

## **Guide to the classification of dangerous goods in terms of their "corrosive effect on living tissue"**

BfR Guide of 1 July 2004

This Guide is designed to help the manufacturers of chemicals or chemical products undertake the self-classification of transport goods in Class 8 (Corrosive substances) on the basis of the UN Recommendations on the Transport of Dangerous Goods (Model Regulations). It outlines the assessment practice of the Federal Institute for Risk Assessment (BfR) subject, however, to expert assessment which, in individual cases, may lead to a deviating assessment due to substance specificities.

The margins of decision left in the statutory dangerous goods provisions, which are to be set out here, suggest references to other regulations including also the risk characteristic "corrosive" using the same database. Hence, the Guide contains various elements of different origins compiled into a regimen whenever this makes sense without contradictions.

It also encompasses the Globally Harmonised System for Classification and Labelling of Dangerous Substances (GHS) which is aimed at the universal harmonisation of hazard identification and communication. Its general procedural proposal of Bridging Rules for the classification of solutions/mixtures/preparations may be taken over in the absence of comparable rules (Annex 1). Otherwise, the special features of existing systems like the conventional calculation method in EU chemicals regulations currently take precedence. They are adapted by means of a criteria comparison to transport regulations (Annex 2).

Divergent classifications of substances cannot be ruled out when comparing the UN and the EU. If this is the case, a classification is required in accordance with the UN system. If a substance has been specifically identified by a substance number or UN number and has been classified in Class 8, its packing group can be taken from the Dangerous Goods List. This also applies to specially listed substance mixtures with constituents within specific concentration limits.

The following assessment regimen is recommended for all cases in which classification is open to a choice of the packing group or exemption from classification by referring to Class 8 criteria in accordance with the definition principle. The same holds for a substance identified by name which hazard potential in a solution or a mixture with non classified substances is different from that of the substance itself.

### **Substance assessment procedure - Class 8**

Whenever recourse is made to EU chemicals regulations and related directives, it must be borne in mind that the three packing groups (PG) in Class 8 (PG I to III) have as a counterpart in EU legislation only two risk categories R34 and R35 (causes burns/ causes severe burns). In principle, a clear distinction can only be made between the three packing groups on the basis of the results from animal testing (very rarely on the basis of human experience). Where appropriate, the bridging rules are to be applied. When weighing animal experiments against the need for an assignment to either PG II or PG III, there is agreement that animal experiments are to be avoided whenever possible and that results from alternative in vitro tests ending in R34 for dangerous goods transport lead, as a precautionary measures, to classification in Class 8 PG II.

The retainment of the systematic division into three parts for transport purposes does not justify any additional animal experiments when, on the other hand, EU chemicals regulations for Supply and Use can do with two parts only for this hazard characteristic (PG III would then be reserved solely for material corrosion.)

There is no known association between the long-term aspect of material corrosion, which always leads where appropriate to a Class 8 PG III, and the effect of short-term exposure on living tissue.

### Synopsis of the classification as *corrosive* in dangerous goods and dangerous substances law

Destruction of full thickness of skin after exposure of:	$\leq 3$ minutes	$> 3 - \leq 60$ minutes	$< 60 - \leq 240$ minutes	Inflammation of the skin without destruction after 4 hours' exposure
Dangerous good	Class 8 PG I	Class 8 PG II	Class 8 PG III	*)
Dangerous substance	C with R35 (Causes severe burns)	C with R34 (Causes Burns)		Xi with R38 (Irritates the skin)

\*) The skin-irritating substances are not to be classified in Class 8 because of a lack of equivalence in the criteria of the statutory dangerous goods provisions.

In both legal areas reference is made to the international standardised toxicological test methods of OECD, in this case OECD Guideline 404 "Acute Dermal Irritation/Corrosion" (1992 with update of 24 April 2002)

Level	Information available				Method	Conclusion*	Comment
1	Usable human experience	→ Yes →			Application of the UN Class 8 criteria	PG I/II/III/NC (NC: No classification)	Relations of sub-categories according to <b>UN GHS EU:</b> PG I 1A R35 PG II 1B R34 PG III 1C R34
	↓ No ↓						
2	Data from animal testing	→ Yes →					
	↓ No ↓						
3	Mixtures: Tests on comparable solutions/mixtures/preparations	→ Yes →			Assimilation considering the GHS <i>bridging rules</i> (Annex 1)	PG I/II/III/NC	The <i>Bridging rules</i> are of assistance when interpreting the term "comparable".
	↓ No ↓						
4	Substances/Mixtures in ionic form (acids, alkalis, salts):	→Yes→	pH ≤ 2 or pH ≥ 11.5	→Yes→	Basic assumption ⇒	<b>Class 8; PG ??: ↓ Level 6</b>	** NC can only be applied here to pure aqueous solutions.
	↓ (No or not applicable) ↓		↓ No ↓		<i>Option:</i> ⇒ Buffer capacity acc. to Young et al (1988) <sup>1</sup> :	Low Buffer capacity: <b>NC**</b>	In the presence of neutral organic or surface active agents: ↓ <b>Stufe 6</b>
			<b>NC**</b>				

In the regimen the possible conclusions are separated by a "/".

Level	Information available				Method	Conclusion*	Comment
5	Are the main components in Annex I of Directive 67/548/EEC <sup>2</sup> classified as corrosive with general or specific concentration limits?			→Yes→	Classification according to the conventional calculation method (Annex 2) <sup>3, 4</sup>	PG I/II/NC	It is not possible to distinguish between PG II and PG III
		↓ No ↓					
6	<i>In vitro</i> tests for the dermal corrosive effect, e.g. transcutaneous electric resistance (TER) or cell death in the skin model <sup>5</sup>			→Yes→		PG I/II/NC <i>Option:</i> Exclusion of false positive results in the TER test through additional dye binding test	It is not possible to distinguish between PG II and PG III

In the regimen the possible conclusions are separated by a "/".

