

Hazard Classification Data – The Good, The Bad, The Ugly

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Why is good classification data so important?

1. We have a legal obligation to classify our substances and mixtures when we place our company labels and Safety Data Sheets on market.
2. We have a regulatory obligation to classify based on sound, accepted scientific principles.
3. We have a moral obligation to protect the workforce and greater public from the hazards associated with our products, whether from intended or unintentional use.



Classification Data - The Ugly Safety Data Sheet Gaps

SECTION 2 – HAZARDS IDENTIFICATION

Skin Corrosion (Category 1B), H314
Eye Damage (Category 1), H318
Skin Sensitization (Category 1), H317
Carcinogen (Category 1), H350

SECTION 11 – TOXICOLOGICAL INFORMATION

- No data available
- Based on available information, the classification criteria are not met
- Skin Corrosion Category 1

Classification Data - The Ugly Safety Data Sheet Gaps

SECTION 2 – HAZARDS IDENTIFICATION

This substance is not classified as hazardous in accordance with 29 CFR 1910.1200 (OSHA HCS)

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute toxicity

- Oral LD50 (rat): 250 mg/kg
- Dermal LD50 (rat): 1000 mg/kg
- Inhalation LC50 (rat): 15 mg/l

Classification Data - The Ugly Safety Data Sheet Gaps

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Chemical XYZ

CAS 20000-00-0

Classification: Skin sensitizer, H317

Concentration: 0.5%

SECTION 11 – TOXICOLOGICAL INFORMATION

- No data available
- Based on available information, the classification criteria are not met

SECTION 2 – HAZARDS IDENTIFICATION

This substance is not classified as hazardous in accordance with EC No 1272/2008 (CLP)

Classification Data - The Ugly Starting From Scratch

What do we do when we have a new R&D chemistry, or new CAS number, where we have no data on-hand for classifying? What if our supplier presents a new CAS number with no data available?



Classification Data - The Bad (Or Less Preferred) ECHA C&L Inventory

C&L Inventory

Inventory listings are a good source of classification decisions and can often indicate harmonization of a classification across notifiers, as well as provide direction for endpoints you should consider further. They often lack context as to how the classification was derived, and there is no guarantee of their accuracy.

How can we effectively use this tool?

1. Verification of a classification compiled from supplier or other data.
2. Guidance on classification endpoints that require further evaluation.
3. Used in the absence of no other data to make a sound classification decision

Classification Data - The Bad (Or Less Preferred) ECHA C&L Inventory

200-362-1	Caffeine	58-08-2
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Notified classification and labelling according to CLP criteria

Classification		Labelling			Specific Concentration limits, M-Factors	Notes	Classification affected by Impurities / Additives	Additional Notified Information	Number of Notifiers	Joint Entries	
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)							
Acute Tox. 4	H302	H302		GHS07 Wng				State/Form	2159		View details
Acute Tox. 4	H302	H302		GHS07 Wng				State/Form	23		View details
Acute Tox. 4	H332	H332									
Acute Tox. 3	H301	H301		GHS06 Dgr				State/Form	9		View details
Not Classified									2		

Classification Data - The Bad (Or Less Preferred) ECHA C&L Inventory

236-675-5	Titanium dioxide	13463-67-7
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Notified classification and labelling according to CLP criteria

Classification		Labelling			Specific Concentration limits, M-Factors	Notes	Classification affected by Impurities / Additives	Additional Notified Information	Number of Notifiers	Joint Entries	
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)							
Not Classified									6840	✓	
Carc. 2	H351 (inhalation)	H351 (by inhalation)		GHS08 Wng		Note W Note 10 Note V		State/Form	3396	✓	View details
Carc. 2	H351 (inhalation)	H351		GHS08 Wng				State/Form	268		View details

Classification Data - The Bad (Or Less Preferred) ECHA C&L Inventory

Note W



It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung.

Note 10



The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1 % or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter $\leq 10 \mu\text{m}$.

Note V



If the substance is to be placed on the market as fibres (with diameter $< 3 \mu\text{m}$, length $> 5 \mu\text{m}$ and aspect ratio $\geq 3:1$) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry, their hazardous properties must be evaluated in accordance with Title II of this Regulation, to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied.

Classification Data - The Bad (Or Less Preferred) ECHA C&L Inventory

Acute Tox. 4	H302	H302								
Acute Tox. 3	H311	H311								
Skin Irrit. 2	H315	H315								
Skin Sens. 1	H317	H317								
Eye Irrit. 2	H319	H319								
STOT RE 2	H373 (other:Intestina...)	H373 (May cause damag...)		GHS08 GHS09 GHS06 Dgr	M(Chronic)=1 M=1				87	View details
Aquatic Acute 1	H400	H400								
Aquatic Chronic 1	H410	H410								
Skin Irrit. 2	H315	H315								
Eye Irrit. 2	H319	H319								
STOT SE 3	H335 (other:respirato...)	H335		GHS07 Wng				State/Form	51	View details
Acute Tox. 4	H302	H302								
Skin Irrit. 2	H315	H315								
Eye Irrit. 2	H319	H319								
STOT SE 3	H335 (Not available)	H335								
STOT SE 3	H335 (other:Not avail...)	H335		GHS07 Wng					37	View details

Classification Data - The Bad (Or Less Preferred) Incomplete or Unreferenced Data

Registry of Toxic Effects of Chemical Substances (RTECS)

- RTECS is a US CDC repository for chemical info (physical/chemical properties, OELs) and contains an overview of tox endpoints, but is often lacking in context or substance.

