

Control Banding Workshop

EU Classification and Labeling and Control Banding

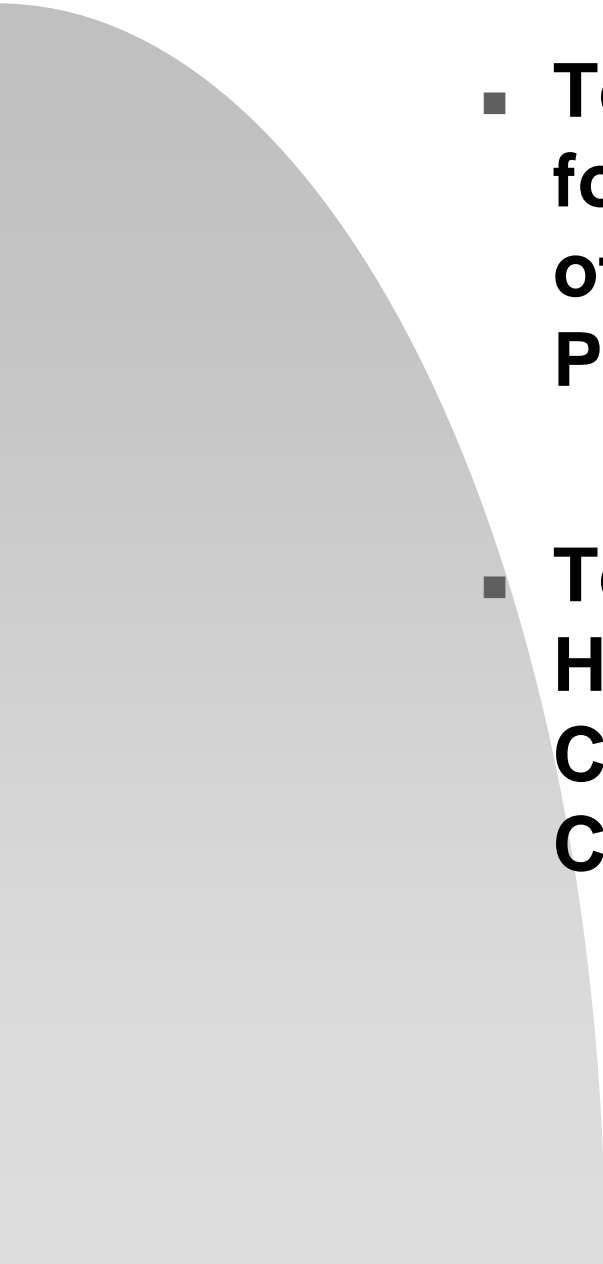
Presented by: Denese A. Deeds, CIH

Industrial Health & Safety Consultants, Inc.

Woodbridge, CT

Why do I need to know about this EU System?

- Control Banding requires a standardized means to identify health hazards that:
 - ◆ Identifies the hazard in a simple manner
 - ◆ Differentiates degree of hazard
 - ◆ Can be applied consistently by different manufacturers of the same chemical
 - ◆ Is available in the workplace

- 
- **Today we can use the EU System for the Classification and Labeling of Dangerous Substances and Preparations**
 - **Tomorrow GHS – the Globally Harmonized System of Classification and Labeling of Chemicals**

Classification

System for evaluating the hazards presented by chemicals and assigning standardized risk phrases.

Based on chemical properties and inherent toxicity.

EU Classification/Labeling Dangerous Substances

- Amended 8 times, major rewrite 92/32/EC (<http://ecb.jrc.it/legislation/>)
- Includes
 - ◆ Definitions
 - ◆ Test Protocols
 - ◆ Classification
 - ◆ Notification of New Chemicals
 - ◆ General Packaging
 - ◆ Labelling
 - ◆ Safety Data Sheets

EU Classification/Labeling Dangerous Substances

- Annex I - Classification of Substances
- Annex II - Symbols / Indications of Danger
- Annex III - Risk Phrases
- Annex IV - Safety Phrases
- Annex V - Test Procedures

EU Classification/Labeling Dangerous Substances

- Annex VI - Classification and Labelling (Substances and Preparations)
- Annex VII and VIII - New Substance Notification
- Annex IX - Child Resistant and Tactile Warnings

