

Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

29 June 2016

Sub-Committee of Experts on the Transport of Dangerous Goods

Forty-ninth session

Geneva, 27 June – 6 July 2016

Item 3 of the provisional agenda

Listing, classification and packing

Proposal for editorial and small content revisions of proposal ST/SG/AC.10/C.3/2016/21, concerning the proposal of revision of Chapter 2.8 of the Model Regulations: introduction of alternative methods for classification and packing group assignment

**Transmitted by the expert from Canada, the European Chemical
Industry Council (CEFIC), and the International Association for Soaps,
Detergents and Maintenance Products (AISE)**

Purpose

1. At the forty-ninth session of the Sub-Committee of Experts on the Transport of Dangerous Goods (TDG), working document ST/SG/AC.10/C.3/2016/21 on proposed changes to Chapter 2.8 of the UN Model Regulations was discussed. The proposal enjoyed support from the delegates, but editorial changes and small content changes were proposed to increase readability of the new text.
2. During a lunch-time session, the proposed editorial and small content changes were discussed. In Annex I of this document an overview is given, with tracked changes, of the proposed content changes (e.g., deletion of redundant text). Annex II contains a clean version which also relocates several text to different sections to improve readability. The full overview of suggested changes to ST/SG/AC.10/C.3/2016/21, with changes tracked, is given in Annex III for those interested.
3. Regarding the definition of substances and mixtures corrosive to skin, two suggestions are added in the document: both the wording currently in the Globally Harmonized System (5th revised edition) and a new wording currently being proposed in the UN SCEGHS in document ST/SG/AC.10/C.4/2016/9. Depending on whether the new proposed text is accepted, a decision can be made on which definition to keep in this proposal.
4. Regarding the removal of section 2.8.3.1.4 for structurally related substances, no agreement was reached on the addition of this method of classifying a substance. A new paper may be developed with a more comprehensive, substantiated proposal to introduce it in Chapter 2.8.

Annex I

Proposal for revision of Chapter 2.8 of the Model Regulations

“Chapter 2.8

Class 8 – Corrosive substances

2.8.1 Definition and general provisions

2.8.1.1 *Corrosive substances* are substances which, by chemical action, will cause irreversible damage to the skin, or, in the case of leakage, will materially damage, or even destroy, other goods or the means of transport.

2.8.1.2 For substances and mixtures that are corrosive to skin, packing group assignment is determined using criteria in section 2.8.2, where they will be assigned to a packing group. [\[Skin corrosion refers to the production of irreversible damage to the skin, namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.\]](#) [A substance is corrosive to skin when it leads to the destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure for up to 4 hours.] ~~Packing group assignment can alternatively be derived for substances using the criteria in section 2.8.3 and for mixtures using the criteria in section 2.8.4.~~

2.8.1.3 Liquids and solids which may become liquid during transport, which are judged not to be skin corrosive shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.2.1 (c) (ii).

2.8.2 Assignment of packing groups

2.8.2.1 Substances and mixtures of Class 8 are divided among the three packing groups according to their degree of [hazard–danger](#) in transport in accordance with the following criteria:

- (a) *Packing group I* is assigned to very dangerous substances and mixtures that cause full thickness destruction of intact skin tissue within an observation period up to 60 minutes starting after the exposure time of three (3) minutes or less;
- (b) *Packing group II* is assigned to substances and mixtures presenting medium danger that cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than three (3) minutes but not more than 60 minutes;
- (c) *Packing group III* is assigned to substances and mixtures that present minor danger and:
 - (i) cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours; or

(ii) are judged not to cause full thickness destruction of intact skin tissue but which exhibit a corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials. For the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37-2), S275J2G3+CR (1.0144 resp. St 44-3), ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type or SAE 1020, and for testing aluminium, non-clad, types 7075-T6 or AZ5GU-T6 shall be used. An acceptable test is prescribed in the Manual of Tests and Criteria, Part III, Section 37.

NOTE: Where an initial test on either steel or aluminium indicates the substance being tested is corrosive the follow up test on the other metal is not required.

Table 2.8.2.1: Table summarizing the criteria in 2.8.2.1

Packing Group	Exposure Time	Observation Period	Effect
I	≤ 3 min	≤ 60 min	Full thickness destruction of intact skin
II	> 3 min ≤ 1 h	≤ 14 d	Full thickness destruction of intact skin
III	> 1 h ≤ 4 h	≤ 14 d	Full thickness destruction of intact skin
III	-	-	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials

2.8.2.2 Allocation of substances listed in the Dangerous Goods List in Chapter 3.2 to the packing groups in Class 8 has been made on the basis of experience taking into account such additional factors as inhalation risk (see 2.8.2.4) and reactivity with water (including the formation of dangerous decomposition products).

2.8.2.3 New substances and mixtures can be assigned to packing groups on the basis of the length of time of contact necessary to produce [full thickness destruction of human skin] in accordance with the criteria in 2.8.2.1; ~~alternatively,~~ [For packing group assignment for substances](#) the criteria in 2.8.3 ~~can shall~~ be used; ~~alternatively, and~~ for mixtures, the criteria in 2.8.4 can be used.

2.8.2.4 A substance or mixture meeting the criteria of Class 8 having an inhalation toxicity of dusts and mists (LC₅₀) in the range of packing group I, but toxicity through oral ingestion or dermal contact only in the range of packing group III or less, shall be allocated to Class 8 (see note under 2.6.2.2.4.1).

