



REACH Annex II SDS Changes

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REACH Annex II SDS Changes

- ✓ The Basics: What, Why, When?
- ✓ Change drivers:
 - ✓ UN GHS Revisions 6 and 7
 - ✓ CLP Regulation: Adaptations to Technical Progress
 - ✓ CLP Regulation: NEW Annex VIII on Poison Centre Notification
 - ✓ REACH Amendments: Registration of Nanoforms
 - ✓ REACH and the European Union framework on endocrine disruptors
 - ✓ REACH: Evolving trends in Substances of Very High Concern
- ✓ Accumulated effects on Section 3 of the SDS



REACH Annex II SDS Changes

WHAT, WHY, WHEN?



What – Amendment to REACH

- COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

REACH Annex II: REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS



Why – the Drivers

- Revision of GHS: 12th ATP of CLP
 - The 12th ATP of CLP sets GHS 6th and 7th Revised edition requirements in effect by 17 October 2020.
- Other changes related to CLP
 - Specific concentration limits, multiplying factors, acute toxicity estimates
 - Annex VIII Poison Centre Notification Unique Formula Identifier (UFI)
- Related to REACH Annexes I, III and VI to XII
 - Nanoforms
 - European Union framework on endocrine disruptors
 - Emerging substances of very high concern (SVHCs)



When – and “Really, when?”

- SHALL APPLY FROM

1 January 2021

- **DEROGATION:** Safety data sheets not complying with the Annex to this Regulation may continue to be provided until...

31 December 2022



Really, when?



When – “without prejudice to...”

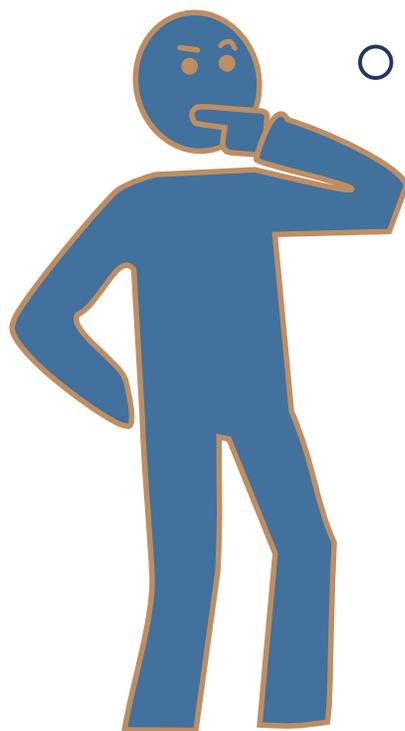
- Cases where the **unique formula identifier is added to safety data sheets** as provided for in section 5 of Part A of Annex VIII to Regulation (EC) No 1272/2008
 - Applies for the required cases which don't have the UFI on the label
- Article 31(9) of Regulation (EC) No 1907/2006

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.*



When ???



Does the
DEROGATION
apply if the **SDS**
must be updated for
other reasons?



When



Gert Roebben (ECHA):

“The obligations to add the UFI or to update the SDS for reasons explained in REACH Article 31(9) do not follow from Annex II itself. Therefore, safety data sheets have to be updated accordingly, also before 31/12/2022.

However, such update, if prior to 31/12/2022, does not require adopting the new Annex II requirements. (It is allowed, but not mandatory.)”



REALLY When - Conclusion

31 December 2022

Voluntary from 1 January 2021 through 31 December 2022 for SDS already on market, even if changes required

Voluntary from 1 January 2021 through 31 December 2022 for all SDS pending clarifications in final guidance



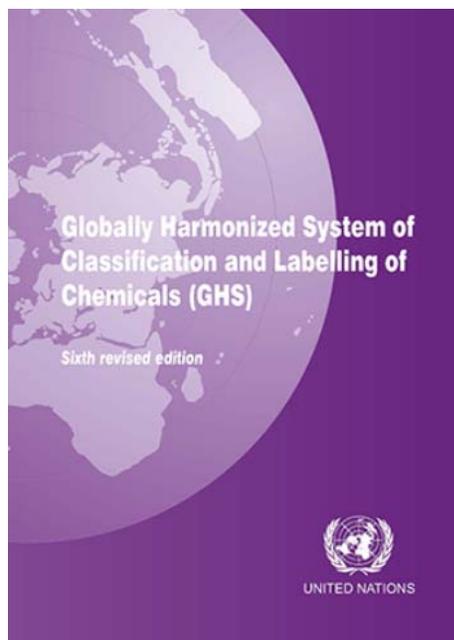
Driver: GHS Revisions

6TH & 7TH REVISED EDITION OF GHS

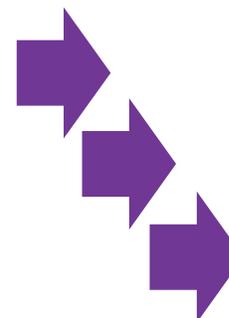
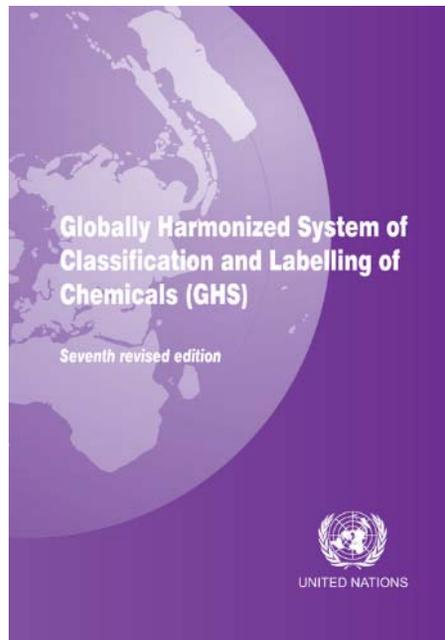


GHS marches on...

