



Science For A Better Life

Impact of REACh/GHS/TDG from a manufacturer's perspective

EAGOSH Meeting

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Agenda

- What does REACh mean for the chemical industry?
- Legal Background of GHS and TDG
- “Harmonization” of GHS and TDG
- Issues and Challenges: Examples
- Solutions



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What does REACh mean for the chemical industry?



Regulatory Framework (general overview)

Registration

REACH requires manufacturers and importers of chemical substances (larger than or equal to 1 tonne/year) to obtain information on the physicochemical, health and environmental properties of their substances and use it to determine how these substances can be used safely. Each manufacturer and importer must submit a registration dossier documenting the data and assessments to ECHA.

Evaluation

ECHA will perform dossier evaluation to assess testing proposals made by the registrant or to check that the registration dossiers comply with the requirements. ECHA will also co-ordinate substance evaluation, which will be conducted by the Member States to investigate more in depth chemicals of concern.

Source: CEFIC

What does REACh mean for the chemical industry?



Authorisation

Authorisation is required for the prioritised substances of very high concern (SVHC) that are included in Annex XIV. Companies applying for authorisation will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks. Applicants will also have to investigate the possibility of substituting these substances with safer alternatives or technologies, and prepare substitution plans, if appropriate.

Restrictions

The European Union can impose restrictions and prohibit or set conditions for the manufacture, placing on the market or use of certain dangerous substances or group of substances when unacceptable risks to humans or the environment have been identified.

Source: CEFIC



What does REACh mean for the chemical industry?

Classification and labelling inventory

A classification and labelling inventory will be developed from notifications submitted by industry on substances (including those below 1 tonne/year if classified as dangerous) and from information on classification and labelling included in registration dossiers.

Communication in the supply chain

Suppliers of substances must pass on information on the health, safety and environmental properties and safe use of their chemicals to their downstream users (via a Safety Data Sheet or other means). Downstream users may only use substances classified as dangerous if they apply risk management measures identified on the basis of exposure scenarios for their use.

- Safety data Sheets
- Labeling and packaging



Source: CEFIC



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Legal background of GHS



What is GHS? **UN-GHS** !

The **GHS (Globally Harmonized System of Classification, Labelling and Packaging of Chemicals)** is an internationally agreed-upon system created by the United Nations. It is designed to replace the various classification and labeling standards used in different countries by using consistent criteria for classification and labeling on a global level and to communicate by providing comprehensive information in Safety Data Sheets.

Globally equal classification criteria, hazard-pictograms, signal words and statements should reduce risks for human health and the environment when chemicals are produced, transported or in use.

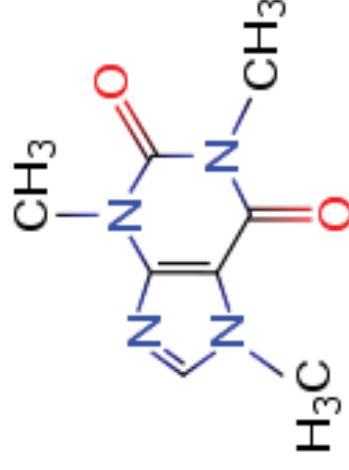


Legal background of GHS

Why do we need GHS?

Substance with LD50:

257mg/kg



GHS	Danger
EU	Hazardous
USA	Toxic
Canada	Toxic
Australia	Hazardous
India	Non toxic
Japan	Toxic
Malaysia	Hazardous
Thailand	Hazardous
New Zealand	Dangerous
China	Non dangerous
Korea	Toxic



Legal background of GHS

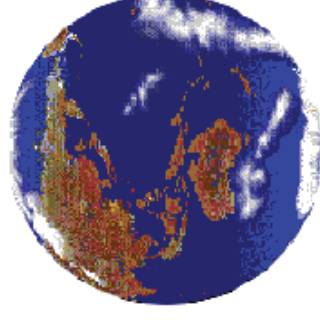
GHS consists of building blocks

Means: A complete harmonization of all affected areas is unlikely!
Even countries (or communities of states) have the choice to select parts of the system within a given frame.