2.8.2.5 When assigning the packing group to a substance or mixture in accordance with 2.8.2.3, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404¹ or 435². A substance or mixture which is determined not to be corrosive in accordance with OECD Test Guideline 430³ or 431⁴ may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

¹ [\[OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 20022015\]](#)

² [\[OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 20062015\]](#)

³ [\[OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test \(TER\)" 20042015\]](#)

2.8.3 Packing group assignment of substances corrosive to skin

~~2.8.3.1 — Classification based on experimental data~~

~~2.8.3.1.1 — A substance is corrosive to skin and assigned to the appropriate packing group when it produces irreversible destruction of skin tissue following the application of the substance for up to 4 hours as per the criteria in 2.8.2.1.~~

2.8.3.1.2 Existing human and animal data including information from single or repeated exposure shall be the first line of evaluation, as they give information directly relevant to effects on the skin.

~~2.8.3.1.23~~ *In vitro* alternatives that have been validated and accepted can be used to make classification decisions and assign packing groups, if the *in vitro* test method is suitable for this. Internationally accepted validated test methods for skin corrosion are listed in 2.8.2.5.

~~2.8.3.1.4 — In some cases sufficient information may be available from structurally-related substances to make classification decisions in accordance with the OECD Guidance on Grouping of Chemicals⁵.~~

2.8.4 Packing group assignment of mixtures corrosive to skin: Step-wise approach

2.8.4.1 General provisions

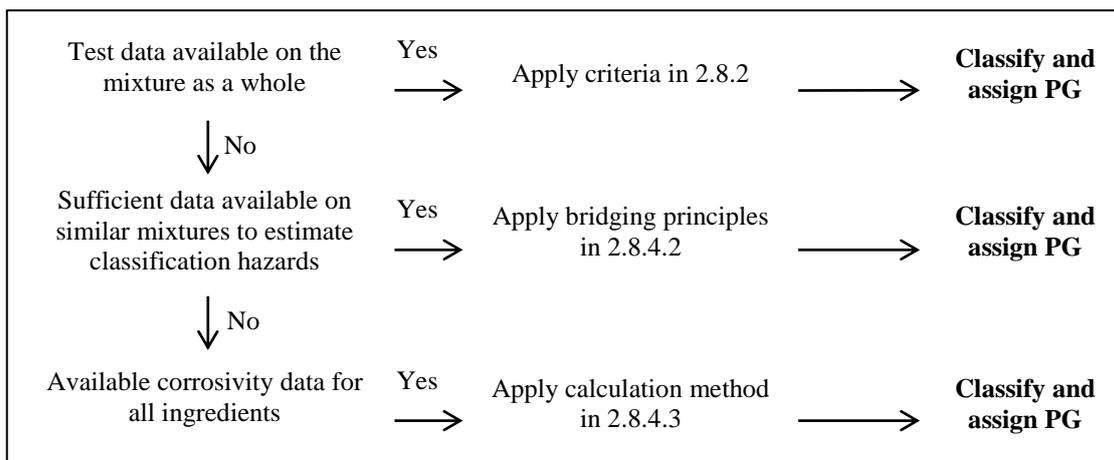
~~2.8.4.1.1 — Where sufficient test data from in vivo or in vitro tests is available for classification, the mixture shall be classified using the criteria for substances in 2.8.2.1 as illustrated in Table 2.8.2.1.~~

2.8.4.1.2.1 For mixtures it is necessary to obtain or derive information that allows the criteria to be applied to the mixture for the purpose of classification and assignment of packing groups. The approach to classification and assignment of packing groups is tiered, and is dependent upon the amount of information available for the mixture itself, for similar mixtures and/or for its ingredients. The flow chart of Figure 2.8.4.1 below outlines the process to be followed:

⁴ [OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2004/2015]

⁵ Organisation for Economic Co-operation and Development. 2014. *Guidance on Grouping of Chemicals, Second Edition*. Paris (FR): OECD, Environment Directorate. (Series on Testing and Assessment No. 194). Report No.: ENV/JM/MONO(2014)4, JT03356214. Available from: [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2014\)4&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en)

Figure 2.8.4.1: Step-wise approach to classify and assign packing group of corrosive mixtures



2.8.4.2 Bridging principles

2.8.4.2.1 Where a mixture has not been tested to determine its skin corrosion potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately classify [and assign a packing group for](#) the mixture, these data [may will](#) be used in accordance with the following bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

- (a) **Dilution:** ~~Unless the consideration of synergistic or antagonistic effects suggests otherwise, if~~ a tested mixture is diluted with a diluent which does not meet the criteria for Class 8 and does not affect the packing group of other ingredients, then the new diluted mixture may be assigned to the same packing group as the original tested mixture.

[Note: in certain cases, diluting a mixture or substance may lead to an increase in the corrosive properties. If this is the case, this bridging principle cannot be used.](#)

- (b) **Batching:** The skin corrosion potential of a tested production batch of a mixture ~~may can~~ be assumed to be substantially equivalent to that of another untested production batch of the same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the skin corrosion potential of the untested batch has changed. If the latter occurs, a new classification is necessary.

- (c) **Concentration of mixtures of packing group I:** If a tested mixture meeting the criteria for inclusion in packing group I is concentrated, the more concentrated untested mixture may be assigned to packing group I without additional testing.

- (d) **Interpolation within one packing group:** For three mixtures (X, Y and Z) with identical ingredients, where mixtures X and Y have been tested and are in the same skin corrosion packing group, and where untested mixture Z has the same ~~active-Class 8~~ ingredients as mixtures X and Y but has concentrations of ~~active-Class 8~~ ingredients intermediate to the

concentrations in mixtures X and Y, then mixture Z is assumed to be in the same skin corrosion packing group as X and Y.

