

Comparison of cut-off values / concentration limits in the GHS and in the EU system

I. Default concentration limits to be used in the evaluation of health and environmental hazards of mixtures

Category of danger of the substance	gaseous preparations % vol/vol		other preparations % w/w	
	EU ^{a)}	GHS ^{b)}	EU ^{a)}	GHS ^{b)}
Very toxic	≥ 0.02		≥ 0.1	
Toxic	≥ 0.02		≥ 0.1	
Harmful	≥ 0.2		≥ 1	
Acute toxicity		≥ 1		≥ 1
TOST – single exposure, Category 1 or 2		≥ 1 / ≥ 10		≥ 1 / ≥ 10
TOST – repeated exposure, Category 1 or 2		≥ 1 / ≥ 10		≥ 1 / ≥ 10
Carcinogenic, Category 1 or 2	≥ 0.02		≥ 0.1	
Carcinogenicity, Category 1		≥ 0.1		≥ 0.1
Mutagenic, Category 1 or 2	≥ 0.02		≥ 0.1	
Germ cell mutagenicity, Category 1		≥ 0.1		≥ 0.1
Toxic for reproduction, Category 1 or 2	≥ 0.02		≥ 0.1	
Reproductive toxicity, Category 1		≥ 0.1 / ≥ 0.3		≥ 0.1 / ≥ 0.3
Corrosive	≥ 0.02		≥ 1	
Irritant	≥ 0.2		≥ 1	
Skin corrosion / irritation		≥ 1		≥ 1
Serious eye damage / eye irritation		≥ 1		≥ 1
Sensitising	≥ 0.2		≥ 1	
Skin sensitizer		≥ 0.1 / ≥ 1		≥ 0.1 / ≥ 1
Respiratory sensitizer		≥ 0.1 / ≥ 0.2		≥ 0.1 / ≥ 1
Carcinogenic, Category 3	≥ 0.2		≥ 1	
Carcinogenicity, Category 2		≥ 0.1 / ≥ 1		≥ 0.1 / ≥ 1
Mutagenic, Category 3	≥ 0.2		≥ 1	
Germ cell mutagenicity, Category 2		≥ 1		≥ 1
Toxic for reproduction, Category 3	≥ 0.2		≥ 1	
Reproductive toxicity, Category 2		≥ 0.1 / ≥ 3		≥ 0.1 / ≥ 3
Dangerous for the environment N			≥ 0.1	
Dangerous for the environment ozone	≥ 0.1		≥ 0.1	
Dangerous for the environment			≥ 1	
Hazardous to the aquatic environment ¹				≥ 1

a) Directive 1999/45/EC, Art. 3 (3)

b) GHS: 1.3.3.2 (pp. 21 f.) and Part 3

¹ If the LC₅₀ or EC₅₀ of a substance in a mixture is lower than 0.1 mg/l, its concentration needs to be multiplied by its respective M-factor before comparing it to the cut-off value.

II. Concentration limits for the classification of health hazards of mixtures

(i) Skin corrosion / irritation

a. GHS: Table 3.2.3, p. 130

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:		
	Skin corrosive	Skin irritant	
	Category 1	Category 2	Category 3
Skin Category 1	≥ 5 %	≥ 1 % but < 5 %	
Skin Category 2		≥ 10 %	≥ 1 % but < 10 %
Skin Category 3			≥ 10 %
(10 * Skin Category 1) + Skin Category 2		≥ 10 %	≥ 1 % but < 10 %
(10 * Skin Category 1) + Skin Category 2 + Skin Category 3			≥ 10 %

b. EU: Directive 1999/45/EC, Annex II, Table IV
non-gaseous preparations

Classification of the substance	Classification of the preparation		
	C with R35	C with R34	X _i with R38
C with R35	≥ 10 %	≥ 5 % but < 10 %	≥ 1 % but < 5 %
C with R34		≥ 10 %	≥ 5 % but < 10 %
X _i with R38			≥ 20 %

EU: Directive 1999/45/EC, Annex II, Table IV A
gaseous preparations

Classification of the substance	Classification of the preparation		
	C with R35	C with R34	X _i with R38
C with R35	≥ 1 %	≥ 0.2 % but < 1 %	≥ 0.02 % but < 0.2 %
C with R34		≥ 5 %	≥ 0.5 % but < 5 %
X _i with R38			≥ 5 %