Result: There is an “UN-GHS”, an EU-GHS”, an US-GHS” ...

- **Transport is UN-GHS oriented (global)**
- **Chemical Regulations in e.g. Germany are EU-GHS (=CLP) oriented**

THIS IS NO GLOBAL HARMONIZATION !





Legal background of GHS

Decision at the UN Conference in Rio de Janeiro 1992 to develop a global System for Classification and Labeling of Chemicals, except e.g. for

- radioactive und infectious substances
- articles, items
- pharmaceuticals, cosmetics

Coverage of

- Workplace and Consumer Safety
- Chemical Regulations (Supply&Use)
- Transport

➔ ***The exceptions cannot be applied for shipments***

Radioactiv: Class 7, Infectious: Class 6.2, Lithiumbatteries Class 9 , etc.





Legal background of GHS

Implementation of GHS into the Dangerous Goods Regulations:

- Global: 14. Revised Edition of the UN Model Regulations
- Land: ADR/RID in 2007 harmonized with UN
- Air: ICAO-TI in 2007/2008 harmonized with UN
- Sea: IMDG in 2008 harmonized with UN

→ **Implementation of GHS finalized for Transport !**

... reason to be happy?



Legal background of GHS

What is CLP? **EU-GHS!**



The new EU-Directive dealing with Classification, Labeling and Packaging of substances and mixtures (CLP, Regulation on Classification, Labelling and Packaging of Substances and Mixtures, (EG) Nr. 1272/2008, succeeds EU-Regulations RL 67/548/EWG and 1999/45/EG). To a large extent it is based on the recommendations of the United Nations, the GHS.

The objective of CLP is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and certain specific articles within the European Union. The global harmonisation of regulations for classification and labeling of substances and mixtures (UN-GHS) for marketing and use on the one hand and for transport on the other aims at protecting human life and the environment as well as simplifying world trade.

