

# Testing of chemicals for classification according to REACH and GHS

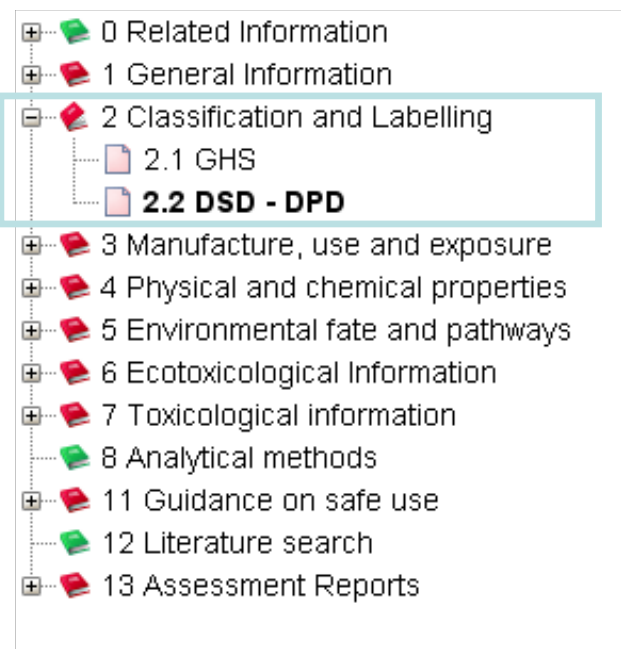
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## Overview on the presentation

- Classification: IUCLID requirements
- Matching DSD with GHS
- Tests to fulfil both DSD and GHS classification requirements

Classification: IUCLID requirements

## IUCLID section tree, classification



### GHS:

Classification according to the Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures

### DSD-DPD:

Classification according to Directives 67/548/EWG ("Dangerous Substances Directive", DSD) and 1999/45/EG ("Dangerous Preparations Directive", DPD)

# IUCLID classification GHS

**Classification**

**Physical hazards**

	Hazard statement	Reason for no classification
Explosives		conclusive but not sufficient for classification
Flammable gases		conclusive but not sufficient for classification
Flammable aerosols		conclusive but not sufficient for classification
Oxidising gases		conclusive but not sufficient for classification
Gases under pressure		conclusive but not sufficient for classification
Flammable liquids	Flam. Liquid 3	H226: Flammable liquid and vapour.
Flammable solids		conclusive but not sufficient for classification
Self-reactive substances and mixtures		
Pyrophoric liquids		
Pyrophoric solids		
Self-heating substances and mixtures		
Substances and mixtures which in contact with water emit flammable gases		
Oxidising liquids		
Oxidising solids		
Organic peroxides		
Corrosive to metals		conclusive but not sufficient for classification

**Pick list**

- data lacking
- inconclusive
- conclusive but not sufficient for classification



# IUCLID classification DSD-DPD

Classification		Reason for no classification
Explosiveness	<input type="text"/>	conclusive but not sufficient for classification
Oxidising properties	<input type="text"/>	conclusive but not sufficient for classification
Flammability	<input type="text"/>	conclusive but not sufficient for classification
Thermal stability	<input type="text"/>	conclusive but not sufficient for classification
Acute toxicity	<input type="text"/>	conclusive but not sufficient for classification
Acute toxicity - irreversible damage after single exposure	▼ Xn; R68/21/22 Harmful; Harmful: possible risk of irreversible effects in contact with skin and if swallowed	<input type="text"/>
Repeated dose toxicity	<input type="text"/>	conclusive but not sufficient for classification
Irritation / Corrosion	<input type="text"/>	conclusive but not sufficient for classification
Sensitisation	<input type="text"/>	conclusive but not sufficient for classification
Carcinogenicity	<input type="text"/>	conclusive but not sufficient for classification
Mutagenicity - Genetic Toxicity	<input type="text"/>	conclusive but not sufficient for classification
Toxicity to reproduction - fertility	<input type="text"/>	conclusive but not sufficient for classification
Toxicity to reproduction - development	<input type="text"/>	data lacking
Toxicity to reproduction - breastfed babies	<input type="text"/>	data lacking
Environment	<input type="text"/>	conclusive but not sufficient for classification

