Application of data for mixtures when additivity may not apply (paras 3.2.3.3.4 and 3.3.3.3.4)

(a) Skin corrosion/irritation

Ingredient information:

Ingredient	Wt%	Classification	Ingredient information
Ingredient 1	4	Skin Category 1	pH = 1.8
Ingredient 2	5	Skin Category 2	-
Ingredient 3	5	Skin Category 3	-
Ingredient 4	86	-	No data available

Mixture information: Mixture pH = 4.0

Answer:

For this mixture, the classification was assigned as a Category 1 because ingredient 1 (Category 1) is in the mixture at ≥ 1%

Rationale:

(a) Classification via application of substance criteria is not possible since test data (other than a pH) was not provided for the mixture (paragraph 3.2.3.1.1);

(b) The overall mixture pH of 4.0 does not result in classification in Category 1 since this does not fall within the criteria of pH ≤ 2 or pH ≥ 11.5 (paragraph 3.2.3.1.2);

(c) Classification via the application of bridging principles is not possible since data on a similar mixture was not provided (paragraph 3.2.3.2.1);

(d) Classification of the mixture based on ingredient data can be considered (paragraph 3.2.3.3);

(e) Ingredient 1 with a pH = 1.8 is an ingredient for which additivity might not apply as described in paragraph 3.2.3.3.4 and summarized in Table 3.2.4. Expert judgment would be needed to determine whether or not additivity applies. Knowledge of the components is important. Given the limited information in this example, the classifier of this mixture chose to apply non-additivity for a conservative approach. Without information on the mode of action of Ingredient 1, the mixture could be corrosive regardless of the overall pH. Therefore, the criteria described in paragraph 3.2.3.3.4 were applied (i.e. "A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table 3.2.3, due to chemical characteristics that make this approach unworkable, should be classified as skin Category 1 if it contains ≥ 1% of a corrosive ingredient and as skin Category 2/3 when it contains ≥ 3% of an irritant ingredient").

(b) Serious eye damage/eye irritation

Ingredient information:

Ingredient	Wt%	Classification	Ingredient information
Ingredient 1	0.5	Eye Category 1	-
Ingredient 2	3.5	Eye Category 2	Surfactant
Ingredient 3	15	-	-
Ingredient 4	15	-	-
Ingredient 5	66	-	No data available

Answer: Mixture is Category 2 because:

(a) Mixture contains 0.5% of an Eye Category 1 which is not ≥ 1% so the mixture is not Category 1;

(b) Mixture contains 3.5% of an Eye Category 2 which is ≥ 3.0% so the mixture is Category 2

Rationale:

(a) Classification via application of substance criteria is not possible since test data was not provided for the mixture (paragraph 3.3.3.1).

(b) Classification considering the pH of the mixture is not possible as the pH was not provided (paragraph 3.3.3.1).

(c) Classification via the application of bridging principles is not possible since data on a similar mixture was not provided (paragraph 3.3.3.2.1).

(d) Classification of the mixture based on ingredient data can be considered (paragraph 3.3.3.3).

(e) Ingredient 2 (Surfactant) is an ingredient for which additivity might not apply as described in paragraph 3.3.3.3.4 and summarized in Table 3.3.4. Expert judgment would be needed to determine whether or not additivity applies. Knowledge of the components is important. Given the limited information in this example, the classifier of this mixture chose to apply non-additivity for a conservative approach. Therefore, the criteria described in paragraph 3.3.3.3.4 apply (i.e., "A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table 3.3.3, due to chemical characteristics that make this approach unworkable, should be classified as Eye Category 1 if it contains ≥ 1% of a corrosive ingredient and as Eye Category 2/3 when it contains ≥ 3% of an irritant ingredient").

(Reference document: ST/SG/AC.10/C.4/2008/23, Annex 2, Example 5)