- (e) **Substantially similar mixtures:** Given the following:
- (i) Two mixtures: (X+Y) and (Z+Y);
 - (ii) The concentration of ingredient Y is the same in both mixtures;
 - (iii) The concentration of ingredient X in mixture (X+Y) equals the concentration of ingredient Z in mixture (Z+Y);
 - (iv) Data on skin corrosion for X and Z are available and substantially equivalent, i.e. they are the same skin corrosion packing group and do not affect the skin corrosion potential of Y.

If mixture (X+Y) or (Z+Y) is already classified based on test data, then the other mixture may be assigned to the same packing group.

2.8.4.3 *Calculation method based on the classification of the substances*

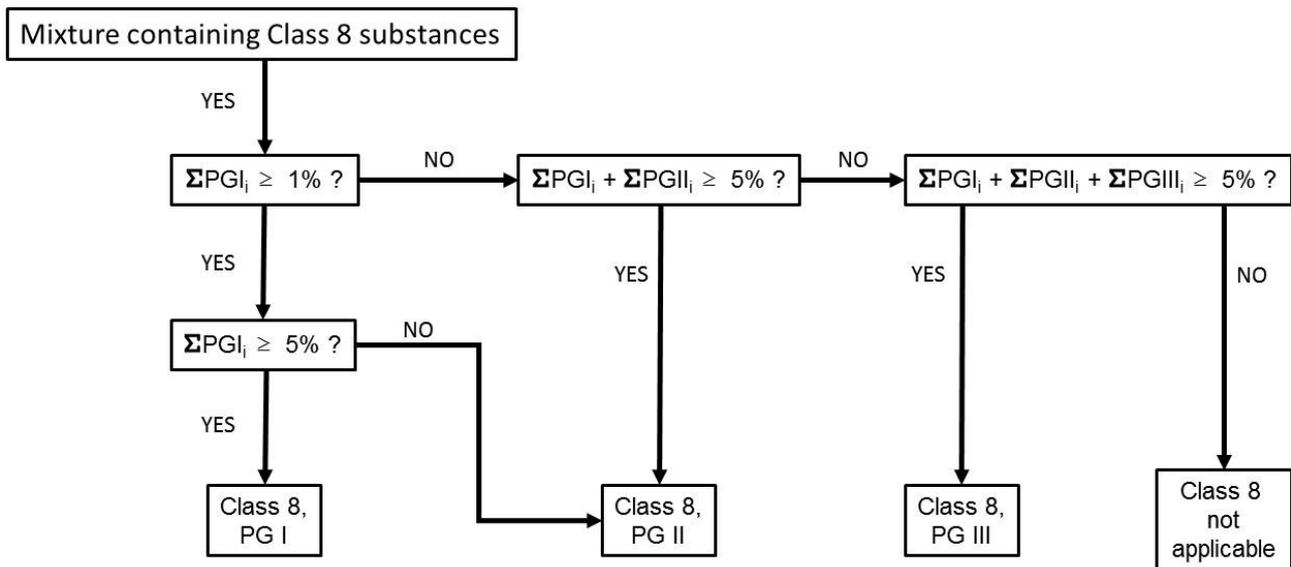
2.8.4.3.1 Where a mixture has not been tested to determine its skin corrosion potential, nor is sufficient data available on similar mixtures, the corrosive properties of the substances in the mixture shall be considered to classify and assign a packing group. This is possible when all substances in the mixture (i.e. present in concentrations of >1%) are considered for classification in accordance with Chapter 2.

Applying the calculation method is only allowed if there are no synergistic effects ~~known~~ that make the mixture more corrosive than the sum of its substances. This restriction applies only if packing group II or III would be assigned to the mixture.

2.8.4.3.2 When using the calculation method, all Class 8 ingredients present at a concentration of $\geq 1\%$ shall be taken into account. The generic cut-off value for the corrosive substances to be taken into account is 1%, or <1% if there is a presumption that these ingredients present at a concentration <1% can still be relevant for classifying the mixture to be corrosive to skin.

2.8.4.3.3 To determine whether a mixture containing corrosive substances shall be considered a corrosive mixture and to assign a packing group, the calculation method in the flow chart in Figure 2.8.4.3 shall be applied. When a specific concentration limit is assigned to a substance following its entry in the Dangerous Goods List or in a Special Provision, this limit shall be used instead of the generic limits in Figure 2.8.4.3.

Figure 2.8.4.3: Calculation method



2.8.5 Substances not accepted for transport

Chemically unstable substances of Class 8 shall not be accepted for transport unless the necessary precautions have been taken to prevent the possibility of a dangerous decomposition or polymerization under normal conditions of transport. For the precautions necessary to prevent polymerization, see special provision 386 of Chapter 3.3. To this end particular care shall be taken to ensure that receptacles and tanks do not contain any substances liable to promote these reactions.”

Annex II

Proposal for revision of Chapter 2.8 of the Model Regulations

“Chapter 2.8

Class 8 – Corrosive substances

2.8.1 Definition and general provisions

2.8.1.1 *Corrosive substances* are substances which, by chemical action, will cause irreversible damage to the skin, or, in the case of leakage, will materially damage, or even destroy, other goods or the means of transport.

2.8.1.2 For substances and mixtures that are corrosive to skin, general classification provisions are provided in section 2.8.2. [Skin corrosion refers to the production of irreversible damage to the skin, namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.] [A substance is corrosive to skin when it leads to the destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure for up to 4 hours.]