EU Classification/Labeling Dangerous Substances

- Annex I Classifies Listed Substances
- If the substance does not appear in Annex I the supplier provisionally classifies based on properties and criteria in Annex VI
- Concentration tables in Annex 1 are used for classification of preparations

Concentration Limits

Specific Concentration Limits

- ◆ Ex: lead alkyls, methanol

■ Default concentration Limits

- ◆ Depends on classification (hazard and category)

- ◆ Examples

- ☞ Harmful 25%, Irritant 20%

- ☞ Toxic (3%-Harmful, 25% Toxic)

- ☞ Very Toxic (0.1% Harmful, 1% Toxic, 7% Very Toxic)

- ☞ Carcinogenic Category 1 and 2 0.1%, Category 3 1%

Important Considerations

- Salts - both hydrates and anhydrous unless specifically noted
- Group entries are based on highest hazard member - if “except those specified elsewhere...” means some members are specifically listed.
- Some substances can be in more than 1 group (lead oxalate) - use most severe classification and all R phrases
- Classification includes the indication of danger (T+, F) and the risk phrases (R25, R45)
- Some classifications have no symbol (R10, R52, R52)

Notes (General Explanatory Notes)

- Found in the Forward to Annex I
- Lettered Notes cover group entries, inclusion of specific concentrations, isomers, stabilizers, qualification of certain hazards
- Notes J, L, N provide details for eliminating carcinogen classification for mineral oils and distillates
- Numbered Notes provide clarification

General Information

Index number	Note (alphabetic)	Note (numeric)
649-465-00-7	HL	

ATP inserted	ATP updated
21	

Substances					EN
Sub	EC No	Cas No	Other Cas No	Name	Type
1	265-155-0	64742-52-5		Distillates (petroleum), hydrotreated heavy naphthenic Baseoil - unspecified [A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C ₂₀ through C ₅₀ and produces a finished oil of at least 100 SUS at 1000F (19cSt at 400C). It contains relatively few normal paraffins.]	

Classification	Risk phrases	Safety phrases	Indication(s) of danger
Carc. Cat. 2; R45	45	53 - 45	T

Symbol(s)


Note L

- The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3% DMSO extract as measured by IP 346

General Information

Index number	Note (alphabetic)	Note (numeric)
649-345-00-4	HP	4

ATP inserted	ATP updated
21	22

Substances						EN
Sub	EC No	Cas No	Other Cas No	Name		Type
1	232-489-3	8052-41-3		Stoddard solvent Low boiling point naphtha - unspecified [A colourless, refined petroleum distillate that is free from rancid or objectionable odors and that boils in a range of approximately 3000F to 4000F.]		

Classification	Risk phrases	Safety phrases	Indication(s) of danger
Carc. Cat. 2; R45 Xn; R65	45 - 65	53 - 45	T

Symbol(s)


Note P

- The classification need not apply if it can be shown that the substance contains less than 0.1% w/w benzene.

EU Classification Criteria - Acute Toxicity

	Very Toxic	Toxic	Harmful
Oral LD50 (mg/kg)	≤25	>25 - ≤200	>200 - ≤2,000
Dermal LD50 (mg/kg)	≤50	>50 - ≤400	>400 - ≤2,000
Inhalation LC50 Gases, Vapors (mg/L)	≤0.5	>0.5 - ≤2	>2 - ≤20
Inhalation LC50 aerosols, particulates (mg/l)	≤0.25	>0.25 - ≤1	>1 - ≤5
EU Indication of Danger (symbol)	Very Toxic (T+)	Toxic (T)	Harmful (Xn)
R Phrase (oral)	R28 Very toxic if swallowed	R25 Toxic if swallowed	R22 Harmful if swallowed
R Phrase (dermal)	R27 Very toxic in contact with skin	R24 Toxic in contact with skin	R21 Harmful in contact with skin
R Phrase (inhalation)	R26 Very toxic by inhalation	R23 Toxic by inhalation	R20 Harmful by inhalation
Mixture concentration limits	≥7% T+ substances	≥1% - <7% T+ Substances or ≥25% T Substances	≥0.1% - 1% T+ Substances, ≥3% - 25% T Substances or ≥25% Xn Substances