## Labelling

Information

## Basis for classification according to DSD-DPD

Explosiveness  
Oxidising properties  
Flammability  
Thermal stability  
Acute toxicity  
Acute toxicity - irreversible damage after single exposure  
Repeated toxicity  
Irritation/Corrosion  
Sensitisation  
Carcinogenicity  
Mutagenicity - genetic toxicity  
Toxicity to reproduction-development  
Toxicity to reproduction-breastfed babies  
Environment

## Basis for classification according to GHS

Explosives

Flammable gases

Flammable aerosols

Oxidising gases

Gases under pressure

Flammable liquids

Flammable solids

Self-reactive substances and mixtures

Pyrophoric liquids

Pyrophoric solids

Self-heating substances and mixtures

Substances and mixtures which in contact with water emit flammable gases

Oxidising liquids

Oxidising solids

Organic peroxides

Corrosive to metals

Acute toxicity - oral

Acute toxicity - dermal

Acute toxicity - inhalation

Skin corrosion / irritation

Serious eye damage / eye irritation

Respiratory sensitisation

Skin sensitisation

Aspiration hazards

Reproductive toxicity

Effects on or via lactation

Germ cell mutagenicity

Carcinogenicity

Specific organ toxicity - single

Specific organ toxicity - repeated

Hazardous to the aquatic environment

Hazardous to the atmospheric environment



# Matching DSD with GHS

## Classification on the basis of physicochemical properties (1)

### **DSD-DPD**

Explosiveness

Oxidising properties

Flammability

### **GHS**

Explosives

Oxidising gases  
Oxidising liquids  
Oxidising solids  
Organic peroxides

Flammable gases  
Flammable aerosols  
Flammable liquids  
Flammable solids  
Substances and mixtures which in contact with water emit flammable gases  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures

## Classification on the basis of physicochemical properties (2)

### **DSD-DPD**

Thermal stability

-

-

### **GHS**

Self-reactive substances and mixtures

Gases under pressure

Corrosive to metals

## Classification on the basis of toxicological properties

### **DSD-DPD**

Acute toxicity

Acute toxicity - irreversible damage after single exposure

Repeated toxicity

Irritation/Corrosion

Sensitisation

### **GHS**

Acute toxicity - oral

Acute toxicity - dermal

Acute toxicity - inhalation

Aspiration hazards

Specific organ toxicity - single

Specific organ toxicity - repeated

Skin corrosion / irritation

Serious eye damage / eye irritation

Respiratory sensitisation

Skin sensitisation

## Classification on the basis of specific effects to human health

### **DSD-DPD**

Carcinogenicity

Mutagenicity - genetic toxicity

Toxicity to reproduction-development

Toxicity to reproduction-breastfed babies

### **GHS**

Carcinogenicity

Germ cell mutagenicity

Reproductive toxicity

Effects on or via lactation

## Classification on the basis of environmental effects

### **DSD-DPD**

Environment

### **GHS**

Hazardous to the aquatic environment  
Hazardous to the atmospheric environment

# Tests to fulfil both DSD and GHS classification requirements

# Data Analysis

## Collection and compilation of existing data

- Own data (clarification of data ownership)
- Data sources, databases  
**See Guidance on information requirements and chemical safety assessment, Chapter R.3: Information gathering**
- Data from SIEF participants
- Data from chemically related substances (grouping, read-across)

Requires **expertise** to interpret the data.

For studies not in the public domain there is the requirement to demonstrate **legal title** to the information in order to protect intellectual property rights of the data owner.



## Data Reliability, examples

Values for **physico-chemical properties** taken from **MSDS**'s and all other company technical data can only be assigned a reliability rating of "4", unless detailed information is available. a)

Values obtained from "**peer reviewed**" data: reliability score = "2" a)

The maximum reliability score for **read-across** is "2". b)

a) ECHA Practical Guide 2: How to report weight of evidence

b) ECHA Practical Guide 6: How to report read-across and categories

## Guidelines

Good Laboratory Practice (GLP)