2.8.1.3 Liquids and solids which may become liquid during transport, which are judged not to be skin corrosive shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.3.3 (c) (ii).

2.8.2 General classification provisions

2.8.2.1 Substances and mixtures of Class 8 are divided among the three packing groups according to their degree of danger in transport:

- (a) *Packing group I* is assigned to very dangerous substances and mixtures;
- (b) *Packing group II* is assigned to substances and mixtures presenting medium danger;
- (c) *Packing group III* is assigned to substances and mixtures that present minor danger.

2.8.2.2 Allocation of substances listed in the Dangerous Goods List in Chapter 3.2 to the packing groups in Class 8 has been made on the basis of experience taking into account such additional factors as inhalation risk (see 2.8.2.4) and reactivity with water (including the formation of dangerous decomposition products).

2.8.2.3 New substances and mixtures can be assigned to packing groups on the basis of the length of time of contact necessary to produce [full thickness destruction of human skin] in accordance with the criteria in 2.8.3. Alternatively, for mixtures, the criteria in 2.8.4 can be used.

2.8.2.4 A substance or mixture meeting the criteria of Class 8 having an inhalation toxicity of dusts and mists (LC₅₀) in the range of packing group I, but toxicity through oral

ingestion or dermal contact only in the range of packing group III or less, shall be allocated to Class 8 (see note under 2.6.2.2.4.1).

2.8.3 Packing group assignment

2.8.3.1 Existing human and animal data including information from single or repeated exposure shall be the first line of evaluation, as they give information directly relevant to effects on the skin.

2.8.3.2 In assigning the packing group in accordance with 2.8.2.2, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404⁶ or 435⁷. A substance or mixture which is determined not to be corrosive in accordance with OECD Test Guideline 430⁸ or 431⁹ may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

2.8.3.3 Packing groups are assigned to corrosive substances in accordance with the following criteria:

- (a) Packing group I is assigned to substances that cause full thickness destruction of the intact skin tissue within an observation period up to 60 minutes starting after the exposure time of three minutes or less;
- (b) Packing group II is assigned to substances that cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than three minutes but not more than 60 minutes;
- (c) Packing group III is assigned to substances that:
 - (i) Cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours; or
 - (ii) are judged not to cause full thickness destruction of intact skin tissue but which exhibit a corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials. For the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37-2), S275J2G3+CR (1.0144 resp. St 44-3), ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type or SAE 1020, and for testing aluminium, non-clad, types 7075-T6 or AZ5GU-T6 shall be used. An acceptable test is prescribed in the Manual of Tests and Criteria, Part III, Section 37.

NOTE: Where an initial test on either steel or aluminium indicates the substance being tested is corrosive the follow up test on the other metal is not required.

Table 2.8.3.4: Table summarizing the criteria in 2.8.3.3

Packing Group	Exposure Time	Observation Period	Effect
I	≤ 3 min	≤ 60 min	Full thickness destruction of intact skin

⁶ [OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2015]

⁷ [OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2015]

⁸ [OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2015]

⁹ [OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2015]

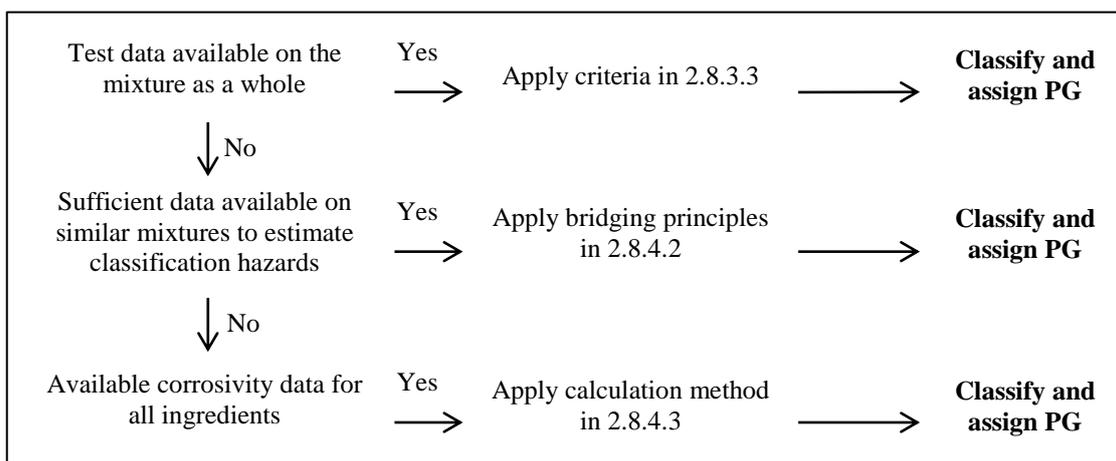
II	> 3 min ≤ 1 h	≤ 14 d	Full thickness destruction of intact skin
III	> 1 h ≤ 4 h	≤ 14 d	Full thickness destruction of intact skin
III	-	-	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials

2.8.4 Alternative packing group assignment methods of mixtures corrosive to skin: Step-wise approach

2.8.4.1 General provisions

2.8.4.1.1 For mixtures it is necessary to obtain or derive information that allows the criteria to be applied to the mixture for the purpose of classification and assignment of packing groups. The approach to classification and assignment of packing groups is tiered, and is dependent upon the amount of information available for the mixture itself, for similar mixtures and/or for its ingredients. The flow chart of Figure 2.8.4.1 below outlines the process to be followed:

Figure 2.8.4.1: Step-wise approach to classify and assign packing group of corrosive mixtures



2.8.4.2 Bridging principles

2.8.4.2.1 Where a mixture has not been tested to determine its skin corrosion potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately classify and assign a packing group for the mixture, these data will be used in accordance with the following bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

- (a) **Dilution:** If a tested mixture is diluted with a diluent which does not meet the criteria for Class 8 and does not affect the packing group of other ingredients, then the new diluted mixture may be assigned to the same packing group as the original tested mixture.