(ii) Serious eye damage / eye irritation

a. GHS: Table 3.3.3, p. 146

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye or Skin Category 1	≥ 3 %	≥ 1 % but < 3 %
Eye Category 2/2A		≥ 10 %
(10 * Eye Category 1) + Eye Category 2/2A		≥ 10 %
Skin Category 1 + Eye Category 1	≥ 3 %	≥ 1 % but < 3 %
10 * (Skin Category 1 + Eye Category 1) + Eye Category 2/2A		≥ 10 %

b. EU: Directive 1999/45/EC, Annex II, Table IV
non-gaseous preparations

Classification of the substance	Classification of the preparation	
	X _i with R41	X _i with R36
C with R35	≥ 5 %	≥ 1 % but < 5 %
C with R34	≥ 10 %	≥ 5 % but < 10 %
X _i with R41	≥ 10 %	≥ 5 % but < 10 %
X _i with R38		≥ 20 %

EU: Directive 1999/45/EC, Annex II, Table IV A
gaseous preparations

Classification of the substance	Classification of the preparation	
	X _i with R41	X _i with R36
C with R35	≥ 0.2 %	≥ 0.02 % but < 0.2 %
C with R34	≥ 5 %	≥ 0.5 % but < 5 %
X _i with R41	≥ 5 %	≥ 0.5 % but < 5 %
X _i with R38		≥ 5 %

(iii) Respiratory or skin sensitization

a. GHS: Table 3.4.1, p. 155

Ingredient classified as:	Cut-off / concentration limits triggering classification of a mixture as:		
	Skin Sensitizer	Respiratory Sensitizer	
	All physical states	Solid / Liquid	Gas
Skin Sensitizer	³ 0.1 %		
	³ 1 %		
Respiratory Sensitizer		³ 0.1 %	³ 0.1 %
		³ 1 %	³ 0.2 %

b. EU: Directive 1999/45/EC, Annex II, Table V
non-gaseous preparations

Classification of the substance	Classification of the preparation	
	Sensitising with R43	Sensitising with R42
Sensitising with R43	³ 1 %	
Sensitising with R42		³ 1 %

EU: Directive 1999/45/EC, Annex II, Table V A
gaseous preparations

Classification of the substance	Classification of the preparation	
	Sensitising with R43	Sensitising with R42
Sensitising with R43	³ 0.2 %	
Sensitising with R42		³ 0.2 %

(iv) Germ cell mutagenicity

a. GHS: Table 3.5.1, p. 162

Ingredient classified as:	Cut-off / concentration limits triggering classification of a mixture as:	
	Category 1 mutagen	Category 2 mutagen
Category 1 mutagen	³ 0.1 %	
Category 2 mutagen		³ 1 %

b. EU: Directive 1999/45/EC, Annex II, Table VI / VI A
non-gaseous / gaseous preparations

Classification of the substance	Classification of the preparation	
	Category 1 or 2 with R46	Category 3 with R68
Mutagenic substances of category 1 or 2 with R46	³ 0.1 %	
Mutagenic substances of category 3 with R68		³ 1 %

(v) Carcinogenicity

a. GHS: Table 3.6.1, p. 170

Ingredient classified as:	Cut-off / concentration limits triggering classification of a mixture as:	
	Category 1 carcinogen	Category 2 carcinogen
Category 1 carcinogen	³ 0.1 %	
Category 2 carcinogen		³ 0.1 %
		³ 1 %

b. EU: Directive 1999/45/EC, Annex II, Table VI / VI A
non-gaseous / gaseous preparations

Classification of the substance	Classification of the preparation	
	Category 1 or 2 with R45 or R49	Category 3 with R40
Carcinogenic substances of category 1 or 2 with R45 or R49	³ 0.1 %	
Carcinogenic substances of category 3 with R40		³ 1 %

(vi) Reproductive toxicity

a. GHS: Table 3.7.1, p. 182

Ingredient classified as:	Cut-off / concentration limits triggering classification of a mixture as:	
	Category 1 reproductive toxicant	Category 2 reproductive toxicant
Category 1 reproductive toxicant	³ 0.1 %	
	³ 0.3 %	
Category 2 reproductive toxicant		³ 0.1 %
		³ 3 %

b. EU: Directive 1999/45/EC, Annex II, Table VI
non-gaseous preparations

Classification of the substance	Classification of the preparation	
	Category 1 or 2 with R60	Category 3 with R62
Substances "toxic of reproduction" of category 1 or 2 with R60 (fertility)	³ 0.5 %	
Substances "toxic of reproduction" of category 3 with R62 (fertility)		³ 5 %
	Category 1 or 2 with R61	Category 3 with R63
Substances "toxic of reproduction" of category 1 or 2 with R61 (development)	³ 0.5 %	
Substances "toxic of reproduction" of category 3 with R63 (development)		³ 5 %

