example 10: Labelling of sets or kits

- Set or Kit is a combination packaging and generally contains 2 or more inner containers of different products.
- When its determined that there is insufficient space to place together, the GHS
 - Pictogram
 - Signal Word
 - Hazard Statements

on each inner container as required in 1.4.10.5.4.1, then these principles can be applied.

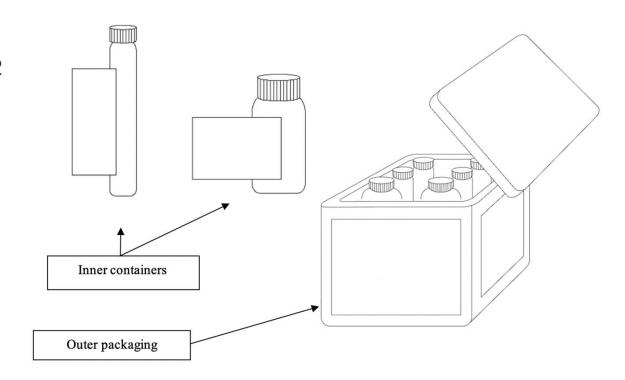
- Insufficient space can occur when, for example:
 - Inner containers are small, or
 - Large number of hazard statements, or
 - There is a need for multiple languages on the label



Scenario A

Outer packaging contains:

- 4 cuvettes of Reagent 1
- 2 larger containers of Reagent 2



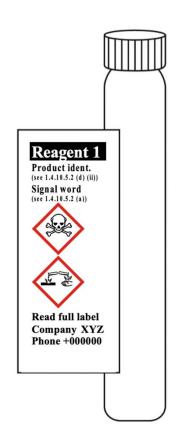




Scenario A

Inner Container Label Requirements:

- Product Identifier
 - Reagent 1
 - Reagent 2
- Pictogram(s)
- Signal Word
- Statement "Read full label"
- Supplier Identification (i.e., name and telephone number)



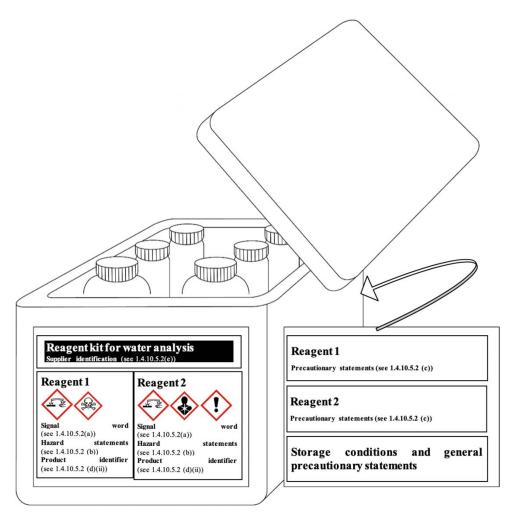




Scenario A

Outer Packaging Label:

- All required label elements appear on the outer packaging for each hazardous substance or mixture
- Label elements are grouped together for each substance or mixture
- Supplier information need appear only once
- Precautionary statements may be located separately from other label elements but must be grouped together on the same side of the outer packaging and on a surface visible under normal conditions.
- General and Storage Precautionary statements need only appear once for the kit as a whole.

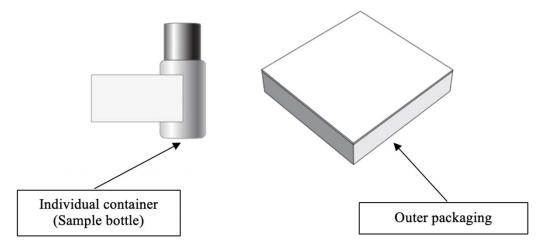




Scenario B

Outer packaging contains:

- Large number of different substances or mixtures in individual containers
- Some or all of the substances or mixtures may be classified as hazardous
- Inner containers are stored in the outer packaging for the lifecycle of the kit



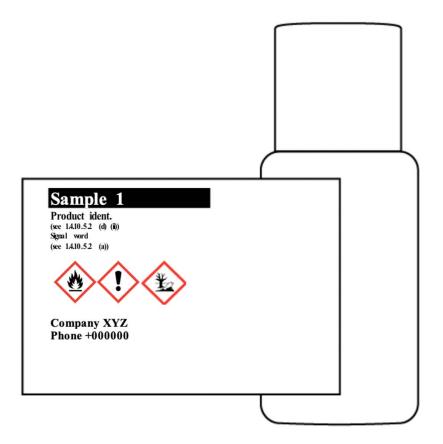




Scenario B

Individual Container Label Requirements:

- Supplier Identification (i.e., name and telephone number)
- Product Identifier
- Pictogram(s)
- Signal Word
- Statement "Read full label enclosed"