Note: in certain cases, diluting a mixture or substance may lead to an increase in the corrosive properties. If this is the case, this bridging principle cannot be used.

- (b) **Batching:** The skin corrosion potential of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the skin corrosion potential of the untested batch has changed. If the latter occurs, a new classification is necessary.
- (c) **Concentration of mixtures of packing group I:** If a tested mixture meeting the criteria for inclusion in packing group I is concentrated, the more concentrated untested mixture may be assigned to packing group I without additional testing.
- (d) **Interpolation within one packing group:** For three mixtures (X, Y and Z) with identical ingredients, where mixtures X and Y have been tested and are in the same skin corrosion packing group, and where untested mixture Z has the same Class 8 ingredients as mixtures X and Y but has concentrations of Class 8 ingredients intermediate to the concentrations in mixtures X and Y, then mixture Z is assumed to be in the same skin corrosion packing group as X and Y.
- (e) **Substantially similar mixtures:** Given the following:
- (i) Two mixtures: (X+Y) and (Z+Y);
 - (ii) The concentration of ingredient Y is the same in both mixtures;
 - (iii) The concentration of ingredient X in mixture (X+Y) equals the concentration of ingredient Z in mixture (Z+Y);
 - (iv) Data on skin corrosion for X and Z are available and substantially equivalent, i.e. they are the same skin corrosion packing group and do not affect the skin corrosion potential of Y.
- If mixture (X+Y) or (Z+Y) is already classified based on test data, then the other mixture may be assigned to the same packing group.

2.8.4.3 *Calculation method based on the classification of the substances*

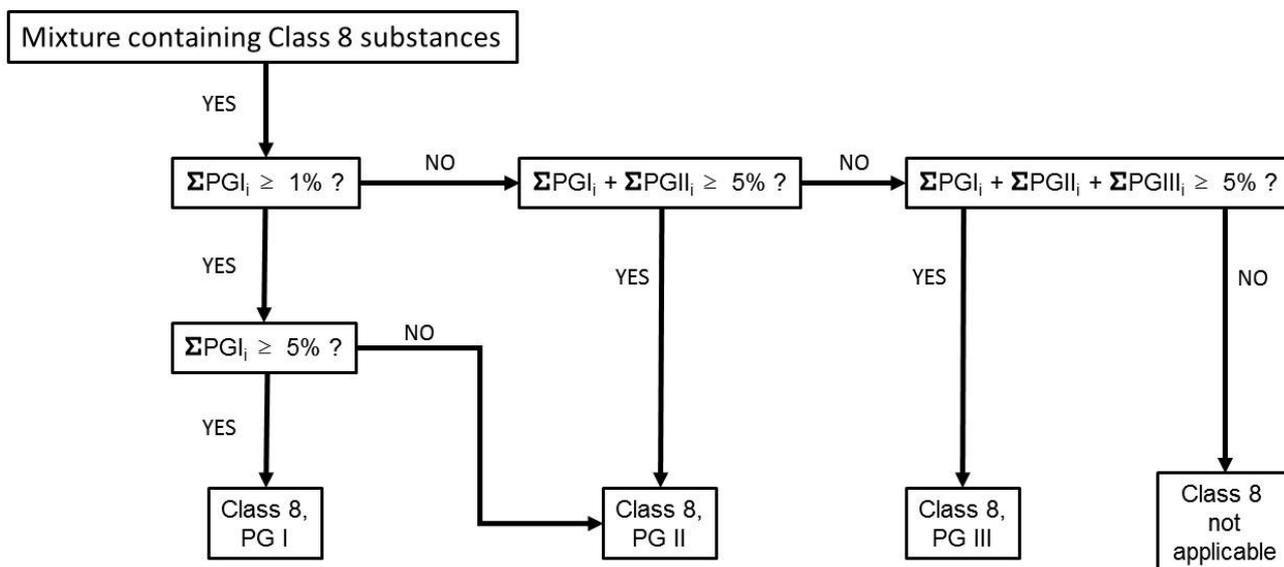
2.8.4.3.1 Where a mixture has not been tested to determine its skin corrosion potential, nor is sufficient data available on similar mixtures, the corrosive properties of the substances in the mixture shall be considered to classify and assign a packing group. This is possible when all substances in the mixture (i.e. present in concentrations of >1%) are considered for classification in accordance with Chapter 2.

Applying the calculation method is only allowed if there are no synergistic effects that make the mixture more corrosive than the sum of its substances. This restriction applies only if packing group II or III would be assigned to the mixture.

2.8.4.3.2 When using the calculation method, all Class 8 ingredients present at a concentration of $\geq 1\%$ shall be taken into account, or $<1\%$ if these ingredients are still relevant for classifying the mixture to be corrosive to skin.

2.8.4.3.3 To determine whether a mixture containing corrosive substances shall be considered a corrosive mixture and to assign a packing group, the calculation method in the flow chart in Figure 2.8.4.3 shall be applied. When a specific concentration limit is assigned to a substance following its entry in the Dangerous Goods List or in a Special Provision, this limit shall be used instead of the generic limits in Figure 2.8.4.3.