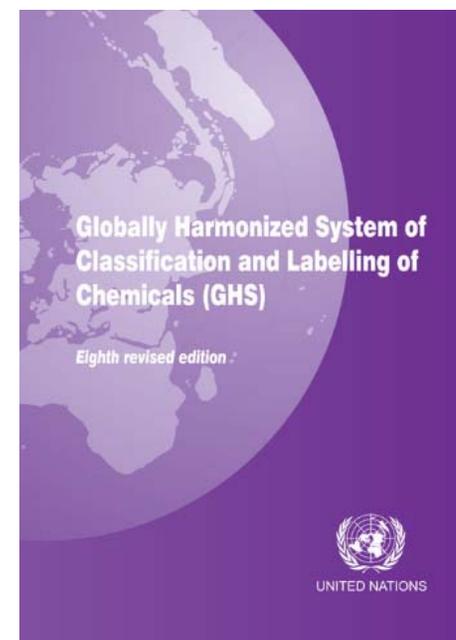
Sixth revised edition
July 2015



Seventh revised edition
July 2017



Eighth revised edition
June 2019





GHS Sixth Revised Edition

Section 9 of the SDS entirely replaced

- Big impact:
 - the competent authorities or supplier may choose to represent the data in section 9 **in any order**
- Significantly more data, grouped into three tables:
 - A4.3.9.1: Properties/characteristics formerly in section 9
 - Obligatory: data or state no information is available or not applicable
 - A4.3.9.2: Properties/characteristics **related to specific hazard classes**
 - A4.3.9.3: **Further** properties/characteristics



GHS Sixth Revised Edition

New hazard classes

- Desensitized explosives

Table 2.17.2: Label elements for desensitized explosives

	Category 1	Category 2	Category 3	Category 4
Symbol	Flame	Flame	Flame	Flame
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 hazard; increased risk of explosion if desensitizing agent is reduced



12th ATP to CLP

- COMMISSION REGULATION (EU) 2019/521 of 27 March 2019 amending, for the purposes of its adaptation to technical and scientific progress Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
- Adapts the CLP to the 6th and 7th revised editions of GHS ...

**...but CLP has no authority
related to the SDS form and content**



REACH Annex II: New section 9

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

9.2. Other information

- No change to the mandatory subheaders 9.1 and 9.2
- But new information added in subdivisions of subsection 9.2:
 - 9.2.1. Information with regard to physical hazard classes
 - 9.2.2. Other safety characteristics



REACH Annex II: New section 9 intro

- *“To enable proper control measures to be taken, all relevant information on the substance or mixture shall be provided.”*
- *“In the case of a mixture, the entries shall clearly indicate to which substance in the mixture the data apply, unless it is valid for the whole mixture.*
- *Reported properties shall be clearly identified and reported in the appropriate measurement units. The method of determination shall be provided, including measurement and reference conditions, if relevant for the interpretation of the numerical value. Unless specified otherwise, standard conditions of temperature and pressure are 20 °C and 101,3 kPa, respectively.*
- *The properties listed in subsections 9.1 and 9.2 may be presented in a form of a list. Within the subsections, the order of listing the properties may be different if deemed appropriate.”*



Subsection 9.1 current / new outline

a) Appearance

b) Odour

c) Odour threshold

d) pH

e) Melting point/freezing point

f) Initial boiling point and boiling range

g) Flash point

h) Evaporation rate

i) Flammability (solid, gas)

j) Upper/lower flammability or explosive limits

k) Vapour pressure

l) Vapour density

m) Relative density

n) Solubility(ies)

o) Partition coefficient: n-octanol/water

p) Auto-ignition temperature

q) Decomposition temperature

r) Viscosity

s) Explosive properties

t) Oxidizing properties

a) Physical state

b) Colour

c) Odour

d) Melting point/freezing point

e) Boiling point or Initial boiling point and boiling range

f) Flammability

g) Lower and upper explosion limit

h) Flash point

i) Auto-ignition temperature

j) Decomposition temperature

k) pH

l) Kinematic viscosity

m) Solubility

n) Partition coefficient n-octanol/water (log value)

o) Vapour pressure

p) Density and/or relative density

q) Relative vapour density

r) Particle characteristics



Subsection 9.1 current / new outline

<p>a) Appearance</p> <p>b) Odour</p> <p>c) Odour threshold</p> <p>d) pH</p> <p>e) Melting point/freezing point</p> <p>f) Initial boiling point boiling point</p> <p>g) Flash point</p> <p>h) Evaporation</p> <p>i) Flammability</p> <p>j) Upper/lower flammability or explosive limits</p>	<p>k) Vapour pressure</p> <p>l) Vapour density</p> <p>m) Relative density</p> <p>n) Solubility(ies)</p> <p>o) Partition coefficient</p> <p>s) Explosive properties</p> <p>t) Oxidizing properties</p>	<p>a) Physical state</p> <p>b) Colour</p> <p>c) Odour</p> <p>g) Lower and upper explosion limit</p> <p>h) Flash point</p> <p>i) Auto-ignition temperature</p>	<p>iv) Viscosity</p> <p>v) Partition coefficient</p> <p>vii) Octanol/water (log value)</p> <p>o) Vapour pressure</p> <p>p) Density and/or relative density</p> <p>q) Relative vapour density</p> <p>r) Particle characteristics</p>
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The order within subsection is no longer mandatory!