EU Classification Criteria - Skin Corrosion/Irritation

Hazard	Criteria	Indication of Danger (symbol)	R Phrases
Corrosive	Destruction of full thickness of skin in up to <u>three minutes</u> exposure or pH ≤ 2 and ≥ 11.5 (if no testing and sufficient acid/alkali reserve). For mixtures, $\geq 10\%$ R35 substances.	Corrosive (C)	R35 Causes severe burns
Corrosive	Destruction of full thickness of skin in up to four hours exposure, organic hydroperoxides. Mixtures with $\geq 5\%$ - $< 10\%$ R35 substances, $\geq 10\%$ R34 substances	Corrosive (C)	R34 Causes burns
Irritant	(1) Mean value of ≥ 2 for erythema/eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours, or Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling, or Human experience that the substance is an irritant Mixtures with $\geq 1\%$ but $< 5\%$ R35 substances, $\geq 5\%$ but $< 10\%$ R34 substances or $\geq 20\%$ R36/37/38 substances	Irritant (Xi)	R38 Irritating to skin

EU Classification of Chemicals

- Substances:
 - ◆ Annex 1 (of the Substance Directive)
67/548/EEC
 - ◆ Self-Classification based on criteria in the Directive
- Preparations:
 - ◆ Data on Mixture based in criteria above
 - ◆ Calculation Method (Conventional Method)
1999/45/EC

EU Preparations Classification

- Physical Hazards - based on preparation properties
- Health and Environmental Hazards - test the preparation (unnecessary animal testing is banned) or calculation method - testing data takes precedence
- Conventional method must be used for CMR - no testing permitted

Conventional Method

- Need classification (Category and R Phrase), percentage and concentration limit for each category of hazard (specific from Annex 1 or default)
- Single Dangerous Substance with non-hazardous - use substance classification and concentration limits
- Components below certain limits need not be considered - different for gases and liquids/solids - See Preparations Directive Article 3 (0.1% (T+, T. CMR 1&2), Others 1%)
- Certain chemicals have lower thresholds - Annex 1 and Prep Direct. Annex II (Gases lower)

Complex Mixtures (Additive)

- Very Toxic
 - ◆ $\text{Sum } (P_A/L_{A(T+)} + P_B/L_{B(T+)}) > 1$
 - ☞ P_A and P_B conc each T+ substance
 - ☞ L concentration limit for each T+ substance
 - ◆ Toxic
 - ◆ $\text{Sum } (P_A/L_{A(T+)} + P_C/L_{C(T)} + P_D/L_{D(T)}) > 1$
 - ☞ P_A conc T+ substances , P_C and P_D conc each T substance
 - ☞ L concentration limit for each T+ or T substance

Complex Mixtures (Additive)

- Harmful

- ◆ $\text{Sum} (P_A/L_{A(T+)} + P_B/L_{B(T)} + P_C/L_{C(Xn)} + P_D/L_{D(Xn)}) > 1$

- ☞ P_A conc each T+ substance

- ☞ P_B conc each T substance

- ☞ P_C and P_D conc each Xn substance

- ☞ L concentration limit for each T+, T or Xn substance

Usage of Additive Method

- Acute Toxicity
 - ◆ T+, R26,R27, R28 (routes combined)
 - ◆ T, R23, R24, R25 (routes combined)
 - ◆ Xn, R20, R21, R22 (routes combined)
 - ◆ C, R34, R35
 - ◆ Xi, R41, R38, R36, R37
 - ◆ Environmental - R50, R51, R52
 - ◆ Not used for CMR or TOST or Sensitizing

EU Classifications

- Health Hazards

- ◆ Acute Lethality

- ☞ T+ (R26, 27, 28)

- ☞ T (R23, 24, 25)

- ☞ Xn (R20, 21, 22)

- ◆ Irreversible, non-lethal effects

- ☞ T+ or T (R39)

- ◆ Serious Chronic Effects

- ☞ T or Xn (R48)

- ☞ Xn (R68)