Figure 2.8.4.3: Calculation method



2.8.5 Substances not accepted for transport

Chemically unstable substances of Class 8 shall not be accepted for transport unless the necessary precautions have been taken to prevent the possibility of a dangerous decomposition or polymerization under normal conditions of transport. For the precautions necessary to prevent polymerization, see special provision 386 of Chapter 3.3. To this end particular care shall be taken to ensure that receptacles and tanks do not contain any substances liable to promote these reactions.

Annex III

Proposal for revision of Chapter 2.8 of the Model Regulations

“Chapter 2.8

Class 8 – Corrosive substances

2.8.1 Definition and general provisions

2.8.1.1 *Corrosive substances* are substances which, by chemical action, will cause irreversible damage to the skin, or, in the case of leakage, will materially damage, or even destroy, other goods or the means of transport.

2.8.1.2 For substances and mixtures that are corrosive to skin, general classification provisions are provided in section 2.8.2. For substances and mixtures that are corrosive to skin, packing group assignment is determined using criteria in section 2.8.2, where they will be assigned to a packing group. [Skin corrosion refers to the production of irreversible damage to the skin, namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.] [A substance is corrosive to skin when it leads to the destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure for up to 4 hours.] Packing group determination can alternatively be derived for substances using the criteria in section 2.8.3 and for mixtures using the criteria in section 2.8.4.

2.8.1.3 Liquids and solids which may become liquid during transport, which are judged not to be skin corrosive shall still be considered for their potential to cause corrosion to certain metal surfaces in accordance with the criteria in 2.8.23.43(c) (ii).

2.8.2 Assignment of packing groups General classification provisions

2.8.2.1 Substances and mixtures of Class 8 are divided among the three packing groups according to their degree of hazard-danger in transport ~~in accordance with the following criteria:~~

- (a) *Packing group I* is assigned to very dangerous substances and mixtures that cause full thickness destruction of intact skin tissue within an observation period up to 60 minutes starting after the exposure time of three (3) minutes or less;
- (b) *Packing group II* is assigned to substances and mixtures presenting medium danger that cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than three (3) minutes but not more than 60 minutes;
- (c) *Packing group III* is assigned to substances and mixtures that present minor danger, ~~and:~~
 - (i) ~~— cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours; or~~

(ii) — are judged not to cause full thickness destruction of intact skin tissue but which exhibit a corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials. For the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37 2), S275J2G3+CR (1.0144 resp. St 44 3), ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type or SAE 1020, and for testing aluminium, non clad, types 7075 T6 or AZ5GU T6 shall be used. An acceptable test is prescribed in the Manual of Tests and Criteria, Part III, Section 37.

NOTE: Where an initial test on either steel or aluminium indicates the substance being tested is corrosive the follow up test on the other metal is not required.

Table 2.8.2.1: Table summarizing the criteria in 2.8.2.1

Packing Group	Exposure Time	Observation Period	Effect
I	≤ 3 min	≤ 60 min	Full thickness destruction of intact skin
II	> 3 min ≤ 1 h	≤ 14 d	Full thickness destruction of intact skin
III	> 1 h ≤ 4 h	≤ 14 d	Full thickness destruction of intact skin
III	—	—	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials

2.8.2.2 Allocation of substances listed in the Dangerous Goods List in Chapter 3.2 to the packing groups in Class 8 has been made on the basis of experience taking into account such additional factors as inhalation risk (see 2.8.2.4) and reactivity with water (including the formation of dangerous decomposition products).

2.8.2.3 New substances and mixtures can be assigned to packing groups on the basis of the length of time of contact necessary to produce full thickness destruction of human skin in accordance with the criteria in 2.8.32.1.3; alternatively, for substances the criteria in 2.8.3 can be used and for mixtures, the criteria in 2.8.4 can be used.

2.8.2.4 A substance or mixture meeting the criteria of Class 8 having an inhalation toxicity of dusts and mists (LC₅₀) in the range of packing group I, but toxicity through oral ingestion or dermal contact only in the range of packing group III or less, shall be allocated to Class 8 (see note under 2.6.2.2.4.1).

2.8.2.5 — When assigning the packing group to a substance or mixture in accordance with 2.8.2.3, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404¹⁰ or 435¹¹. A substance or mixture which is determined not to be corrosive in accordance with OECD Test Guideline 430¹² or 431¹³ may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

¹⁰ OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 201502

¹¹ OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 201506

¹² OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 20042015

2.8.3 Packing group assignment of substances corrosive to skin

2.8.3.1 Classification based on experimental data

2.8.3.1.1 A substance is corrosive to skin and assigned to the appropriate packing group when it produces irreversible destruction of skin tissue following the application of the substance for up to 4 hours as per the criteria in 2.8.2.1.

2.8.3.1.2 Existing human and animal data including information from single or repeated exposure shall be the first line of evaluation, as they give information directly relevant to effects on the skin.

2.8.3.1.23 In assigning the packing group in accordance with 2.8.2.2, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404¹⁴ or 435¹⁵. A substance or mixture which is determined not to be corrosive in accordance with OECD Test Guideline 430¹⁶ or 431¹⁷ may be considered not to be corrosive to skin for the purposes of these Regulations without further testing. *In vitro* alternatives that have been validated and accepted can be used to make classification decisions and assign packing groups, if the *in vitro* test method is suitable for this. Internationally accepted validated test methods for skin corrosion are listed in 2.8.2.5.