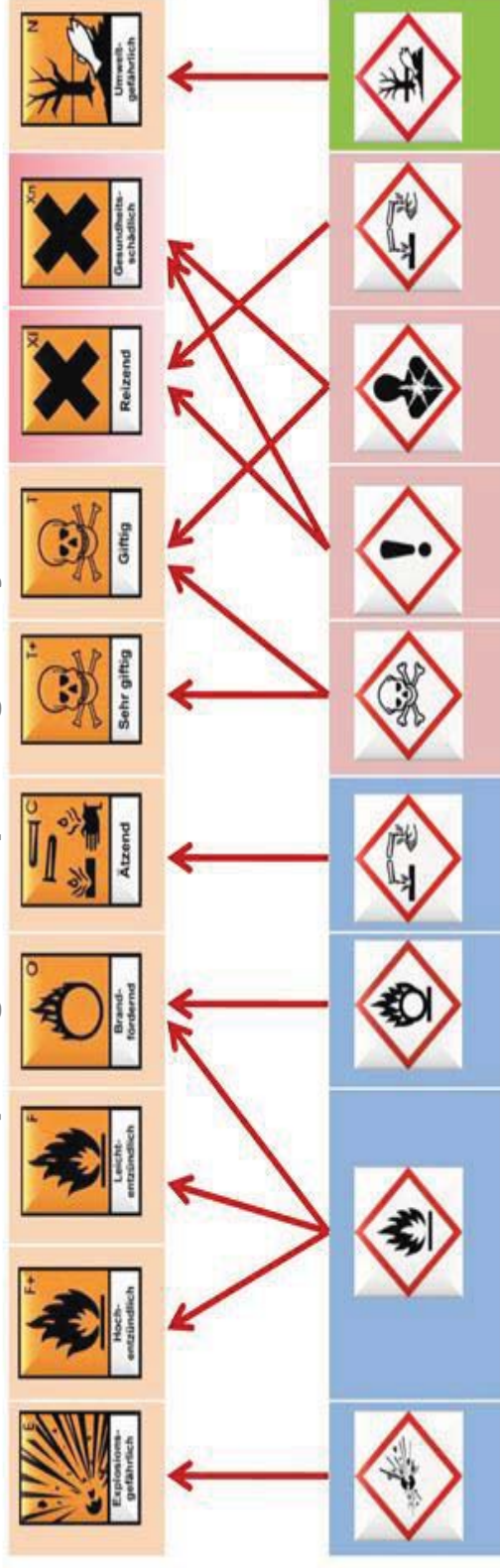
Source: BAUA



Legal background of GHS

GHS - Piktogramme ersetzen EU-Symbole

GHS pictograms replacing EU symbols



Für dieses neue Piktogramm besteht keine Entsprechung zu einem bisherigen Symbol.



Dieses Symbol entfällt. Es besteht keine direkte Entsprechung zu einem GHS Piktogramm.

For this pictogram there is no appropriate symbol in the former regulation.

This symbol is omitted.

There is no direct equivalent in GHS.

Source: BG



Legal background of TDG



What is TDG? **Transport of dangerous goods !**

Dangerous goods are solids, liquids, or gases that can harm people, other living organisms, property, or the environment. They are often subject to chemical regulations. Dangerous goods include materials that are e.g. radioactive, flammable, explosive, corrosive, oxidizing, biohazardous, toxic, pathogenic, etc. Also included are physical conditions such as compressed gases and liquids or hot materials, including all goods containing such materials or chemicals, or may have other characteristics that render them hazardous in specific circumstances during transport.

Dangerous Goods/HazMats are not equal to Hazardous Substances !
(Gefahrgut ≠ Gefahrstoff)



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“Harmonization” of GHS and TDG

1.1.3.1.2 For transport, it is expected that application of the GHS will be similar to application of current transport requirements. Containers of dangerous goods will be marked with pictograms that address acute toxicity, physical hazards, and environmental hazards. As is true for workers in other sectors, workers in the transport sector will be trained. The elements of the GHS that address such elements as signal words and hazard statements are not expected to be adopted in the transport sector.

Transport is generally incorporated in GHS (for phys.-chem. hazards), but UN Model Regulations, resp. mode-specific regulations apply.

FLAMMABLE GASES (INCLUDING CHEMICALLY UNSTABLE GASES)					Note
Flammable gases		Chemically unstable gases			
Category 1	Category 2	Category A	Category B		
	No pictogram	No additional pictogram	No additional pictogram	No additional pictogram	Under the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, the symbol, number and border line may be shown in black instead of white. The background colour stays red in both cases.
Danger Extremely flammable gas	Warning Flammable gas	No additional signal word May react explosively even in the absence of air	No additional signal word May react explosively even in the absence of air at elevated pressure and/or temperature		
					Not required under the UN Model Regulations

Source: E.Kessler



“Harmonization” of GHS and TDG

GHS/CLP = Supply&Use

- Information to employees, dealing with substances/mixtures on an daily basis
- Every day, all work lifetime, protection of workers (workplace safety)
- Information about all intrinsic hazards



not DG relevant

Transport

- Safe transport from A to B, limited period of shipment
- Determined transport conditions and packaging
- Contact with product only in case of incident (single occurrence), removal of spills by fire brigade/emergency responders or qualified personnel
 - ➔ Not all hazards have to be communicated (precedence of hazards)
 - ➔ Not all hazards of supply&use are relevant for transport (e.g. minor, reversible, chronic hazards)
 - ➔ Transport has focus on physical hazards

Source: E.Kessler



“Harmonization” of GHS and TDG

Comparison of official lists (Supply&Use vs. Transport) has shown:

- about 990 substances are listed with identical classifications
- about 340 substances are listed with different classifications



Who alignes to the other?

Is harmonisation the right way forward?