Clarification of the scope and content

- **Physical state:** as defined in Section 1.0 of Annex I to Regulation (EC) No 1272/2008.
- **Colour:** “various” is explicitly supported for grouped SDSs
- **Odour:** no longer required “if perceptible” but if “well-known or described in the literature”
- **Melting point/freezing point:** high standard of care for communicating special cases such as lack of melting up to limit of method, decomposition or sublimation, softening of waxes/pastes, or mixtures for which it is technically not possible to determine the m.p.
- **Boiling point or initial boiling point and boiling range:** high standard of care for communicating special cases such as non-STP data, lack of boiling up to limit of method, decomposition, or mixtures for which it is technically not possible to determine the b.p.
- **Flammability:** extended to liquids in addition to solids, gases. Indication of ignitable and if appropriate, results other than normal combustion (e.g. explosion) and ignitability under non-standard conditions. Not to be redundant with information in 9.2.1.



Clarification of the scope and content

- **Lower and upper explosion limit:** not applicable to solids. At least lower required for flammable liquids. Provisions cited for use of data at non-standard conditions when necessary.
- **Flash point:** not applicable to gases, aerosols, solids. Mixture data required if available; otherwise the data of the substance(s) with the lowest value should be indicated.
- **Auto-ignition temperature:** only applicable to gases, liquids. Mixture data required if available; otherwise the data of the substance(s) with the lowest value should be indicated.
- **Decomposition temperature:** Only applies to self-reactive substances and mixtures, organic peroxides, and other substances and mixtures that may decompose.
 - *The self-accelerating decomposition temperature (SADT) and the volume to which it applies, or the decomposition onset temperature shall be indicated.*
 - *It shall be indicated whether the temperature given is the SADT or the decomposition onset temperature.*
 - *If no decomposition was observed, it shall be indicated up to which temperature no decomposition was observed, e.g. “no decomposition observed up to x °C”.*



Clarification of the scope and content

- **pH:** not applicable to gases. For liquids, “*shall be indicated*”. For solids, the pH in aqueous solution and the concentration “*shall be indicated*”.
- **Kinematic viscosity:** only applies to liquids. Units “*shall be mm²/s*”. For non-Newtonian liquids, the thixotropic or rheopexic behaviour shall be indicated.
- **Solubility:** generally indicated at standard temperature. Solubility in water “*shall be indicated.*” Solubility in other polar and non-polar solvents may also be included.
 - *As regards mixtures, it shall be indicated if the mixture is fully or only partially soluble in or miscible with water or other solvent.*
 - *As regards nanoforms, the dissolution rate in water or in other relevant biological or environmental media shall be indicated in addition to the water solubility.*



Clarification of the scope and content

- **Partition coefficient n-octanol/water (log value):** not applicable to inorganic and ionic liquids and mixtures (generally). Indicate basis on testing or on calculation.
 - *As regards nanoforms of a substance for which the n-octanol/water partition coefficient does not apply, the dispersion stability in different media shall be indicated.*
- **Vapour pressure:** generally at standard temperature, but also at 50 °C for volatile fluids. High standard of care for communicating special cases such as one SDS for variants, liquid mixtures or liquefied gas mixtures, and information such as saturated vapor concentration.



Clarification of the scope and content

- **Density and/or relative density:** only apply to liquids, solids. Generally at STP. Either absolute density and/or the relative density based on water at 4 °C as reference (\approx specific gravity) “*shall be indicated.*” Ranges may be used for variable batches or group SDSs.
 - *The safety data sheet shall indicate whether the absolute density (units e.g. g/cm³ or kg/m³) and/or the relative density (dimensionless) is being reported.*
- **Relative vapour density:** only applies to gases, liquids. As regards gases, the relative density of the gas based on air at 20 °C as reference shall be indicated. As regards liquids, the relative vapour density based on air at 20 °C as reference shall be indicated. And the relative density D_m of the vapour/air-mixture at 20 °C may also be indicated.



Clarification of the scope and content

- **Particle characteristics:** only apply to solids.
 - *The particle size (median equivalent diameter, method of calculation of the diameter (number-, surface- or volume-based) and the range in which this median value varies), shall be indicated. Other properties may also be indicated, such as size distribution (e.g. as a range), shape and aspect ratio, aggregation and agglomeration state, specific surface area and dustiness.*

If the substance is in nanoform or if the mixture supplied contains a nanoform, those characteristics shall be indicated in this subsection, if not already specified elsewhere in the safety data sheet.



Section 9.2 Other information

9.2.1. Information with regard to physical hazard classes

- *Properties, safety characteristics and test results*
- *May be useful to include in the safety data sheet when a substance or mixture is classified in the respective physical hazard class*
- *negative test results close to the criterion may also be appropriate to indicate.*



(a) Explosives

This point also applies to substances and mixtures referred to in Note 2 of section 2.1.3. of Annex I of Regulation (EC) No 1272/2008, and to other substances and mixtures which show a positive effect if heated under confinement.