EU Classifications

- Health Hazards

- ◆ Carcinogenic

- ☞ T (R45, 49) Cat 1 and 2
 - ☞ Xn (R40) Cat 3

- ◆ Mutagenic

- ☞ T (R46) Cat 1 and 2
 - ☞ Xn (R68) Cat 3

- ◆ Toxic to Reproduction

- ☞ T (R60, 61) Cat 1 and 2
 - ☞ Xn (R62,62) Cat 3



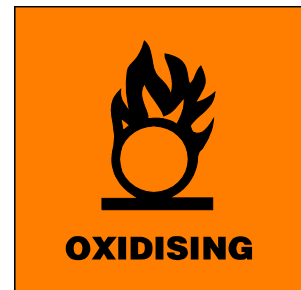
EU Classifications

- Health Hazards
 - ◆ Corrosive
 - ☞ C (R34, 35)
 - ◆ Irritant
 - ☞ Xi (R36,37,38,41)
 - ◆ Sensitizer
 - ☞ Xn (R42 inhalation)
 - ☞ Xi (R43 skin)
 - ◆ Aspiration Hazard
 - ☞ Xn (R65)



EU Classifications

- Physical Hazards
 - ◆ Explosive (R2, R3)
 - ◆ Oxidizer (R8, R9, R7)
 - ◆ Extremely Flammable (R12)
 - ◆ Highly Flammable
 - ◆ R11, R15, R17)
 - ◆ Flammable (R10) No Symbol



EU Classifications

- Environmental Hazards

- ◆ Aquatic Toxicity

- ◆ Persistence

- ☞ R50, R51, R53

- ☞ R52 (Harmful - No Symbol)

- ◆ Non-Aquatic Toxicity

- ☞ R54 through 59 - Symbol



Where can I find R Phrases?

EU Chemicals Bureau

<http://ecb.jrc.it/classification-labelling/>

Australian Hazardous Substances
Website

<http://www.nohsc.gov.au/applications/hsis/searchhs.aspx>

Assessment of Chemicals

- [Biocides](#)
- [Existing Chemicals](#)
- [Export-Import](#)
- [New Chemicals](#)

QSARs

REACH

- [Classification & Labelling](#)
- [Testing Methods](#)

REACH.IT & Informatics


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Details on Substances Classified in Annex I to Directive 67/548/EEC

[General information](#) |
 [Specific Concentration Limits](#) |
 [Seveso Data](#)

General Information					
Index number	Note (alphabetic)		Note (numeric)		
605-001-00-5	B D				
ATP inserted			ATP updated		
19			22		
Substances					EN
Sub	EC No	Cas No	Other Cas No	Name	Type
1	200-001-8	50-00-0		formaldehyde ...%	
Classification		Risk phrases	Safety phrases	Indication(s) of danger	
Carc. Cat. 3; R40 T; R23/24/25 C; R34 R43		23/24/25 - 34 - 40 - 43	1/2 - 26 - 36/37/39 - 45 - 51	T	
Symbol(s)					
					

[top](#)

Specific Concentration Limits	
Concentration	Classification
$C \geq 25 \%$	T; R23/24/25-34-40-43
$5 \% \leq C < 25 \%$	Xn; R20/21/22-36/37/38-40-43
$1 \% \leq C < 5 \%$	Xn; R40-43
$0,2 \% \leq C < 1 \%$	Xi; R43

CAS No: - -

Name:

UN No:

Classification:

Labelling:

Cut Offs:

Source:

Sort By:

Show Exposure Standard Details:

Health (H) Physicochemical (D) Ecotoxicological (E)

[Search](#) [Clear](#) [Print/ Save](#)

7 record(s) found.

