

**EUROPEAN
RESIN
MANUFACTURERS
ASSOCIATION**

**ERMA SEMINAR
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GHS

Global Harmonisation System

IMPACT ON RESIN PRODUCERS PRODUCTS

Presentation developed by the ERMA Technical Committee

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Conclusion

GHS : Globally Harmonized System

1. Is a new WW system for :

- ❑ Classification and labelling of :

Chemical substances and mixtures

- ❑ Information exchange :

- ◆ based on intrinsic properties
- ◆ starting from existing systems
- ◆ ensuring the level of protection

2. GHS CRITERIA COULD REPLACE ALL EXISTING EU, C&L REGULATIONS & DIRECTIVES

Conclusion

GHS IMPLEMENTATION IMPACT ON ERMA MEMBER PRODUCTS

**Could be changes to the
Classification & Labelling of “
Substances and Mixtures* ”**

* Mixture: means a mixture or a solution composed of two or more substances **in which they do not react**

Key Guiding Principles

- Protection level will not be reduced
- Will be based on intrinsic properties (hazards) of chemicals
- All types of chemicals will be covered
- All systems will have to be changed
- Involvement of all stakeholders should be ensured
- Comprehensibility must be addressed

Key Guiding Principles- Definitions

- Classification (C)

Assignment to a chemical of both a:

- Hazard Class (nature of hazard) and a
- Hazard Category (degree of hazard)

- Labelling (L)

Hazard communication via:

- Label (package)
- Safety Data Sheet

GHS Implementation Impact on ERMA Member Products

Impacts- Physical Hazards

- Most important changes compared to the EU are different limits for the **flash-point**

Haz. Cat.	Criteria	Label elements	
1	FP<23°C BP≤35°C	Symbol : Signal Word: Hazard Statement :	Flame Danger Extremely flammable liquid and vapour
2	FP<23°C BP>35°C	Symbol: Signal Word: Hazard Statement:	Flame Danger Highly flammable liquid and vapour
3	FP≥23°C FP≤60°C	Symbol: Signal Word: Hazard Statement:	Flame Warning Flammable liquid and vapour
4	FP<60°C FP≤93°C	Symbol: Signal Word: Hazard Statement:	None Warning Combustible liquid

Impacts - Health Hazards

- Acute toxicity
 - oral/dermal/inhalation
- Corrosion/Irritation
 - On skin and eye
- Sensitisation
 - Skin/respiratory organs
- Mutagenicity
- Carcinogenicity
- Reproductive toxicity
- Target organ and systemic toxicity (TOST)

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Comparison GHS – EU Acute Toxicity (oral)

GHS

EU

Category	Dose [mg/kg]
1	≤ 5
2	> 5 to ≤ 50
3	> 50 to ≤ 300
4	> 300 to ≤ 2000
5	> 2000 to ≤ 5000

	Dose [mg/kg]
danger	
very toxic	≤ 25
toxic	> 25 bis ≤ 200
harmful	> 200 bis ≤ 2000

Missing

Impacts – Environmental Hazards

- ❑ Acute Toxicity
- ❑ Chronic Toxicity
- ❑ Biological degradation

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Impacts for “substances and mixtures”

In relation to

- Physical hazards
- Health hazards
- Environmental hazards

Provisions for

- Transport
- Worker protection
- Consumer protection

No provisions for :

- articles
- waste

Impacts for “substances and mixtures”

- Classification of substances
- Classification of mixtures
- WW applicable system for :
 - ❖ Safety data sheets
 - ❖ Labelling

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Impacts for “substances and mixtures”

- **No risk consideration :**

- >> determination of the danger based on intrinsic properties

- **No obligation to run tests :**

- >> existing data only were used for classification (?)

- **Focus on :**

- >> Worker & end users protection

- **Classification to serve for hazard communication :**

- >> Downstream applications

- **Application methodology :**

- >> “Building Block”

Mixture Classification

Definition:

- ❑ **Mixture** means a mixture or a solution composed of two or more substances **in which they do not react**;
- ❑ **cut-off values/concentration limits**
 - ❖ In general 1 %, except
 - that at lower concentrations than the harmonized cut-off value/concentration limit that still pose an identifiable hazard or
 - that harmonized cut-off value/concentration limit is considerably lower than could be expected on the basis of an established non-hazardous level for an ingredient.
 - ❖ In these cases the mixture could be classified according to the existing hazards.