The following information may be provided:

- i. sensitivity to shock;
- ii. effect of heating under confinement;
- iii. effect of ignition under confinement;
- iv. sensitivity to impact;
- v. sensitivity to friction;
- vi. thermal stability;
- vii. package (type, size, net mass of substance or mixture), based on which the ‘division’ within the explosive class was assigned, or based on which the substance or mixture was exempted from classification as explosive.



(b) Flammable gases

As regards pure flammable gas, the following information may be provided in addition to data on the explosion limits referred to in point (g) of subsection 9.1.:

- i. the T_{Ci} (maximum content of flammable gas which, when mixed with nitrogen, is not flammable in air, in mol. %);
- ii. the fundamental burning velocity if the gas is classified as Category 1B based on fundamental burning velocity.

As regards a flammable gas mixture, the following information may be provided in addition to data on the explosion limits referred to in point (g) of subsection 9.1.:

- i. explosion limits, if tested, or an indication of whether the classification and category assignment is based on calculation;
- ii. fundamental burning velocity if the gas mixture is classified as Category 1B based on fundamental burning velocity.



(c) Aerosols

The following total percentage (by mass) of flammable components may be provided, unless the aerosol is classified as Aerosol category 1 because it contains more than 1 % (by mass) flammable components or has a heat of combustion of at least 20 kJ/g and is not submitted to the flammability classification procedures (see the Note in Paragraph 2.3.2.2 of Annex I to Regulation (EC) No 1272/2008);



(d) Oxidising gases

As regards pure gas, the C_i (coefficient of oxygen equivalency) as per ISO 10156 'Gases and gas mixtures - Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets', or as per an equivalent method, may be provided;

As regards a gas mixture, the words "'oxidising gas Category 1 (tested as per ISO 10156 (or as per an equivalent method))'" may be indicated as regards tested mixtures, or the calculated oxidising power as per ISO 10156 or as per an equivalent method; [sic]



(e) Gases under pressure

As regards pure gas, critical temperature may be provided.

As regards gas mixture, pseudo-critical temperature may be provided;



(f) Flammable liquids

When the substance or mixture is classified as flammable liquid, data on the boiling point and flash point do not need to be provided under this point as that data are to be indicated in accordance with the subsection 9.1. Information on sustained combustibility may be provided.



(g) Flammable solids

The following information may be provided:

- i. burning rate, or burning time as regards metal powders,
- ii. statement on whether the wetted zone has been passed;



(h) Self-reactive substances and mixtures

In addition to the indication of the SADT as specified in point (j) of subsection 9.1, the following information may be provided:

- i. decomposition temperature,
- ii. detonation properties,
- iii. deflagration properties,
- iv. effect of heating under confinement,
- v. explosive power, if applicable;



(i) Pyrophoric liquids

Information on whether spontaneous ignition or charring of filter paper occurs may be provided.

(j) Pyrophoric solids

The following information may be provided:

- i. statement on whether spontaneous ignition occurs when poured or within five minutes thereafter, as regards solids in powder form,
- ii. statement on whether pyrophoric properties could change over time.



(k) Self-heating substances and mixtures

The following information may be provided:

- i. statement on whether spontaneous ignition occurs and the maximum temperature rise obtained,
- ii. results of screening tests referred to in section 2.11.4.2 of Annex I to Regulation (EC) No 1272/2008, if relevant and available;



(I) Substances and mixtures, which emit flammable gases in contact with water

The following information may be provided:

- i. identity of the emitted gas, if known,
- ii. statement on whether the emitted gas ignites spontaneously,
- iii. gas evolution rate;



(m) Oxidising liquids

Information on whether spontaneous ignition occurs when mixed with cellulose may be provided.

(n) Oxidising solids

Information on whether spontaneous ignition occurs when mixed with cellulose may be provided.



(o) Organic peroxides

In addition to the indication of the SADT as specified in point (j) of subsection 9.1, the following information may be provided:

- i. decomposition temperature,
- ii. detonation properties,
- iii. deflagration properties,
- iv. effect of heating under confinement,
- v. explosive power;



(p) Corrosive to metals

The following information may be provided:

- i. metals that are corroded by the substance or mixture,
- ii. corrosion rate and statement on whether it refers to steel or aluminium,
- iii. reference to other sections of the safety data sheet with regard to compatible or incompatible materials.



(q) Desensitised explosives

The following information may be provided:

- i. desensitising agent used,
- ii. exothermic decomposition energy,
- iii. corrected burning rate (A_c);
- iv. explosive properties of the desensitised explosive in that state.



Section 9.2 Other information

9.2.1. Information with regard to physical hazard classes

- *Properties, safety characteristics and test results*
- *May be useful to include in the safety data sheet when a substance or mixture is classified in the respective physical hazard class*
- *negative test results close to the criterion may also be appropriate to indicate.*

9.2.2. Other safety characteristics

- *Properties, safety characteristics and test results*
- *May be useful to indicate as regards a substance or a mixture*



9.2.2. Other safety characteristics

- a) mechanical sensitivity;
- b) self-accelerating polymerisation temperature;
- c) formation of explosible dust/air mixtures;
- d) acid/alkaline reserve;
- e) evaporation rate;
- f) miscibility;
- g) conductivity;
- h) corrosiveness;
- i) gas group;
- j) redox potential;
- k) radical formation potential;
- l) photocatalytic properties.

Other physical and chemical parameters shall be indicated...

“if their indication is relevant for the safe use of the substance or mixture.”



REACH Annex II: Section 10

In subsection 10.2 on chemical stability, a new requirement:

“As regards desensitised explosives, information on the shelf life and instructions on how to verify desensitisation shall be provided, and it shall be indicated that removal of the desensitising agent will turn the product into an explosive.”