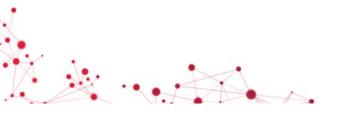




Scenario B

- The full label information is contained within the outer packaging and should be organized and printed in a format that allows the user to readily identify information for each container
- The sheets of the full label are permanently connected to the inside of the combination packaging using a secure method (e.g. fold out label adhered to the box or tie tag as shown)







Scenario B

Full GHS label information for each individual container containing a hazardous substance or mixture

Product identifier (see 1.4.10.5.2 (d) (ii))	Pictogram(s) (see 1.4.10.4)		Hazard statement(s) (see 1.4.10.5.2 (b))	Precautionary statement(s) (see 1.4.10.5.2 (c))	Supplemental information (see 1.4.10.5.4.2)
123		Warning	Flammable liquid and vapour. Causes skin irritation. Toxic to aquatic life with long lasting effects.	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Use explosion-proof equipment. Use non-sparking tools. Take action to prevent static discharge. Avoid release to the environment. Wear protective gloves. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected areas with water. In case of fire: Use dry sand, dry chemical or alcoholresistant foam for extinction. Store in a well-ventilated place. Keep cool.	





Scenario B

Outer Packaging Label will display:

- Kit identifier (name of kit)
- Signal word (most stringent assigned to any component)
- Pictograms for each single substance or mixture, without duplication
- Storage and general precautionary statements for the kit as a whole
- Statement "Read full label enclosed"
- Supplier Identification

MARKET KIT

Product ident. (see 1.4.10.5.2 (d) (ii))

Signal word (see 1.4.10.5.2 (a))



Precautionary Storage Statements (see 1.4.10.5.2 (c))

Read full label enclosed

Supplier identification (see 1.4.10.5.2 (e))





Dust Explosion Hazard

New Annex 11: Guidance on Other Hazards Not Resulting in Classification



Guidance on Dust Explosion Hazard

- Annex 11 Guidance on Hazards Not Resulting in Classification
 - A11.1 This guidance aims to provide information that facilitates the identification of hazards which
 do not result in classification, but which may need to be assessed and communicated
- A11.2 Dust Explosions Scope and Applicability
 - A risk assessment may be need for many substances, mixtures or solid materials, not just those classified as flammable solids
 - Dusts may be formed (intentionally or unintentionally) during transfer or movement, or in a facility during handling or mechanical processing (e.g., milling, grinding) of substances/mixtures/solid materials (e.g., agricultural commodities, wood products, pharmaceuticals, dyes, coal, metals, plastics)
 - The formation of small particles and their potential accumulation should be assessed
 - When a dust explosion risk is identified, effective preventive and protective measures should be implemented





Guidance on Dust Explosion Hazard

A11.2 Dust Explosions Scope and Applicability

- The guidance identifies when combustible dusts may be present and when the risk of a dust explosion should be considered. The guidance:
 - a) Gives a flow chart specifying the key steps to identify a possible combustible dust;
 - Identifies the factors contributing to a dust explosion;
 - c) Sets out principles of hazard and risk management; and
 - d) Indicates where expert knowledge is required.

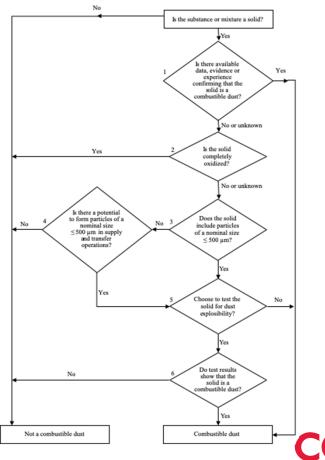




Guidance on Dust Explosion Hazard

Section	Content
2.2	Definitions
2.3	Identification of combustible dust
2.4	Factors contributing to dust explosion
2.5	Other factors impacting the severity of a dust explosion
2.6	Hazard prevention, risk assessment and mitigation
2.7	Supplemental information for hazard and risk communication
2.8	References

Figure A11.2.1





2.7 Supplemental Information for Hazard and Risk Communication

- Competent authorities may require the use of the following phrases on Labels, SDSs and/or in operating instructions or may leave the choice to the manufacture or supplier:
 - a) When a substance or mixture is a combustible dust using Figure A11.2.1 then use:
 - May form explosible dust-air mixture if dispersed
 - b) When a substance, mixture or solid material is processed in such a way that creates a combustible dust (see guidance in A11.2.6.2.1 and Figure A11.21) then use:
 - May form explosible dust-air mixture if small particles are generated during further processing, handling, or by other means.
 - c) In addition the phrase **Warning** may be used in conjunction with items a) or b).