Do we need differences due to different safety objective?

Many countries apply list principle for substances:

South Korea 910 entries, Thailand 1500, Japan 2000, China 3000 etc

Most countries have decided for an implementation of GHS in waves (schedule not aligned)...

source:FCIO



“Harmonization” of GHS and TDG

<u>Substance</u>	<u>CAS-Number</u>	CLP Regulation 1272/2008	UN Model Regulations
<u>Acetic acid...%</u>	64-19-7	Flam. Liq. 3 > 90% Skin Corr. 1A 25 – 90% Skin Corr 1B 10 – 25% Skin Corr 2	> 80% 8+3, VG II 50 – 80% 8, VG II 10 – 50% 8, VG III

b. Translation of classifications using Annex VII of the CLP regulation

For the translation of the classification for the CLP regulation of substances or mixtures corrosive to the skin, a worst case approach has been selected:

EU directive 67/548/EC	CLP-regulation 1272/2008
C, R35	1A
C, R34	1B

This means that there is no classification into subcategory 1C in the Annex VI of the CLP regulation. If

Source: CEFIC

“Harmonization” of GHS and TDG



Benzin Gemisch verschiedener Stoffe

Gefahr

Gefahrenhinweise:
H225 Flüssig und Dampf leicht entzündlich.
H304 Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein.
H315 Verursacht Hautreizungen.
H336 Kann Schläfrigkeit und Benommenheit verursachen.
H411 Giftig für Wasserorganismen, mit langfristiger Wirkung.

Sicherheitshinweise:
P210 Von Hitze/Funkenspritzern/Faunen/heißen Oberflächen fernhalten. Nicht rauchen.
P233 Behälter dicht verschlossen halten.
P273 Freisetzung in die Umwelt vermeiden.
P280 Schutzhandschuhe/Schutzkleidung/Augenschutz/Geschütztat tragen.
P301+P310 Bei Verschlucken: Sofort ärztlichen Rat einholen. Von Erbrochenem nichts essen.
P310 Sofort GIFTGEMISCHTENSITZUM oder AIZ einholen.

Ottokraftstoff enthält: Benzin, Benzolgehalt 0,1 - 1%.

Hochentzündlich **Giftig** **Umweltgefährlich**

Hinweise auf besondere Gefahren: Kann Krebs erzeugen. Reizt die Haut. Auch gesundheitsschädlich: Gefahr ernster Gesundheitsschäden bei längerer Exposition durch Einatmen, Berührung mit der Haut und durch Verschlucken. Kann beim Verschlucken Lungenschäden verursachen. Giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkung haben.

Sicherheitsratschläge: Exposition vermeiden. Darf nicht in die Hände von Kindern gelangen. Dampf nicht einatmen. Berührung mit der Haut vermeiden. Nicht in die Kanalisation gelangen lassen. Bei Verschlucken kein Erbrechen herbeiführen. Sofort ärztlichen Rat einholen. Von Erbrochenem nichts essen. Bei Unfall oder Unwohlsein sofort Arzt hinzuziehen. Freisetzung in die Umwelt vermeiden.