#### Table footnotes:

1 J.R. Young, M.J. How, A.P. Walker and W.M.H. Worth (1988): Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without testing on animals. Toxic. In Vitro 2(1): pp. 19-26. [not an OECD standard method but included as a footnote in Annex VI to Directive 2001/59/EG (Classification and Labelling Requirements)]

2 Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28<sup>th</sup> time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances (OJ L 225, 21.8.2001, p. 1)

3 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7. 1999, p. 1)

4 Commission Directive 2001/60/EC of 7 August 2001 adapting to technical progress Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 226, 22. 8. 2001, p. 5):

"Please note: The use of the conventional method for preparations classified as corrosive or irritating, can lead to an overestimation or underestimation of the risk when other relevant factors (like the pH of the preparation) are not taken into account. Hence, when classifying the corrosive effect, consideration should be given to the comments in Section 3.2.5 of Annex VI to Directive 67/548/EEC and in Article 6 paragraph 3 (second and third indent) of this Directive."

5 Commission Directive 2000/33/EC of 25 April 2000 adapting to technical progress for the 27<sup>th</sup> time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances OF L 136,8.6.2000, here: ANNEX I, B.40. TESTING FOR SKIN CORROSIVITY (pp. 90-97)

## Annex 1:

### Bridging Rules

A mixture that has not been tested to determine its corrosive effect can be classified without animal testing if there are sufficient data on the effects of the individual constituents and corresponding test results are available for a comparable mixture. The comparison can be undertaken in various ways.

- A) Dilution principle: A mixture is deemed to be a dilution when it contains a substance that is not more corrosive than the least corrosive constituent of the known comparable mixture. As long as there is no interaction with the other constituents, the mixture can be classified like the comparable mixture as it has a lower proportion of the more corrosive constituents. In the case of pure dilutions, the other option is to use the conventional calculation method.
- B) If the known mixture was classified in Packing Group I and the unknown mixture contains higher concentrations of the corrosive ingredients, then the unknown mixture is to be classified in the same way without further testing.
- C) If two different mixtures, A and B, with identical constituents have been classified in the same Packing Group, then an unknown third mixture C with the same toxicologically relevant constituents is to be classified in the same way as long as the concentrations of the individual constituents remain within the range of those of A and B.
- D) The corrosive effect of various batches of a specific mixture are considered to be equivalent when the mixture has been produced as a commercial product under the responsibility of a manufacturer. This does not apply if there is reason to believe that changes in production methods have led to the goods having a different toxicity.
- E) Substantially similar mixtures:

Given the following:

(a) Two mixtures

- (i) A + B
- (ii) C + B

- (b) The concentration of constituent B is essentially the same in both mixtures;
- (c) The concentration of constituent A in mixture (i) corresponds to that of ingredient C in mixture (II);
- (d) Data are available on the corrosive effect of A and C. They are equivalent, i.e. they lead to the same Packing Group and are not expected to affect the corrosivity of B.

If mixture (i) has already been classified on the basis of tests, then mixture (ii) can be classified like mixture (i).

**Annex 2:****Conventional calculation method for the assessment of corrosive properties**

1. Preparations are classified as **Class 8 PG I**
  - (a) which contain one or more substances classified as corrosive to which phrase R35 has been assigned in individual concentrations equal to or greater than the concentration specified in Annex 1 to Directive 67/548/EEC for the substance(s) under consideration

or

  - (b) equal to or greater than the concentration specified in the following table where the substance(s) under consideration do not appear in Annex I to Directive 67/548/EEC or appear there without concentration limits;

Preparations containing more than one substance classified as corrosive to which phrase 35 has been assigned in lower individual concentrations than specified under (a) or (b) if

$$\sum \left( \frac{P_{C, R35}}{L_{C, R35}} \right) \geq 1$$

where:

$P_{C, R35}$  = is the percentage by weight or by volume of each corrosive substance which is assigned phrase R35 in the preparation,

$L_{C, R35}$  = is the corrosive limit R35 specified for each corrosive substance to which phrase R35 has been assigned, expressed as a percentage by weight or by volume;

2. Preparations are classified as **Class 8 PG II**,
  - (a) which contain one or more substances classified as corrosive to which phrase R35 or R34 has been assigned in individual concentrations equal to or greater than the concentration specified in Annex 1 to Directive 67/548/EEC for the substance(s) under consideration

or

  - (b) equal to or greater than the concentration specified in the following table where the substance(s) do not appear in Annex I to Directive 67/548/EEC or appear there without concentration limits;

Preparations containing more than one substance classified as corrosive to which phrase 35 or phrase 34 has been assigned in lower individual concentrations than specified under (a) or (b) if

$$\sum \left( \frac{P_{C, R35}}{L_{C, R34}} + \frac{P_{C, R34}}{L_{C, R34}} \right) \geq 1$$

where:

$P_{C, R35}$  = is the percentage by weight or volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C, R34}$  = is the percentage by weight or volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$L_{C, R34}$  = is the respective corrosive limit R34 specified for each corrosive substance to which is assigned phrase R35 or R34 expressed as a percentage by weight or by volume.

**Table of general concentration limits (not substance-specific)**

Substance classification	Preparation classification		
	Class 8 PG I	Class 8 PG II	NC (no classification)
C with R35	Concentration $\geq 10$ %	$5\% \leq$ Concentration $< 10$ %	Concentration $< 5$ %
C with R34		Concentration $\geq 10$ %	Concentration $< 10$ %