2.8.3.1.4 In some cases, sufficient information may be available from structurally related substances to make classification decisions in accordance with the OECD Guidance on Grouping of Chemicals¹⁸.

2.8.3.3 Packing groups are assigned to corrosive substances in accordance with the following criteria:

(a) Packing group I is assigned to substances that cause full thickness destruction of the intact skin tissue within an observation period up to 60 minutes starting after the exposure time of three minutes or less;

(b) Packing group II is assigned to substances that cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than three minutes but not more than 60 minutes;

(c) Packing group III is assigned to substances that:

(i) Cause full thickness destruction of intact skin tissue within an observation period up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours; or

¹³ OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2015⁰⁴

¹⁴ [OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2015]

¹⁵ [OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2015]

¹⁶ [OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2015]

¹⁷ [OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" 2015]

¹⁸ Organisation for Economic Co-operation and Development. 2014. Guidance on Grouping of Chemicals, Second Edition. Paris (FR): OECD, Environment Directorate. (Series on Testing and Assessment No. 194). Report No.: ENV/JM/MONO(2014)4, JT03356214. Available from: [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2014\)4&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en)

(ii) are judged not to cause full thickness destruction of intact skin tissue but which exhibit a corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials. For the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37-2), S275J2G3+CR (1.0144 resp. St 44-3), ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type or SAE 1020, and for testing aluminium, non-clad, types 7075-T6 or AZ5GU-T6 shall be used. An acceptable test is prescribed in the Manual of Tests and Criteria, Part III, Section 37.

NOTE: Where an initial test on either steel or aluminium indicates the substance being tested is corrosive the follow up test on the other metal is not required.

Table 2.8.3.4: Table summarizing the criteria in 2.8.3.4

Packing Group	Exposure Time	Observation Period	Effect
I	< 3 min	≤ 60 min	Full thickness destruction of intact skin
II	> 3 min < 1 h	≤ 14 d	Full thickness destruction of intact skin
III	> 1 h < 4 h	≤ 14 d	Full thickness destruction of intact skin
III	I	I	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55 °C when tested on both materials

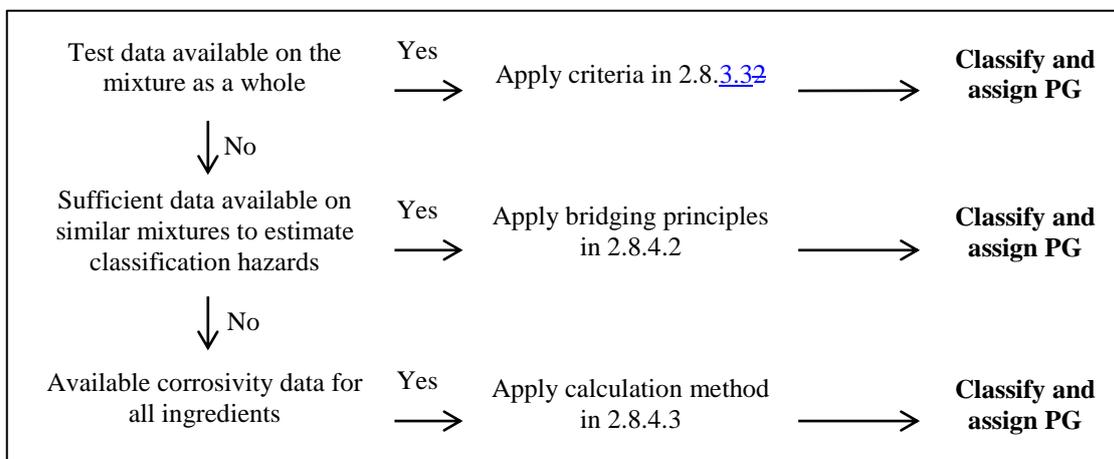
2.8.4 Packing Alternative packing group assignment methods of mixtures corrosive to skin: Step-wise approach

2.8.4.1 General provisions

2.8.4.1.1 Where sufficient test data from in vivo or in vitro tests is available for classification, the mixture shall be classified using the criteria for substances in 2.8.2.1 as illustrated in Table 2.8.2.1.

2.8.4.1.2.1 For mixtures, it is necessary to obtain or derive information that allows the criteria to be applied to the mixture for the purpose of classification and assignment of packing groups. The approach to classification and assignment of packing groups is tiered, and is dependent upon the amount of information available for the mixture itself, for similar mixtures and/or for its ingredients. The flow chart of Figure 2.8.4.1 below outlines the process to be followed:

Figure 2.8.4.1: Step-wise approach to classify and assign packing group of corrosive mixtures



2.8.4.2 *Bridging principles*

2.8.4.2.1 Where a mixture has not been tested to determine its skin corrosion potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately classify [and assign a packing group for](#) the mixture, these data [may will](#) be used in accordance with the following bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

- (a) **Dilution:** ~~Unless the consideration of synergistic or antagonistic effects suggests otherwise, if~~ a tested mixture is diluted with a diluent which does not meet the criteria for Class 8 and does not affect the packing group of other ingredients, then the new diluted mixture may be assigned to the same packing group as the original tested mixture.

[Note: in certain cases, diluting a mixture or substance may lead to an increase in the corrosive properties. If this is the case, this bridging principle cannot be used.](#)

- (b) **Batching:** The skin corrosion potential of a tested production batch of a mixture [may can](#) be assumed to be substantially equivalent to that of another untested production batch of the same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the skin corrosion potential of the untested batch has changed. If the latter occurs, a new classification is necessary.