**mandatory** for toxicological and ecotoxicological testing,  
**not mandatory** for physico-chemical testing

=> not compliant with other regulations or with non-EU member states

Council regulation (EC) No 440/2008 from 30 May 2008

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:142:0001:0739:EN:PDF>

OECD methods (Section 4: Health effects) may be used in some cases

[http://titania.sourceoecd.org/vl=14974079/cl=11/nw=1/rpsv/periodical/p15\\_about.htm?jnlissn=1607310x](http://titania.sourceoecd.org/vl=14974079/cl=11/nw=1/rpsv/periodical/p15_about.htm?jnlissn=1607310x)

UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria

## Physicochemical properties (1)

Classification criteria (GHS)	Test methods	Endpoint REACH Annex VII
Explosives	DSC, Test Series 1	7.11
Oxidising gases	ISO 10156	7.13
Oxidising liquids	A.21, UN-O.2	7.13
Oxidising solids	UN-O.1	7.13
Organic peroxides	chemical structure UN methods, Part II, Sect. 28	-
Flammable gases	flammable range with air at 20 °C	7.9, 7.10
Flammable aerosols	contains flammable liquids, gases or solids	7.9, 7.10
Flammable liquids	A.9, A.12/A.13	7.9, 7.10
Flammable solids	A.10, A.12/A.13	7.9, 7.10
Substances and mixtures which in contact with water emit flammable gases	A.12, N.5	7.9, 7.10

## Physicochemical properties (2)

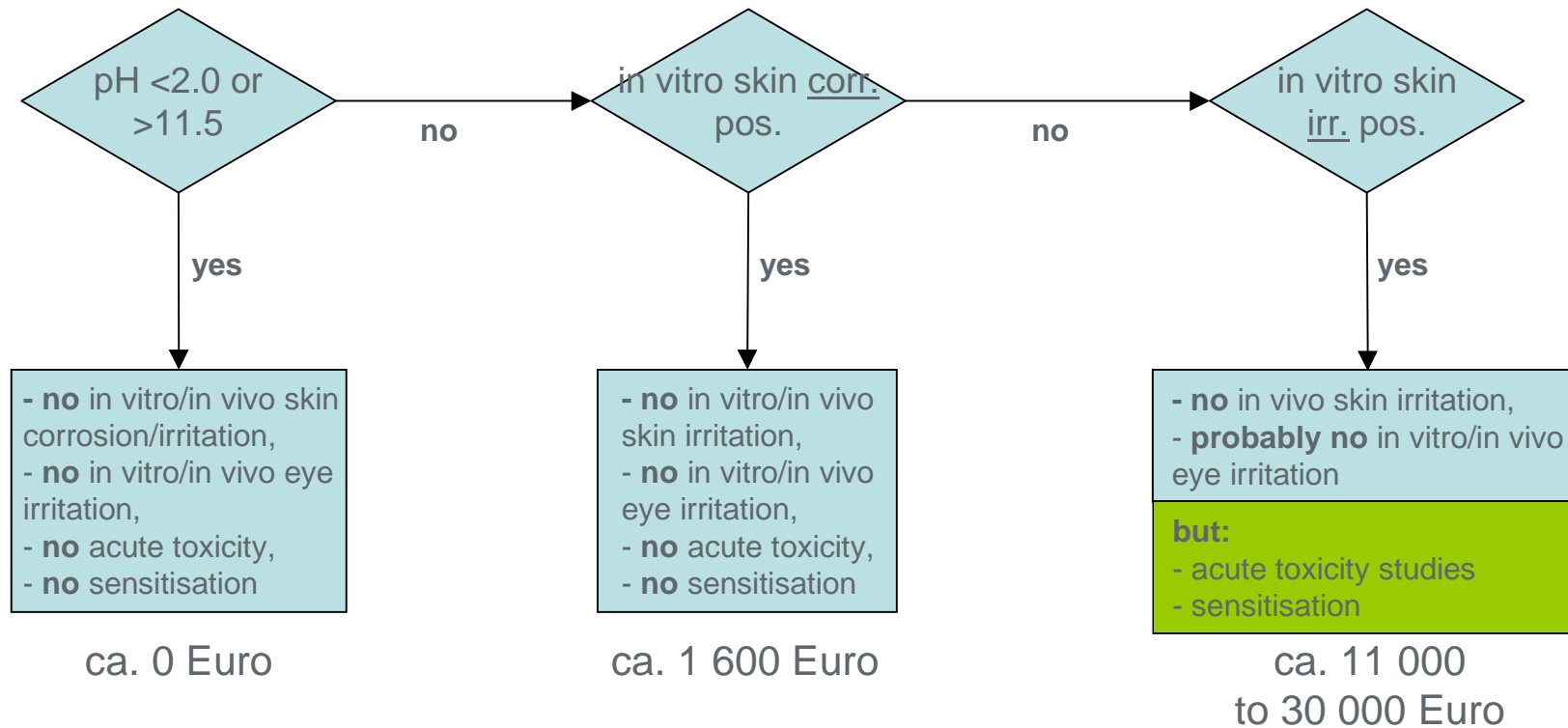
Classification criteria (GHS)	Test methods	Endpoint REACH Annex VII
Pyrophoric liquids	A.13, N.3	7.12
Pyrophoric solids	A.13, N.2	7.12
Self-heating substances and mixtures	N.4	~ 7.12
Self-reactive substances and mixtures	UN methods, Part II, Sect. 28	-
Gases under pressure	>200 kPa or liquefied pure gases: see UN Recommendations on the Transport of Dangerous Goods, Model Regulations	-
Corrosive to metals	C.1	-