In subsection 10.4 on Conditions to avoid, a new requirement:

“As regards desensitised explosives, information on measures to be taken in order to avoid the unintentional removal of the desensitising agent shall be provided, and conditions to avoid shall be listed if the substance or mixture is not sufficiently desensitised.”



GHS Seventh Revised Edition

Section 14 updates

- Change to Section 14.7 subheader
 - ~~Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code~~

14.7 Transport in bulk according to IMO instruments

- Additional guidance extends the coverage of section 14 to all bulk cargoes transported under instruments of the International Maritime Organization (IMO), regardless of their physical state



REACH Annex II: New section 14

SECTION 14: Transport information

14.1. UN number [or ID number](#)

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

14.6. Special precautions for user

~~14.7. Transport in bulk according to Annex II of Marpol and the IBC Code~~

14.7. [Maritime transport in bulk according to IMO instruments](#)

- **READ THE FINE PRINT: UN proper shipping name!**



Issue: UN Proper shipping name

UN Model Regulations

3.1.2.1 The proper shipping name is that portion of the entry most accurately describing the goods in the Dangerous Goods List, which is shown in **UPPER CASE CHARACTERS** ... Portions of an entry appearing in lower case need not be considered as part of the proper shipping name but may be used.

REACH Annex II

The proper shipping name **as provided in column 2**, 'Name and description', of Table A of Chapter 3.2 Dangerous Goods List of the UN Model Regulations ... supplemented, when applicable, with the **technical name** in brackets as required, shall be provided



Technical name?

Answer from ECHA

To paraphrase: the (correct) technical names must be shown in section 14 of the SDS, if applicable. Example:

14.2. UN proper shipping name:
Corrosive liquid, toxic, N.O.S. (hydrofluoric acid, nitric acid)



UPPER CASE or “as provided in column 2”?

1382	POTASSIUM SULPHIDE, ANHYDROUS or POTASSIUM SULPHIDE with less than 30 % water of crystallization
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UN PROPER SHIPPING NAME

- Potassium sulphide

REACH subsection 14.2. - ?

- Potassium sulphide with less than 30% water of crystallization



ECHA Answer INC000000283176

The idea behind the amendment was to have at least the name in the capital written correctly in SDS, in order to ensure consistence with transport rules.

Ideally, you would write the complete name for transport, because there is a difference between “Anhydrous” and “less than 30% water of crystallization”.

Furthermore, **there are other UN nos for Potassium sulphide**, i.e.

UN 1847 POTASSIUM SULPHATE, HYDRATED (SIC) with not less than 30% water of crystallization”.

As the 30% is the criteria for differentiation to the substances, it's not useful to only have the name in capitals. The downstream users of the SDS will not be correctly informed about: the substance that is supposed to be carried, and the dangers associated with it.

According to RID/ADR/ADN, there is a clear task for the consignor to “ascertain that the dangerous goods are classified and authorized for carriage” in accordance with these agreements (1.4.2.1.1) and also to “furnish to the carrier the with info and data in a traceable form”.

Furthermore, section 3.1.2 of RID/ADR/ADN gives further guidance on the use of the proper shipping name.

It is ultimately the decision of the producer => it's department dealing with transport classification+ DGSA how to quote the proper shipping name on *a case by case basis*.



ECHA Answer INC000000283176

The idea behind the amendment was to have at least the name in the capital written correctly in SDS, in order to ensure consistence with transport rules.

Ideally, you would write the complete name for transport, because there is a difference between “Anhydrous” and “less than 30% water of crystallization”.

Furthermore, **there are other UN nos for Potassium sulphide,** i.e.

UN 1847 POTASSIUM SULPHATE (SIC), HYDRATED with not less than 30% water of crystallization”.

As the 30% is the criteria for differentiation to the substances, it's not useful to only have the name in capitals. The downstream users of the SDS will not be correctly informed about: the substance that is supposed to be carried, and the dangers associated with it.



ECHA Answer INC000000283176 - Focus

According to RID/ADR/ADN, there is a clear task for the consignor to “ascertain that the dangerous goods are classified and authorized for carriage” in accordance with these agreements (1.4.2.1.1) and also to “**furnish to the carrier the with info and data in a traceable form**”.

It is ultimately the **decision of the producer** => it's department dealing with transport classification+ DGSA how to quote the proper shipping name on *a case by case basis*.



UN Model Regulations

- Not a valid legal instrument AND the lower case often differs in the regulations adopted for specific modes of transport or by different competent authorities
 - IF choosing to display the lowercase additional descriptors, consider to use UN Model Regulations as the source



Lower case differences - examples

UN Model Regulation

1139	COATING SOLUTION (includes surface treatments or coatings used for industrial or other purposes such as vehicle undercoating, drum or barrel lining)
1139	COATING SOLUTION (includes surface treatments or coatings used for industrial or other purposes such as vehicle undercoating, drum or barrel lining)

ADR 2019

1139	COATING SOLUTION (includes surface treatments or coatings used for industrial or other purposes such as vehicle under coating, drum or barrel lining)
1139	COATING SOLUTION (includes surface treatments or coatings used for industrial or other purposes such as vehicle under coating, drum or barrel lining) (vapour pressure at 50 °C more than 110 kPa)



UN Model Regulations

- Not a valid legal instrument BUT the lower case often differs in the regulations adopted for specific modes of transport or by different competent authorities
 - IF choosing to display the lowercase additional descriptors, be sure to use UN Model Regulations as the source
- Remember that it is also important to show the information specific to ADR, in RID, and in Tables A and C of Chapter 3.2 of ADN, from IMDG, or other relevant modes of transport.