These changes are not expected to impact any existing classifications

Scope	Reconciles principles in Annex 11 with the scope of the GHS
Bridging Principles	2 Documents a principle explicit in the concept of bridging
Aerosols	3 Criteria translated from the Decision Logic into words for Table 2.3.1
Specific Target Organ Toxicity	Clarifies that – Single and – Repeated Exposure Classifications are to be evaluated independently

Scope

Reconciles principles in Annex 11 with the scope of the GHS

Detail

1.1.2.6.1 The GHS is not intended to harmonize risk assessment procedures or risk management decisions (such as establishment of a permissible exposure limit for employee exposure), which generally require some risk assessment in addition to hazard classification. However, information on risk management is occasionally provided in the GHS on a case-by-case basis for guidance purposes. Competent authorities are best placed to determine in regulations or standards the appropriate risk assessment procedures and risk management measures. In addition, chemical inventory requirements in various countries are not related to the GHS.

Bridging Principles

Documents a principle explicit in the concept of bridging

Detail

1.3.2.3.1

b) Where test data are not available for the mixture itself, then bridging principles included and explained in each specific chapter should be considered to see whether they permit classification of the mixture.

Bridging may also be applied when test data conclusively show that no classification is warranted;



Aerosols

Criteria translated from the Decision Logic into words for Table 2.3.1

Detail

Table 2.3.1: Criteria for aerosols

Category	Criteria		
1	 Any aerosol that contains ≥ 85% flammable components (by mass) and has a heat of combustion of ≥ 30 kJ/g; 		
	Any aerosol that dispenses a spray that, in the ignition distance test, has an ignition distance of ≥ 75 cm; or		
	(3) Any aerosol that dispenses a foam that, in the foam flammability test, has:		
	(a) a flame height of ≥ 20 cm and a flame duration of ≥ 2 s; or		
	(b) a flame height of ≥ 4 cm and a flame duration of ≥ 7 s.		
2	(1) Any aerosol that dispenses a spray that, based on the results of the ignition distance test, does not meet the criteria for Category 1, and which has:		
	(a) a heat of combustion of $\geq 20 \text{ kJ/g}$;		
	(b) a heat of combustion of < 20 kJ/g along with an ignition distance of ≥ 15 cm; or		
	(c) a heat of combustion of < 20 kJ/g and an ignition distance of < 15 cm along with either, in the enclosed space ignition test:		
	- a time equivalent of ≤ 300 s/m³; or		
	- a deflagration density of $\leq 300 \text{ g/m}^3$; or		
	(2) Any aerosol that dispenses a foam that, based on the results of the aerosol foam flammability test, does not meet the criteria for Category 1, and which has a flame height of ≥ 4 cm and a flame duration of ≥ 2 s.		
3	(1) Any aerosol that contains ≤ 1% flammable components (by mass) and that has a heat of combustion < 20 kJ/g; or		
	(2) Any aerosol that contains > 1% (by mass) flammable components or which has a heat of combustion of ≥ 20 kJ/g but which, based on the results of the ignition distance test, the enclosed space ignition test or the aerosol foam flammability test, does not meet the criteria for Category 1 or Category 2.		

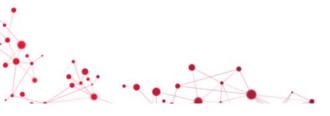


Specific Target Organ Toxicity

Clarifies that – Single and – Repeated Exposure Classifications are to be evaluated independently

Single Exposure

- 3.8.1.6 Specific target organ toxicity following a repeated exposure is addressed in the GHS as described in Chapter 3.9 and is therefore excluded from the present chapter. <u>Substances and mixtures should</u> be classified for single and repeated dose toxicity independently.
- 3.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. <u>As with substances, mixtures should be classified for specific target organ toxicity for single and repeated exposure (Chapter 3.9) independently.</u>
- 3.8.3.4.2 These cut-off values and consequent classifications should be applied equally and appropriately to both single- and repeated-dose target organ toxicants.
- 3.8.3.4.3 Mixtures should be classified for either or both single and repeated dose toxicity independently.





Specific Target Organ Toxicity

Clarifies that – Single and – Repeated Exposure Classifications are to be evaluated independently

Repeated Exposure

- 3.9.1.6 Non-lethal toxic effects observed after a single-event exposure are classified in the GHS as described in *Specific target organ toxicity Single exposure* (Chapter 3.8) and are therefore excluded from the present chapter. <u>Substances and mixtures should be classified for single and repeated dose toxicity independently.</u>
- 3.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures should be classified for specific target organ toxicity for single (Chapter 3.8) and repeated exposure independently.
- 3.9.3.4.3 Mixtures should be classified for either or both single and repeated dose toxicity independently.



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