EU: Directive 1999/45/EC, Annex II, Table VI A
gaseous preparations

Classification of the substance	Classification of the preparation	
	Category 1 or 2 with R60	Category 3 with R62
Substances "toxic of reproduction" of category 1 or 2 with R60 (fertility)	³ 0.2 %	
Substances "toxic of reproduction" of category 3 with R62 (fertility)		³ 1 %
	Category 1 or 2 with R61	Category 3 with R63
Substances "toxic of reproduction" of category 1 or 2 with R61 (development)	³ 0.2 %	
Substances "toxic of reproduction" of category 3 with R63 (development)		³ 1 %

(vi) TOST – single exposure

a. GHS: Table 3.8.2, p. 193

Ingredient classified as:	Cut-off / concentration limits triggering classification of a mixture as:	
	Category 1	Category 2
Category 1 Target Organ Systemic Toxicant	≥ 1 %	≥ 1 % but < 10 %
	≥ 10 %	
Category 2 Target Organ Systemic Toxicant		≥ 1 %
		≥ 10 %

b. EU: Directive 1999/45/EC, Annex II, Table II
non-gaseous preparations

Classification of the substance	Classification of the preparation		
	T ⁺ with R39	T with R39	X _n with R68
T ⁺ with R39	≥ 10 %	≥ 1 % but < 10 %	≥ 0.1 % but < 1 %
T with R39		≥ 10 %	≥ 1 % but < 10 %
X _n with R68			≥ 10 %

EU: Directive 1999/45/EC, Annex II, Table II A
gaseous preparations

Classification of the substance	Classification of the preparation		
	T ⁺ with R39	T with R39	X _n with R68
T ⁺ with R39	≥ 1 %	≥ 0.2 % but < 1 %	≥ 0.02 % but < 0.2 %
T with R39		≥ 5 %	≥ 0.5 % but < 5 %
X _n with R68			≥ 5 %

(vii) TOST – repeated exposure

a. GHS: Table 3.9.3, p. 204

Ingredient classified as:	Cut-off / concentration limits triggering classification of a mixture as:	
	Category 1	Category 2
Category 1 Target Organ Systemic Toxicant	³ 1 %	³ 1 % but < 10 %
	³ 10 %	
Category 2 Target Organ Systemic Toxicant		³ 1 %
		³ 10 %

b. EU: Directive 1999/45/EC, Annex II, Table III
non-gaseous preparations

Classification of the substance	Classification of the preparation	
	T with R48	X _n with R48
T with R48	³ 10 %	³ 1 % but < 10 %
X _n with R48		³ 10 %

EU: Directive 1999/45/EC, Annex II, Table III A
gaseous preparations

Classification of the substance	Classification of the preparation	
	T with R48	X _n with R48
T with R48	³ 5 %	³ 0.5 % but < 5 %
X _n with R48		³ 5 %

(viii) Environment – acute aquatic toxicity

a. GHS: Table 3.10.2, p. 221

Sum of components classified as:	Cut-off / concentration limits triggering classification of a mixture as:		
	Acute 1	Acute 2	Acute 3
Acute 1 * M	25		
(Acute 1 * M * 10) + Acute 2		25	
(Acute 1 * M * 100) + (Acute 2 * 10) + Acute 3			25

b. EU: Directive 1999/45/EC, Annex III, Table 2

Classification of the substance	Classification of the preparation	
	N, R50	R 52
N, R50	$C_n \cdot 25\%$	
N, R50 – 53	$C_n \cdot 25\%$	
R 52		$C_n \cdot 25\%$

(ix) Environment – chronic aquatic toxicity

a. GHS: Table 3.10.3, p. 222

Sum of components classified as:	Cut-off / concentration limits triggering classification of a mixture as:			
	Chronic 1	Chronic 2	Chronic 3	Chronic 4
Chronic 1 * M	25			
(Chronic 1 * M * 10) + Chronic 2		25		
(Chronic 1 * M * 100) + (Chronic 2 * 10) + Chronic 3			25	
Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4				25

b. EU: Directive 1999/45/EC, Annex III, Table 1 and Table 4

Classification of the substance	Classification of the preparation			
	N, R50 – 53	N, R51 – 53	R 52 – 53	R 53
N, R50 – 53	$C_n \cdot 25\%$	$2.5 \cdot C_n < 25\%$	$0.25 \cdot C_n < 2.5\%$	$C_n \cdot 25\%$
N, R51 – 53		$C_n \cdot 25\%$	$2.5 \cdot C_n < 25\%$	$C_n \cdot 25\%$
R 52 – 53			$C_n \cdot 25\%$	$C_n \cdot 25\%$
R 53				$C_n \cdot 25\%$

(x) Environment – dangerous for the ozone layer

a. GHS: not existing

b. EU: Directive 1999/45/EC, Annex III, Table 5

Classification of the substance	Classification of the preparation	
	N, R59	R 59
N with R 59	C • 0.1 %	
R 59		C • 0.1 %