Driver: CLP Regulation

OTHER ADAPTATIONS TO TECHNICAL PROGRESS



Specific Conc. Limits, M-factors and ATE

- COMMISSION REGULATION (EU) **2017/776** of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
 - AKA the 10th ATP to CLP
- ATEs are added to Annex VI
 - Remember, in “GHS-speak,” the ATE, or **Acute Toxicity Estimate**, is determined by a hierarchy of
 - The actual LD/LC50 if available
 - The conversion value from table 3.1.2 based on the results of a range test, or based on the classification category



10th ATP TO CLP: ATE ON NICOTINE

Index No	International Chemical Identification	Specific Conc. Limits, M-Factors and ATE						Specific Conc. Limits, M-factors and ATE	Notes
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614-001-00-4	nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 Aquatic Chronic 2	H330 H310 H300 H411	GHS06 GHS09 Dgr	H330 H310 H300 H411	inhalation: ATE = 0.19 mg/L (dusts or mists) dermal: ATE = 70 mg/kg oral: ATE (*) = 5 mg/kg	
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10th ATP TO CLP: ATE ON NICOTINE

614-001-00-4	nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-	200-193-3	54-11-5	Acute Tox. 2 Acute Tox. 2	H330 H310	GHS06 GHS09	H330 H310	inhalation: ATE = 0.19 mg/L
'614-001-00-4	nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5					dermal: ATE = 70 mg/kg oral: ATE (*) = 5 mg/kg
	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 Aquatic Chronic 2				inhalation: ATE = 0.19 mg/L (dusts or mists)			



A Reminder: Table 3.1.2 of CLP Annex I

Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for use in the formulas for the classification of mixtures

- *Highlights indicate ATE values that create a conflict if used as inputs to re-classify a substance as the pure substance*

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg body-weight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg body-weight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05
	0,5 < Category 2 ≤ 2,0	0,5
	2,0 < Category 3 ≤ 10,0	3
	10,0 < Category 4 ≤ 20,0	11



SDS Section 3.1. Substances

Section 3.1. Substances

- The **specific concentration limit, the M-factor and the acute toxicity estimate** for substances included in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or determined in accordance with Annex I to that Regulation shall be indicated, if available.

Section 3.2. Mixtures

- For the substances indicated in subsection 3.2.:
- the **specific concentration limit, the M-factor and the acute toxicity estimate** for the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or as determined in accordance with Annex I to that Regulation shall be indicated, if available.



Chemical names in translation

- COMMISSION REGULATION (EU) **2018/669** of 16 April 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
 - AKA the 11th ATP to CLP
- Translations of chemical names in ALL EU languages
 - Safety Data Sheets should communicate these Annex VI substances using the official chemical name translations

CAUTION: Do NOT use the text of 2018/669 for C&L data!



Driver: CLP Regulation

NEW ANNEX VIII

POISON CENTRE NOTIFICATION



CLP ANNEX VIII

If you don't know it yet by "Annex VIII," you've probably heard about:

POISON CENTRES NOTIFICATION

<https://poisoncentres.echa.europa.eu/>

The screenshot shows the 'Poison Centres' section of the ECHA website. It features a purple starburst icon with an exclamation mark. Below the icon is a navigation menu with four buttons: 'About us', 'Steps for industry', 'Tools', and 'Support'. Underneath the menu is a box for the 'ECHA Submission portal For industry' with a cloud icon and an upward arrow. At the bottom is a box for 'PCN format' with a document icon labeled 'PCN'.



CLP Annex VIII

- COMMISSION REGULATION (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on **harmonised information relating to emergency health response**
 - 1ST AMENDMENT:
 - COMMISSION DELEGATED REGULATION (EU) 2020/11 of 29 October 2019 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response
 - 2ND AMENDMENT: Workability Review
 - Pending in summer 2020? For October IUCLID update? For 1 Jan 2021 Deadline? **!**



Unique Formula Identifier (UFI)

- Paragraph 7 to Article 25: **UFI must be included on the label**

So does a UFI affect the Safety Data Sheet?

- Per CLP Annex VIII, Section 5.3, the UFI is not required to appear in the SDS except where derogation is used for
 - industrial use mixtures (*i.e. no consumer/professional supply*) or
 - mixtures which are not packaged, so no UFI appears on the label



Guess where the UFI belongs

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1. Product identifier
- 1.2. Relevant identified uses of the substance or mixture and uses advised against
- 1.3. Details of the supplier of the safety data sheet
- 1.4. Emergency telephone number

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture
- 2.2. Label elements
- 2.3. Other hazards





REACH Annex II

1.1. Product identifier

Other means of identification

...

Where a mixture has a unique formula identifier (UFI) in accordance with section 5 of Part A of Annex VIII to Regulation (EC) No 1272/2008 and that UFI is indicated in the safety data sheet, then the UFI shall be provided in this subsection.