UN - 1203 **Benzin**

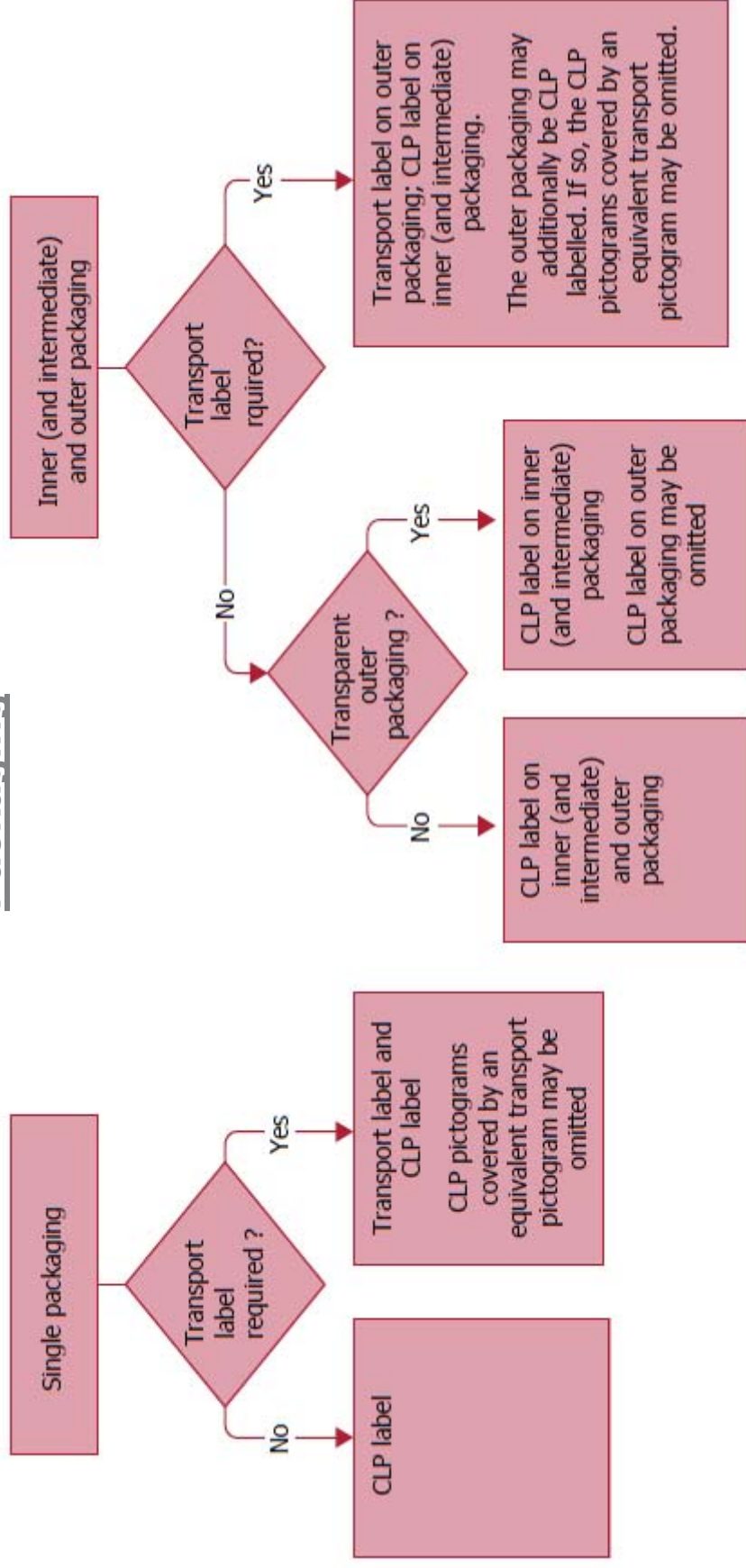


33
1203



“Harmonization” of GHS and TDG

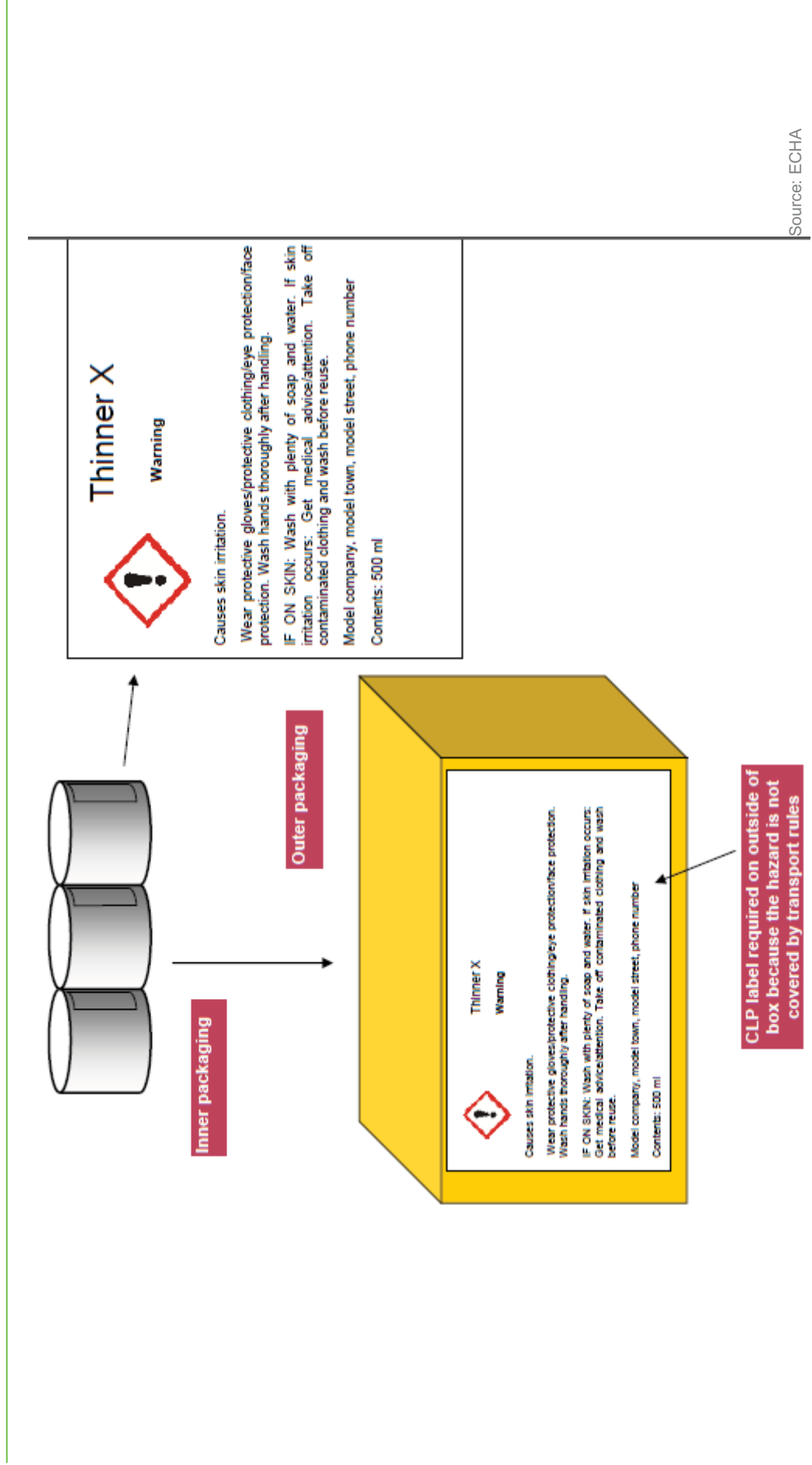
Packaging



Source: ECHA



“Harmonization” of GHS and TDG





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Issues and Challenges: Example Phenols

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

1.1 Product identifiers

Product name : Phenol

Product Number : W322318

Brand : Aldrich

Index-No. : 604-001-00-2

REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

CAS-No. : 108-95-2

Classification according to EU Directives 67/548/EEC or 1999/45/EC

R68

R23/24/25

R34

R48/20/21/22

T Toxic
C Corrosive
Xn Harmful



Pictogram

Signal word **Danger**

Hazard statement(s)

H301

H311

H314

H331

H341

H373

Toxic if swallowed.

Toxic in contact with skin.

Causes severe skin burns and eye damage.

Toxic if inhaled.

Suspected of causing genetic defects.

May cause damage to organs through prolonged or repeated exposure.

