

## Application of the guidance in para 3.8.3.4.5: whether or not additivity should be considered for specific target organ toxicity – single exposure Category 3 transient effects

Ingredient information:

Ingredient	Wt%	Classification
Ingredient 1	0.5	-
Ingredient 2	3.5	Category 3 – Respiratory Tract Irritation
Ingredient 3	15	Category 3 - Narcotic effects
Ingredient 4	15	Category 3 - Narcotic effects
Ingredient 5	66	-

Answer:

Mixture is Category 3 – Narcotic effects

$\Sigma\%$ Category 3 – Narcotic effects = 15% + 15% = 30% which is > 20%, therefore classify as Category 3 – Narcotic Effects

$\Sigma\%$ Category 3 – Respiratory Irritation = 3.5%, which is < 20%, not classified for Respiratory Irritation

Rationale:

- Classification via application of substance criteria is not possible since test data was not provided for the mixture (paragraph 3.8.3.2);
- Classification via the application of bridging principles is not possible since data on a similar mixture was not provided (paragraph 3.8.3.3.1);
- Application of paragraph 3.8.3.4.5 is used for classification. Expert judgement is necessary when applying this paragraph. Paragraph 3.8.3.4.5 notes that a cut-off value/concentration limit of 20% has been suggested, but that the cut-off value/concentration limit at which effects occur may be higher or less depending on the Category 3 ingredient(s). In this case, the classifiers judged that 30% is sufficient to classify.

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(Reference document: ST/SG/AC.10/C.4/2008/23, Annex 2, Example 7)