- Per REACH Annex II: IF a UFI is indicated in the SDS – due to derogation or voluntarily – it **must be communicated in subsection 1.1**



Conclusion: where the UFI belongs

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier



1.2. Relevant identified uses of the substance or mixture and uses advised against

1.3. Details of the supplier of the safety data sheet

1.4. Emergency telephone number

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.2. Label elements

2.3. Other hazards



Driver: REACH Regulation

REACH AMENDMENTS: NANOFORMS



REACH Dossiers: Nanoforms

- Commission Regulation (EU) **2018/1881** of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances
 - Annexes I, III and VI - XII to Regulation (EC) No 1907/2006 are amended
 - Introduces nano-specific clarifications and new provisions in the chemical safety assessment (Annex I), registration information requirements (Annex III and VI-XI) and downstream user obligations (Annex XII).

Applicability date : 1 Jan 2020



Definitions: Nanoform

- According to Annex VI of the REACH Regulation, a “nanoform” is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm
- Source: Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification, Version 1.0, December 2019
https://echa.europa.eu/documents/10162/13655/how_to_register_nano_en.pdf/



Safety Data Sheet: Nanoforms

Significant enhancements for the treatment of nanoforms include:

- Intro: Requires use of the term ‘nanoform’ when applicable
- The term “nanoform” should appear as an identifier if the SDS covers nanoforms
- Clear indications of which information relates to which form for an SDS covering different forms



Safety Data Sheet: Section I

The term “nanoform” should appear as a product identifier if the SDS covers nanoforms.

“Where different forms of a substance are covered by one safety data sheet, relevant information shall be included, clearly indicating which information is related to which form.

Alternatively, a separate safety data sheet may be prepared per form or group of forms.

If the safety data sheet pertains to one or more nanoforms, or substances that include nanoforms, this shall be indicated by using the word ‘nanoform’.”



Safety Data Sheet: Section 3

Section 3.1. Substances

- If the substance is registered and it covers a nanoform, the particle characteristics that specify the nanoform, as described in Annex VI, shall be indicated.
- If the substance is not registered, but the safety data sheet covers nanoforms, the particle characteristics of which have impact on the safety of the substance, those characteristics shall be indicated.

Section 3.2. Mixtures

- if the substance as used in the mixture is in nanoform and is as such registered or addressed by the downstream user chemical safety report, the particle characteristics that specify the nanoform, as described in Annex VI, shall be indicated. If the substance as used in the mixture is in nanoform but is not registered or addressed by the downstream user chemical safety report, the particle characteristics which have impact on the safety of the mixture, shall be provided.



Safety Data Sheet: Section 9

Solubility

“As regards nanoforms, the dissolution rate in water or in other relevant biological or environmental media shall be indicated in addition to the water solubility.”

Partition coefficient

“As regards nanoforms of a substance for which the n-octanol/water partition coefficient does not apply, the dispersion stability in different media shall be indicated.”



Safety Data Sheet: Section 9

Particle characteristics: only apply to solids.

“The particle size (median equivalent diameter, method of calculation of the diameter (number-, surface- or volume-based) and the range in which this median value varies), shall be indicated. Other properties may also be indicated, such as size distribution (e.g. as a range), shape and aspect ratio, aggregation and agglomeration state, specific surface area and dustiness. If the substance is in **nanof orm** or if the mixture supplied **contains a nanof orm**, those characteristics shall be indicated in this subsection, if not already specified elsewhere in the safety data sheet.”



Driver: REACH Regulation

EU FRAMEWORK ON ENDOCRINE DISRUPTORS



Recital 6: Whereas...

- The Commission Communication of 7 November 2018 ‘Towards a comprehensive European Union framework on endocrine disruptors’ indicates that the Commission is assessing how to improve the communication through the supply chain for endocrine disruptors under Regulation (EC) No 1907/2006 in the context of the work on safety data sheets.
- A number of specific requirements for safety data sheets have been identified as relevant for substances and mixtures with endocrine disrupting properties and Annex II of this Regulation should therefore be modified accordingly.



Safety Data Sheet: Section 2

2.3. Other hazards

- Information shall be provided on whether the substance meets the criteria for persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Annex XIII, whether the substance was included in the list established in accordance with **Article 59(1)** for having endocrine disrupting properties, and whether the substance is a substance identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) **2017/2100** or Commission Regulation (EU) **2018/605**.
- For a mixture, information shall be provided for each such substance that is present in the mixture at a concentration **equal to or greater than 0.1%** by weight.



Safety Data Sheet: Section 2

Article 59(I)

- Requires ECHA to identify substances of very high concern (SVHC) in a candidate list for eventual inclusion in REACH Annex XIV (substance subject to authorization)
- Criteria: Substances which are
 - CMR IA or IB
 - PBT or vPvB per Annex XIII
 - Raising equivalent level of concern, such as those having endocrine disrupting properties

<https://echa.europa.eu/candidate-list-table>



Safety Data Sheet: Section 2

Commission Delegated Regulation (EU) 2017/2100

Commission Regulation (EU) 2018/605

Set out scientific criteria for the determination of endocrine-disrupting properties

- In the context of the biocidal products regulation
- In the context of the plant protection products regulation



Safety Data Sheet: Section 2

2.3. Other hazards

In summary, if a substance

- is listed in the candidate list of SVHC per REACH
- Meets the criteria set out for endocrine-disrupting properties in the authorization process for the
 - Biocidal products market
 - Plant protection products market

Disclose this in section 2.3!



Safety Data Sheet: Section 11

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

11.2 Information on other hazards

- Change to subheader 11.1
- New subheader 11.2 now mandatory



Safety Data Sheet: Section 11

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

Information on adverse health effects caused by endocrine disrupting properties shall be provided, where available, for the substances identified as having endocrine disrupting properties in Subsection 2.3. This information shall consist of brief summaries of the information derived from application of the assessment criteria laid down in the corresponding Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605), that is relevant to assess endocrine disrupting properties for human health.