CAS No	Substance Name	UN No	Classification	Labelling	CutOffs	Source	H Type	
67-56-1	Methyl alcohol [Methanol]	1230	F; R11 T; R23/24/25 T; R39/23/24/25	F ; T ; R; 11 - 23/24/25 - 39/23/24/25, S; (1/2) - 7 - 16 - 36/37 - 45	Conc>=20%: T; R23/24/25; R39/23/24/25 >=10%Conc<20%: T; R20/21/22; R39/23/24/25 >=3%Conc<10%: Xn; R20/21/22; R68/20/21/22	Eu; A	H	View History
97-99-4	Tetrahydro-2-furylmethanol [Tetrahydrofurfuryl alcohol]		Xi; R36	Xi ; R; 36 , S; (2) - 39	Conc>=10%: Xi; R36	Eu	H	
104-80-3	Tetrahydrofuran-2,5-diylidimethanol		Xi; R36/37/38	Xi ; R; 36/37/38 , S; (2) - 39	Conc>=10%: Xi; R36/37/38	Eu	H	
124-41-4	Sodium methanolate [Sodium methoxide; Sodium methylate] (Note: see also CAS No 865-33-8 & 865-34-9)	1289 1431	F; R11 R14 C; R34	F ; C ; R; 11 - 14 - 34, S; (1/2) - 8 - 16 - 26 - 43 - 45	Conc>=10%: C; R34 >=5%Conc<10% Xi; R36/38	Eu	H	View History
865-33-8	Potassium methanolate [Potassium methoxide] (Note: see also CAS No 124-41-4 & 865-34-9)		F; R11 R14 C; R34	F ; C ; R; 11 - 14 - 34, S; (1/2) - 8 - 16 - 26 - 43 - 45	Conc>=10%: C; R34 >=5%Conc<10% Xi; R36/38	Eu	H	
865-34-9	Lithium methanolate [Lithium methoxide] (Note: see also CAS No 124-41-4 & 865-33-8)		F; R11 R14 C; R34	F ; C ; R; 11 - 14 - 34, S; (1/2) - 8 - 16 - 26 - 43 - 45	Conc>=10%: C; R34 >=5%Conc<10% Xi; R36/38	Eu	H	
224635-63-6	Acetophenone, Formaldehyde, Cyclohexylamine, Methanol and Acetic acid, reaction product of		R10 Carc. Cat.3; R40 C; R34 Xn; R20 R43 N; R50-53	C ; N ; R; 10 - 20 - 34 - 40 - 43 - 50/53, S; (1/2) - 26 - 36/37/39 - 45 - 60 - 61	Conc>=25%: C; R40; R34; R20; R43 >=10%Conc<25%: C; R40; R34; R43 >=5%Conc<10%: Xn; R40; R36/38; R43 >=1%Conc<5%: Xn; R40; R43	Eu	H	

Where can I find R Phrases?

- EU Safety Data Sheet
 - ◆ Section 2: Classification of Ingredients (don't use those unless pure substance)
 - ◆ Section 3: Classification of Preparation
 - ◆ Section 15: EU Labeling Information
- US MSDS
 - ◆ Section 15: EU Labeling Information
- Call Supplier

SDS Labeling Information - Section 15

Supplier MSDS (Cyclohexane/Polymer Solution)



R10 Flammable
R20 Harmful by inhalation.
R36/38 Irritating to eyes and skin.
R43 May cause sensitization by skin contact.
S24/25 Avoid contact with the skin and eyes.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S37 Wear suitable gloves.
S51 Use only in well ventilated areas.
S60 This material and its container must be disposed of as hazardous waste.

Fisher Scientific MSDS

Lead Oxide

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols:

T N

Risk Phrases:

R 20/22 Harmful by inhalation and if swallowed.

R 33 Danger of cumulative effects.

R 61 May cause harm to the unborn child.

R 62 Possible risk of impaired fertility.

R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

<https://www1.fishersci.com/av/searchresults.jsp>

Sigma-Aldrich MSDS

Cadmium

EU ADDITIONAL CLASSIFICATION

Symbol of Danger: T

Indication of Danger: Toxic.

R: 45-20/21/22

Risk Statements: May cause cancer. Harmful by inhalation, in contact with skin and if swallowed.

<http://www.sigmaaldrich.com/>

If All Else Fails....

Call Denese Deeds

203-929-3473

Fax MSDS to

203-929-5823

Email MSDS to

d.deeds@ih-sc.com

Mention the Control Banding Workshop

What's Next: GHS

Globally Harmonized System for the Classification and Labeling of Chemicals

Adoption 2008?