Source: Aldrich



Issues and Challenges: Example Phenols

SECTION 14: Transport information

14.1 UN number ADR/RID: 1671	IMDG: 1671	IATA: 1671
14.2 UN proper shipping name ADR/RID: PHENOL, SOLID IMDG: PHENOL, SOLID IATA: Phenol, solid		
14.3 Transport hazard class(es) ADR/RID: 6.1	IMDG: 6.1	IATA: 6.1
14.4 Packaging group ADR/RID: II	IMDG: II	IATA: II
14.5 Environmental hazards ADR/RID: no	IMDG Marine pollutant: no	IATA: no
14.6 Special precautions for user no data available		

Source: Aldrich



Issues and Challenges: Example Alcojet

2 Hazards identification

- 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS05 corrosion

Eye Dam. 1 ; H318: Causes serious eye damage.



GHS07

Skin Irrit. 2 ; H315 : Causes skin irritation.

STOT SE 3; H335: May cause respiratory irritation.

Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.

Hazard description:

WHMIS-symbols:

D2B - Toxic material causing other toxic effects

E - Corrosive material



NFPA ratings (scale 0 - 4)



Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Xn; Harmful

R22: Harmful if swallowed.

Xi; Irritant

R38-41: Irritating to skin. Risk of serious damage to eyes.



Source: Alcojet



Issues and Challenges: Example Alcojet

14 Transport information	
<ul style="list-style-type: none"> 14.1 UN-Number DOT, ADR, ADN, IMDG, IATA, ICAO 	Not Regulated
<ul style="list-style-type: none"> 14.2 UN proper shipping name DOT, ADR, ADN, IMDG, IATA, ICAO 	Not Regulated
<ul style="list-style-type: none"> 14.3 Transport hazard class(es) DOT, ADR, IMDG, IATA, ICAO Class Label ADN/R Class: 	Not Regulated Not Regulated Not Regulated
<ul style="list-style-type: none"> 14.4 Packing group DOT, ADR, IMDG, IATA, ICAO 	Not Regulated
<ul style="list-style-type: none"> 14.5 Environmental hazards: Marine pollutant: 	No
<ul style="list-style-type: none"> 14.6 Special precautions for user Danger code (Kemler): EMS Number: Segregation groups 	Not applicable. Not applicable. Not applicable. Acids
<ul style="list-style-type: none"> 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 	Not applicable.

· Transport/Additional information:

- ADR
- Tunnel restriction code
- UN "Model Regulation":

Not applicable.
Not Regulated



Source: Alcojet



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Solutions



Transportation Safety and Chemical Regulation

the e-learning Trainings of Bayer CropScience





Solutions

Draft IATA 56th, circulated by CEFIC

Should also be incorporated
in the DGR Training Books !

SECTION 9

9.1.7 Consumer Product Warnings

An article or package may bear a warning symbol or consumer hazard labelling. The article or substance contained in the package may not necessarily meet the criteria for air transport classification shown in Section 3. Clarification may be obtained from the shipper, if required, before accepting the package as "Not Restricted".

9.1.7.1 one of the consumer hazard labelling systems is the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which is a system that defines and classifies the hazards of chemical products for supply and use, and communicates health and safety information on labels. This system needs to be implemented in the countries / regions and therefore may show different symbols / texts for the same product, if labelled for different countries. There are nine (9) GHS pictograms which could appear on single packagings or on outer packagings of combination packagings.

Note:

Diamond-shaped GHS pictograms on packages indicate the presence of substances that pose a hazard for supply and use. Based on classification criteria specific for transport these substances may also be classified as dangerous goods which is indicated by additional hazard labels. Although the related classification criteria may be different, some of the GHS pictograms contain symbols that are largely equivalent to the symbols contained in the hazard labels used in transport. For more information, see Appendix B, Table B.4.A and http://www.unece.org/trans/danger/publi/ghs/welcome_e.html.

Source: CEFIC



Flexible solution...



Source: private



Science For A Better Life

Thank you!