- (c) **Concentration of mixtures of packing group I:** If a tested mixture meeting the criteria for inclusion in packing group I is concentrated, the more concentrated untested mixture may be assigned to packing group I without additional testing.

- (d) **Interpolation within one packing group:** For three mixtures (X, Y and Z) with identical ingredients, where mixtures X and Y have been tested and are in the same skin corrosion packing group, and where untested mixture Z has the same [active-Class 8](#) ingredients as mixtures X and Y but has concentrations of [active-Class 8](#) ingredients intermediate to the concentrations in mixtures X and Y, then mixture Z is assumed to be in the same skin corrosion packing group as X and Y.

- (e) **Substantially similar mixtures:** Given the following:
- (i) Two mixtures: (X+Y) and (Z+Y);
 - (ii) The concentration of ingredient Y is the same in both mixtures;
 - (iii) The concentration of ingredient X in mixture (X+Y) equals the concentration of ingredient Z in mixture (Z+Y);
 - (iv) Data on skin corrosion for X and Z are available and substantially equivalent, i.e. they are the same skin corrosion packing group, and do not affect the skin corrosion potential of Y.

If mixture (X+Y) or (Z+Y) is already classified based on test data, then the other mixture may be assigned to the same packing group.

2.8.4.3 *Calculation method based on the classification of the substances*

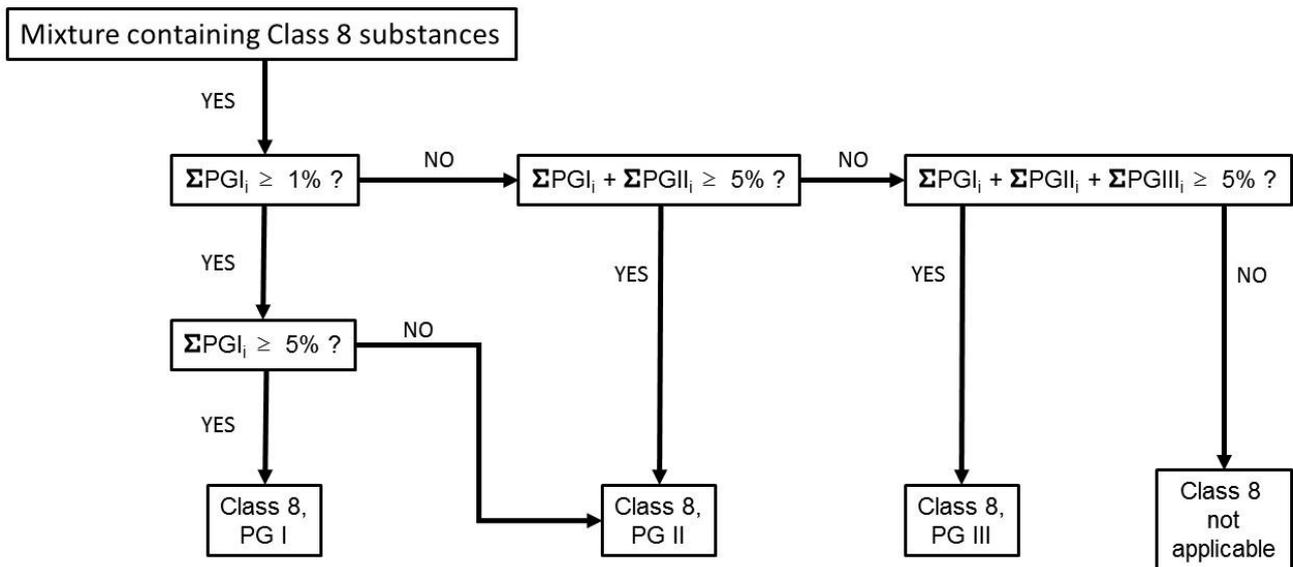
2.8.4.3.1 Where a mixture has not been tested to determine its skin corrosion potential, nor is sufficient data available on similar mixtures, the corrosive properties of the substances in the mixture shall be considered to classify and assign a packing group. This is possible when all substances in the mixture (i.e. present in concentrations of >1%) are considered for classification in accordance with Chapter 2.

Applying the calculation method is only allowed if there are no synergistic effects ~~known~~ that make the mixture more corrosive than the sum of its substances. This restriction applies only if packing group II or III would be assigned to the mixture.

2.8.4.3.2 When using the calculation method, all Class 8 ingredients present at a concentration of > 1% shall be taken into account. The generic cut off value for the corrosive substances to be taken into account is 1%, or <1% if there is a presumption that these ingredients present at a concentration <1% can still be relevant for classifying the mixture to be corrosive to skin.

2.8.4.3.3 To determine whether a mixture containing corrosive substances shall be considered a corrosive mixture and to assign a packing group, the calculation method in the flow chart in Figure 2.8.4.3 shall be applied. When a specific concentration limit is assigned to a substance following its entry in the Dangerous Goods List or in a Special Provision, this limit shall be used instead of the generic limits in Figure 2.8.4.3.

Figure 2.8.4.3: Calculation method



2.8.5 Substances not accepted for transport

Chemically unstable substances of Class 8 shall not be accepted for transport unless the necessary precautions have been taken to prevent the possibility of a dangerous decomposition or polymerization under normal conditions of transport. For the precautions necessary to prevent polymerization, see special provision 386 of Chapter 3.3. To this end particular care shall be taken to ensure that receptacles and tanks do not contain any substances liable to promote these reactions.