- Standard Classification Indicated by
 - ◆ Signal Words
 - ◆ Symbols (Pictograms)
 - ◆ Hazard Statements
- Harmonized Safety Data Sheets

Signal Word

Indicates relative degree of hazard

- Warning
- Danger

GHS Symbols



Hazard Statements

Generally LD/LC50	Category 1	Category 2	Category 3	Category 4	Category 5 Exists – will not be used **
Oral (mg/kg)	<5	≥5 - <50	≥50 - <300	>300 - <2000	
Dermal (mg/kg)	<50	≥50 - <200	≥200 - <1000	≥1000 - <2000	
Gases (ppm)	<100	≥100 - <500	≥500 - <2500	≥2500 - <5000	
Vapours (mg/l)	<0.5	≥0.5 - <2.0	≥2.0 - <10	≥10 - <20	
Dusts and Mists (mg/l)	<0.05	≥0.05 - <0.5	≥0.5 - <1.0	≥1.0 - <5	
Signal Word	Danger	Danger	Danger	Warning	
Statement of Known Hazard (oral)	Fatal if swallowed	Fatal if swallowed	Toxic if swallowed	Harmful if swallowed	
Statement of known hazard (dermal)	Fatal in contact with skin	Fatal in contact with skin	Toxic in contact with skin	Harmful in contact with skin	
Statement of known hazard (inhalation)	Fatal if inhaled	Fatal if inhaled	Toxic if inhaled	Harmful if inhaled	

Control Banding - GHS

- Classification System very similar to EU
- Uses standard statements very similar to the R Phrases
- Classification and Statements indicated the relative degree of hazard
- COSHH Essentials can be adapted to use GHS Classes (EU is planning to assign numbers)

EU-GHS Comparison

Health Hazards	
Very Toxic (T+) R28	→ Acute Toxicity category 1 (oral)
Toxic (T) R25	→ Acute Toxicity category 2 and 3 (oral)
Harmful (Xn) R22	→ Acute Toxicity category 4 (oral)
Very Toxic (T+) R27	→ Acute Toxicity category 1 (dermal)
Toxic (T) R24	→ Acute Toxicity category 2 (dermal)
Harmful (Xn) R21	→ Acute Toxicity category 3 and 4 (dermal)
Very Toxic (T+) R26 (gases)	→ Acute Toxicity category 1 (inhalation of gases)
Toxic (T) R23 (gases)	→ Acute Toxicity category 2 (inhalation of gases)
Harmful (Xn) R20 (gases)	→ Acute Toxicity category 3 and 4 (inhalation of gases)
Very Toxic (T+) R26 (vapours)	→ Acute Toxicity category 1 (inhalation of vapours)
Toxic (T) R23 (vapours)	→ Acute Toxicity category 2 (inhalation of vapours)
Harmful (Xn) R20 (vapours)	→ Acute Toxicity category 3 and 4 (inhalation of vapours)
Very Toxic (T+) R26 (aerosols & particulates)	→ Acute Toxicity category 1 (inhalation of dust/ mist / fume)
Toxic (T) R23 (aerosols & particulates)	→ Acute Toxicity category 2 or 3 (inhalation of dust/ mist / fume)
Harmful (Xn) R20 (aerosols & particulates)	→ Acute Toxicity category 4 (inhalation of dust/ mist/ fume)

EU – GHS Comparison

Mutagen category 1 (T) R46	→ Germ Cell Mutagenicity category 1A
Mutagen category 2 (T) R46	→ Germ Cell Mutagenicity category 1B
Mutagen category 1 (Xn) R68	→ Germ Cell Mutagenicity category 2
Carcinogen category 1 (T) R45 or R49	→ Carcinogenicity category 1A
Carcinogen category 2 (T) R45 or R49	→ Carcinogenicity category 1B
Carcinogen category 2 (Xn) R40	→ Carcinogenicity category 2
Toxic to Reproduction category 1 (T) R60 or R61	→ Reproductive Toxicity category 1A
Toxic to Reproduction category 2 (T) R60 or R61	→ Reproductive Toxicity category 1B
Toxic to Reproduction category 3 (Xn) R62 or R63	→ Reproductive Toxicity category 2
<i>(R64- R phrase only as additional labeling requirement)</i>	<i>→ Reproductive toxicity effects on or via lactation</i>

Note: From EU Proposed Legislation adopting the GHS