Styrene	
RTECS #	CAS #
WL3675000	100-42-5; 79637-11-9 See: NMAM or OSHA Methods

Classification Data - The Bad (Or Less Preferred) Incomplete or Unreferenced Data

Skin and Eye Irritation and References

Route/Organism	Dose	Effect	Reference
eye /human	50 ppm	mild	ENTOX* -,105,2005
eye /rabbit	100 mg	severe	AJOPAA 29,1363,1946
eye /rabbit	100 mg/24H	moderate	85JCAE -,32,1986
skin /human	500 mg rinse		INMEAF 17,199,1948
skin /rabbit	500 mg open irritation test	mild	UCDS** 12/13/1963
skin /rabbit	100%	moderate	AMIHAB 14,387,1956

intraperitoneal/rat	lethal dose (50 percent kill): 898 mg/kg		ENVRAL 40,411,1986
intravenous/mouse	lethal dose (50 percent kill): 90 mg/kg		ARZNAD 19,617,1969



 Centers for Disease Control and Prevention

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Annex VI: Fact or Fiction?

Just kidding.....



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Classification Data – The Good Internal Testing Data

The best data can be generated specific to your preparation

- Know what you need and why. What question am I trying to answer?
- Be sure you understand the study you're placing.
- Communicate to internal stakeholders expectations for the results. What happens if the results are 'unfavorable' for the classification outcome preferred?
- **AUDIT** your CRO labs.

Classification Data – The Good Literature Sources

PubChem

- NIH chemical database with well summarized and sourced Tox data
- <https://pubchem.ncbi.nlm.nih.gov/>

eChem Portal

- OECD chemical database with a wide variety of chemical and toxicological information
- <https://www.echemportal.org/echemportal/>

EPA CompTox Chemicals Database

- Provides a variety of chemical data and information on both experimental and predicted values
- <https://comptox.epa.gov/dashboard/>

ToxPlanet

- Well sourced and reviewed database of toxicological and chemical hazard data (subscription required)
- <https://www.enhesa.com/sustainablechemistry/our-solutions/toxplanet/>

Classification Data – The Good Literature Sources

ECHA Registration Dossiers (alongside CLH reports and RAC opinions)

- <https://echa.europa.eu/information-on-chemicals>

Agency for Toxic Substances and Disease Registry (ASTDR)

- ASTDR tox profiles are comprehensive evaluations, summaries, and interpretation of toxicological and epidemiological information for listed chemicals.
- <https://www.atsdr.cdc.gov/toxprofiledocs/index.html>

EPA Integrated Risk Information System (IRIS) Assessments

- Specific chemicals reviewed contain weigh-of-evidence and full toxicological profiles
- <https://www.epa.gov/iris>

EPA Reregistration Eligibility Decision (RED) Assessments

- Pesticide registration dossiers, however they often contain thorough toxicology assessments
- <https://ordspub.epa.gov/ords/pesticides/f?p=chemicalsearch:1>

Classification Data – The Good Literature Sources

US EPA ECOTOX

- Compilation of aquatic and terrestrial toxicological data
- <https://cfpub.epa.gov/ecotox/>

OECD Screening Information Data Set (SIDS) Reports

- Database of well sourced and summarized chemical information and toxicological data.
- <https://hpvchemicals.oecd.org/ui/Default.aspx#Published> OECD Assessments

International Agency for Research on Cancer (IARC) Monographs

- Well researched profiles on not just carcinogen risks, but other tox and environmental fate endpoints
- <https://monographs.iarc.who.int/>

Classification Data – The Good Literature Sources

National Toxicology Program (NTP) Study Reports

- Toxicology and Carcinogenesis study reports
- <https://ntp.niehs.nih.gov/publications/reports>

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

- Summary evaluations of flavors, food additives, and contaminants. Often most useful for data related to food and personal care applications
- <https://apps.who.int/food-additives-contaminants-jecfa-database/>

Human and Environmental Risk Assessment (HERA) Reports

- Database of toxicological and risk assessments on cleaning product ingredient chemicals
- <https://www.heraproject.com/RiskAssessment.cfm>

Classification Data – The Good Literature Sources

Scientific Committee on Consumer Safety (SCCS)

- EC tox summaries and opinions on a variety of consumer-use chemicals
- https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs_en

Cosmetic Ingredient Review (CIR)

- Independent expert panel toxicology/human health review of cosmetic ingredients
- <https://www.cir-safety.org/>

In addition, your corporate librarian, or journal subscription services, are a valuable tool/resource when searching for classification data.

Classification Data – The Good Use of Human Data

- Human epidemiological or case study data can be a reliable source of information when classifying, however there are factors we must consider:
 - Are we evaluating a single case report in one individual vs. multiple individuals?
 - Is the data observational (case reports, health surveillance) or experimental (e.g., clinical trials)
 - Is the exposure being described relevant to the classification?
 - What population is being studied?
 - Industrial workers
 - Specific geographies or races, cultures
 - Are there potential comorbidities in the patients being cited in the report?
 - Are there proper protocols and/or controls in place?
 - Is the study group large enough for statistical conclusions to be made?

Classification Support

- If you have questions about your hazard classification data, or are in a situation with very little to no usable data, your, hazard classification SME, corporate Toxicologist or Toxicology consultant can assist with:
 - A review of the data available, including the use of tools such as Quantitative Structure-Activity Relationship (QSAR) modeling, to perform a weight-of-evidence determination.
 - Reviewing potential read-across chemicals to the substance in question
 - Placing the appropriate study to provide quality data.

Strengthening Our Classifications

How can we strengthen our classification decisions when evaluating our data?

1. Do not be afraid to ask questions of your suppliers and their classifications.
2. Where possible, use more than one source of information.
3. Use regulatory databases, credible industry publications, and peer-reviewed sources of information wherever possible.
4. Document, document, document and cite your decision

In the end, you are responsible for defending your process and decision, and ensuring your classification adequately warns and protects your downstream users.