Acute Toxicity Classification Criteria

Acute toxicity (ATE)	Cat.1	Cat. 2	Cat. 3	Cat. 4	Cat. 5
Oral (mg/kg)	5	50	300	2000	5000
Dermal (mg/kg)	50	200	1000	2000	Equivalent doses for dermal and inhalation ATE = Acute Toxicity Estimate (e.g. LD ₅₀ or LC ₅₀ = Median Lethal Dose /Concentration)
Gases (ppm)	100	500	2500	5000	
Vapours (mg/l)	0.5	2	10	20	
Dusts and mists (mg/l)	0.05	0.5	1	5	

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Classification of Mixtures Hierarchy

- Test results (like substances)
- Bridging rules
- Hazard determination based on known information on ingredients
- Each route of application will be considered separately

$$\frac{100}{ATE_{mix}} = \sum_{\eta} \frac{C_i}{ATE_i}$$

- C_i = concentration of ingredient 'i'
 - η = Index of ingredients of 1 to η
 - $ATE_i = (LD_{50})$ –value of ingredient 'i'
 - $ATE_{mix} = LD_{50}$ –value of the mixture
- ATE = Acute Toxicity Estimate

Classification of Mixture Missing Information on Ingredients

$$\frac{100 - (C_{unknown})}{ATE_{mix}} = \sum_{\eta} \frac{C_i}{ATE_i}$$

$C_{unknown} > 10\%$ resulting a classification reduced to the part of the mixture with available information.

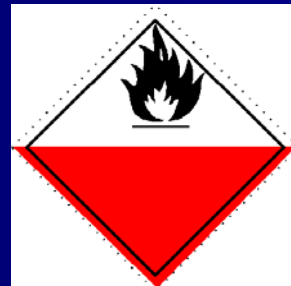
No dilution of the hazardous components by ingredients for which no information is available, e.g. polymers

Labelling

- ❑ Symbols (standardized)
- ❑ Signal words (standardized)
 - ❖ Danger
 - ❖ Warning
- ❑ Hazard Statements (standardized)
- ❑ Precautionary Statements
- ❑ Product Name
- ❑ Hazardous substance name
 - ❖ Confidentiality of substance names
 - National provisions have preference compared to requirements for disclosure

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Applicable Transport Symbols



GHS Implementation Impact on ERMA Member Products

GHS Symbols



Safety Data Sheet

16 mandatory sections

- Like EU safety data sheet, but section 2 and 3 are exchanged
- Guideline for preparation of safety data sheets has been completed :

“like annex to the EU safety data sheet directive”

GHS Implementation Impact on ERMA Member Products

GHS Issues on existing ER Regulations : Conflicts with REACH

- ❑ REACH does not & probably would not include the C&L, but refers to :
 - ✓ Substance classification (Dir. 67/548/EEC)
 - ✓ Preparation classification (Dir. 1999/45/EC)
 - ✓ Safety Data Sheets (REACH Annex I a)

- ❑ REACH would not include GHS, but it will be linked
 - ✓ Registration information (CSR,...)
 - ✓ Information in supply chain (SDS, ..)
 - ✓ Authorisation (CMR substances, ..)

- ❑ GHS Application target at EU :
 - ✓ Same time as Reach
 - ✓ Equivalent processes (CSR,...)
 - ✓ 1st substances then mixtures
 - ✓ Living document (update 1x/ 2 years)

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GHS Issues on existing ER Regulations :

□ VOC (Dir. 1999/13/EC & 2004/42/EC)

Impacts :

- ✓ Scope effect : lower cut-off concentration for mixture with reprotox substances
- ✓ Additional labelling : **Reproductive tox, Hazard, Aquatic Env.**
NO SPECIFIC ACTION NEEDED

**Hazard
& Risk
based**

□ Eco-label (Dir. 67/548/EEC & related EC 1980/2000)

Impacts :

- ✓ Scope effect (acute toxicity, TOST, skin irritation, ...)
- ✓ Additional labelling : **Reproductive tox, Hazard, Aquatic Env.**
- ✓ NEED TO CHECK THE PRODUCT INDIVIDUALLY

**Hazard
based**

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GHS Issues on existing ER Regulations :

❑ **Cosmetics (Specific application : Dir. 1976/768/EC & 67/548/EEC)**

Impacts :

- ✓ **Scope effect “ GHS will Classify CRMs substances as doing by Cosmetic directives ?? ”**