## Toxicological properties (1)

<b>Classification criteria (GHS)</b>	<b>Test methods: OECD, EU</b>	<b>Endpoint REACH (Annex ..., No.)</b>
Acute toxicity - oral	Acute toxicity,	VII, 8.5.1
Acute toxicity - dermal	Viscosity	VIII, 8.5.2, 8.5.3
Acute toxicity - inhalation		IX, 7.17
Aspiration hazards		
Specific organ toxicity - single	Acute toxicity	VII, 8.5.1 VIII, 8.5.2, 8.5.3
Specific organ toxicity - repeated	Repeated dose toxicity	VIII, 8.6.1 IX, 8.6.2 X, 8.6.3/4
Skin corrosion / irritation	In vitro and in vivo studies	VII / VIII, 8.1
Serious eye damage / eye irritation	In vitro and in vivo studies	VII / VIII, 8.2
Respiratory sensitisation	-	-
Skin sensitisation	Skin sensitisation studies	VII, 8.3

# Test dependencies

example for toxicological properties



## Toxicological properties (2)

<b>Classification criteria (GHS)</b>	<b>Test methods: OECD, EU</b>	<b>Endpoint REACH (Annex ..., No.)</b>
Carcinogenicity	Mutagenicity studies, Carcinogenicity studies	VII, 8.4.1 VIII, 8.4.2, 8.4.3 IX, 8.4 X, 8.9.1
Germ cell mutagenicity	Mutagenicity studies, (Developmental toxicity)	VII, 8.4.1 VIII, 8.4.2, 8.4.3 IX, 8.4 X, 8.9.1 (IX, 8.7.2)
Reproductive toxicity	Screening tests, Developmental toxicity, Reproduction toxicity	VIII, 8.7.1 IX / X, 8.7.2, 8.7.3
Effects on or via lactation	(Screening tests) Reproduction toxicity	(VIII, 8.7.1) IX / X, 8.7.3

## Ecotoxicological properties

Classification criteria (GHS)	Test methods: OECD, EU	Endpoint REACH (Annex ..., No.)
Hazardous to the aquatic environment	Acute toxicity tests on aquatic organisms Long-term studies on aquatic organisms Surface tension Partition coefficient n-octanol/water Dissociation constant Water solubility Biodegradability Adsorption/desorption studies Bioaccumulation studies	VII, 7.6, 7.7, 7.8, 9.1.1, 9.1.2, 9.2.1.1 VIII, 9.1.3, 9.1.4. 9.2.2.1, 9.3.1 IX, 7.16, 9.2.1.2, 9.3.2
Hazardous to the atmospheric environment	-	-





# Seibersdorf Labor GmbH

Vienna is very near – and so are we

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## Reliability of data (Klimisch et al.)

**1 = reliable without restrictions:** “studies or data...generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline...or in which all parameters described are closely related/comparable to a guideline method.”

**2 = reliable with restrictions:** “studies or data...(mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”

**3 = not reliable:** “studies or data...in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., unphysiologic pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”

**4 = not assignable:** “studies or data....which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”