Application of the relevant ingredients concept for mixtures in the Skin/Eye chapters

Serious eye damage/Eye irritation

<u>Ingredient information:</u>

Ingredient	Wt%	Classification	Ingredient information
Ingredient 1	91	-	-
Ingredient 2	5	Eye Category 2A	-
Ingredient 3	3	-	-
Ingredient 4	0.9	Eye Category 1	-
Ingredient 5	0.1	-	-

<u>Answer:</u>

Mixture is Category 2 because:

Equations from Table 3.3.3

Category 1 calculations:

(a) $\sum$%Eye Category 1 = 0.9 which is not $\geq$ 3%
(b) $\sum$%Skin Category 1 = 0.0 which is not $\geq$ 3%
(c) $\sum$%Skin Category 1 + $\sum$%Eye Cat 1 = 0.9 which is not $\geq$ 3%

Category 2 calculations:

(d) $\sum$%Eye Category 1= 0.9 which is not $\geq$ 1% but < 3%
(e) $\sum$% Skin Category 1 = 0 which is not $\geq$ 1% but < 3%
(f) $\sum$%Eye Category 2/2A = 5 which is not $\geq$ 10%
(g)   (10$\times$ $\sum$%Eye Category 1) + $\sum$%Eye Category 2/2A = (10 $\times$ 0.9) + 5 = 14% which is $\geq$ 10%

<u>Rationale:</u>

(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 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)   Expert judgment is necessary when applying the "relevant ingredients" concept from paragraph 3.3.3.3.1 since ingredient 4 (Eye Category 1) is below 1%. In this case the relatively high concentration of Ingredient 4 (i.e., 0.9%) and application of the additivity approach which includes a weighting factor for Category 1 ingredients weighs in favor of including ingredient 4 in the additivity calculations. In fact, for this particular example if ingredient 4 was not considered relevant and was ignored during the calculations the mixture would not be classified because the concentration of ingredient 2 (Eye Category 2A) is not high enough to cause the additivity equations in Table 3.3.3 to exceed the cut-off value/concentration limits;

(f)   The additivity approach described in paragraphs 3.3.3.3.2 and 3.3.3.3.3 applies and the cut-off value/concentration limits provided in Table 3.3.3 are used for classification.

(Ref. doc.: ST/SG/AC.10/C.4/2008/23, Annex 2, Example 6)