11.2.2. Other information

Other relevant information on adverse health effects shall be included even when not required by the classification criteria



Safety Data Sheet: Section 12

SECTION 12: Ecological information

...

12.6. Endocrine disrupting properties

12.7. Other adverse effects

- New subheader 12.6 now mandatory
- Other adverse effects drops to item 12.7



Driver: REACH Regulation

EVOLVING SUBSTANCES OF VERY HIGH CONCERN



Equivalent level of concern

Article 59(I)

- Requires ECHA to identify substances of very high concern (SVHC) in a candidate list for eventual inclusion in REACH Annex XIV (substance subject to authorization)
- Criteria: Substances which are
 - CMR IA or IB
 - PBT or vPvB per Annex XIII
 - **Raising equivalent level of concern**, such as those having endocrine disrupting properties

<https://echa.europa.eu/candidate-list-table>



A problem and a proposal

- Drinking water protection regulations are failing
- HAZCOM, Classification of hazards and safety data sheet information on safe handling and use of chemicals unnecessary
 - But no specific pathway to protect drinking water
 - mobile
 - persistent and
- The REACH regulation goes further: placing the burden of proof of safe use on manufacturers underpinned by the “precautionary principle”
 - But REACH has no specific pathway to **protect drinking water**

**Proposed solution:
a new class of hazard**



Result: PMT and vPvM

- Risk is similar to PBT/vPvB
 - Instead of accumulating in the food chain, these substances are mobile and persistent – ensuring a steady, low dose over years
 - Difficult (and expensive) to remove from aquifers once contamination occurs
- Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) Statement on emerging health and environmental issues (2018)
https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_s_002.pdf
 - 4.7 Substance Mobility: a new criterion in chemicals regulation
- Substances have started entering the candidate list due to persistent, mobile and toxic properties



Example: PMT and vPvM

The following remark is added for perfluorobutane sulfonic acid (PFBS) and its salts:

"The combined intrinsic properties justifying the inclusion as a substance for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern are the following: very high persistence, high mobility in water and soil, high potential for long-range transport, and difficulty of remediation and water purification as well as moderate bioaccumulation in humans. The observed probable serious effects for human health and the environment are thyroid hormonal disturbances and reproductive toxicity seen in rodents, and effects on liver, kidney and haematological system in rats, hormonal disturbances and effects on reproduction in marine medaka fish and effects on expression of hormone receptors in tadpoles. Together, these elements lead to a very high potential for irreversible effects."



MISC.

TWO MISCELLANEOUS ITEMS



Two miscellaneous changes

- Section 8: Personal protective equipment
 - Council Directive 89/686/EEC is updated to refer to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC
- Section 15: REACH Authorisation conditions
 - A specific requirement is added: “*Where an authorisation granted under Title VII imposes conditions or monitoring arrangements to a downstream user of the substance or mixture, they shall be provided.*”



SDS SECTION 3

EFFECT OF ACCUMULATED CHANGES



For a mixture classified hazardous under CLP

- Aspiration hazards
 - 3.2.1.(a)(II) Disclosure limit lowered from 10% to 1%
- Clarification related to sensitizers:
 - 3.2.1.(a)(vi) Disclosure is required for substances \geq “one tenth of the specific concentration limit for a substance classified as skin sensitiser or respiratory sensitiser with a specific concentration limit;”
- Sensitizers
 - Table I.1: Limit for sensitizers in class IA established at 0.01%

Sensitizer disclosures not really new!



For a mixture classified hazardous under CLP

3.2.1(c) At concentration $\geq 0,1$:

- PBT or vPvB per Annex XIII
- In the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a) of this subsection such as endocrine disrupting properties,
- Identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605



For a mixture NOT hazardous under CLP

- 1% threshold lowered to 0.1% for:
 - Skin sensitizer I or IB
 - Respiratory sensitizer I or IB
 - Carcinogen 2
 - Toxic to reproduction 1A, 1B, 2 or with effects on or via lactation
- 1% threshold lowered to 0.01% for:
 - Skin sensitizer 1A
 - Respiratory sensitizer 1A
- 1% threshold lowered to 1/10th of the SCL for skin or respiratory sensitizer



Additional substance information to disclose

- Supplemental hazard statement(s)
 - EUH-codes suffice, with full texts in section 16
- Specific concentration limits
- M-factor(s)
- Acute toxicity estimates – from Annex VI or self-classification
- Nanoform



- **REACH:** Regulation (EC) No 1907/2006 concerning the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals
- **CLP:** Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
- **PCN:** Poison Centre Notification
- **ATP:** Adaptation to Technical Progress, an efficient method for frequent updates due to scientific rather than policy changes
- **SCL:** Specific concentration limit, a classification threshold specific to the substance, set either in Annex VI of CLP or reported to the ECHA Classification and Labelling (C&L) Inventory



- **PMT:** Persistent, Mobile, and Toxic
- **vPvM:** very Persistent and very Mobile
- **GHS:** Globally Harmonized System of Classification and Labelling of Chemicals
- **ECHA:** European Chemicals Agency
- **UBA:** Umweltbundesamt, the German Environmental Protection Agency



Thank you for your attention

For a marked-up copy of the new Annex II,
or documents on PMT email me at:

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