NEED TIME TO SEE THE HARMONISATION

**Hazard
& Risk
based**

❑ **SEVESO II (Dir. 1996/82/EC & 67/548/EC)**

Impacts :

- ✓ **Scope effect : Mixture**
- ✓ **More classified substances and mixtures may trigger the lower or upper tier requirements**
- ✓ **Volume provision will be reinforced**

NEED TO CHECK SUBSTANCES & MIXTURES INDIVIDUALLY

**Hazard
based**

GHS Implementation Impact on ERMA Member Products

GHS by Examples:

Exp : phenol modified resin

Composition	%	EU C & A
Rosin	80	Xi, R43
Bisphenol A	2	Xn, R37- 41- 43- 62
Formaldehyde	2	T, R23/24/25 - 34- 40- 43
Penta	12	
4-tert.-Octylphenol	4	C, N, R34 – 50/53

Final Product C&L:

Phenol modified resin CAS : 91081-52-6	100	No labelling
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GHS by Examples:

Example of Printing Ink

Composition		content (%)	EU-Classification	
			Symbol	R-phrases
Pigments				
	Pigment (Amine based)	15	Xi	41-52/53
Binders				
	Ca-Zn-resinate	20	-	-
	phenol modified resin	5	-	-
Solvent				
	Toluene	60	F, Xn	11-38-48/20-63-65-67
Yellow Ink :			F,Xn	11,38,41,48/20,63,65,67

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EU & GHS Symbols comparison

Yellow ink		
EU-Label	GHS-Label	Transport
 <p>R 11 Highly flammable. R 38 Irritating to skin. R 41 Risk of serious damage to eyes. R 48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation. R 63 Possible risk of harm to the unborn child. R 65 Harmful: may cause lung damage if swallowed. R 67 Vapours may cause drowsiness and dizziness.</p>	<p>FlamCat 2, ReproCat 2, EyeIrritantCat 1, SkinIrritantCat 2, AspirationCat 1, TargetOrganSingleCat 3, EnvCatChronic 3,</p>  <p>Danger H 114: Highly flammable liquid and vapour. H 117: Causes serious eye damage. H 201: May be fatal if swallowed and enters airways. Warning H 227: Suspected of damaging the unborn child. H 215: Causes skin irritation. H 234: May cause drowsiness or dizziness. H 305: Harmful to aquatic life with long lasting effects</p>	 <p>UN 1294</p>

ERMA Position = CEFIC Position

- **MEMBERS ADVISED TO PREPARE GHS IMPLEMENTATION:**
 - ❖ Start reclassification evaluation,
 - ❖ Check GHS application/ implementation,
 - ❖ Make GHS available with EU C&L for all products,
 - ❖ Make GHS classification available in Section 16 of Safety Data Sheets
 - ❖ Provide feedbacks to CEFIC

- **GHS WILL TO BE IMPLEMENTED IN 2 PHASES:**
 1. Reclassification of all substances according to GHS, at the same time as registration under REACH.
 2. Reclassification of mixtures in accordance to GHS.

GHS Implementation Impact on ERMA Member Products

REFERENCE :

- ❑ **UN : GLOBALY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS) :**
 - 2003 NY & Geneva
- ❑ **EUROPEAN COMMISSION NOTIFICATION :**
 - 25/05/2004, To : EU Chemicals Associations
- ❑ **EU MS Co-ordination Meeting on GHS :**
 - 14/06/ 2005 Helsinki
- ❑ **EUROPEAN COMMISSION STAKEHOLDERS MEETING :**
 - 18/11/2005 ISPRA
- ❑ **CEFIC “ REACH AWARENESS WORKSHOP ” :**
 - 18/01/2006 CEFIC
- ❑ **OTHER :**
 - ✓ CEFIC communication & Recommendation
 - ✓ Dangerous Substance Dir.(67/548/EEC)
 - ✓ Dangerous Preparation Dir.(1999/45/EC)
 - ✓ CEPE
 - ✓ ERMA
 - ✓ Others

Address for Information update

- Purple Book

http://www.unece.org/trans/danger/publi/ghs/ghs_rev00/00files_e.html

- Mandate of the sub committees to ECOSOC

<http://www.unece.org/trans/danger/publi/ghs/mandate.html>

- Symbols

<http://www.unece.org/trans/danger/publi/ghs/pictograms.html>

- Ongoing Activities

<http://www.unece.org/trans/main/dqdb/dgsubc4/activities.html>

CEFIC :

<http://www.cefic.org>