

Classification Process

This process is a guide to help experts through classification for skin and eye irritancy/corrosion endpoints.

Step 1: Identify all the ingredients (including impurities, additives, etc.) in the mixture along with their % w/w concentration, skin/eye classifications (including source of classification and any Specific Concentration Limit) and ingredient type/family (e.g. anionic surfactant, builder, organic acid, etc.). Highlight those that have an irritation potential (see Table 3 in the body text).

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Step 2: Check pH of the formulation:

- a. Extreme pH (pH ≤ 2 or ≥ 11.5):
 - i. First refer to the fourth paragraph of the ECHA guidance '3.2.3.2.1.1 Mixtures with extreme pH' or the first paragraph of the ECHA guidance '3.3.3.2.1.1 Mixtures with extreme pH'¹: *'Where the mixture has an extreme pH value but the only corrosive/irritant ingredient present in the mixture is an acid or base with an assigned SCL (either CLP Annex VI or set by supplier), then the mixture should be classified accordingly. In this instance, pH of the mixture should not be considered a second time since it would have already been taken into account when deriving the SCL for the substance.'*
 - ii. If (i) is not applicable, measure acid/alkaline reserve; if no test data on mixture itself, apply Bridging Principles as of step 3 with the condition of matching pH/AR or
 - iii. test depending on pH/AR (following extreme pH provisions)
- b. Not extreme pH:
 - i. if no ingredients classified for skin present, then mixture is not classified for skin; same applies for eye; document classification decision accordingly
 - ii. if ingredients are classified for skin/eye, go to step 3

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Step 3: If mixture is a modification² (e.g. minor changes in ingredient levels, substitution or addition of one or more ingredients) of a previously tested mixture classified as hazardous³, can 'permitted variations' Bridging Principle (CLP Art 15 + Annex 1, 1.1.3.6) be applied?

If YES, classify accordingly

If No, go to step 4

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Step 4:

If dilution⁴ or batching⁴ criteria apply: classify accordingly. Otherwise go to step 5.

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Step 5

If no data on the mixture itself or available data but not adequate for using the classification criteria for substances (CLP Annex 1, 3.2.2 for skin effects and 3.3.2 for eye effects), select possible tested mixtures and apply bridging principles;

¹ See ECHA Guidance on the application of CLP criteria (http://echa.europa.eu/documents/10162/13562/clp_en.pdf)

² See section 2 of the body text: '2.Evaluation of the degree of mixture modification: the concept of "Minor Modifications"'

³ Refer to example in Appendix 4 on Expert judgment for using 'permitted variations' in case of a non-classified mixture.

⁴ See section 3 of body text: '3. Assessment of new mixtures on the basis of existing toxicological information on similar mixtures'

Go to Step 6

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Step 6: Are there two possible tested mixtures with same hazard classification which could be used for 'interpolation within one hazard category'⁵ Bridging Principle (as strictly defined in CLP Annex 1, 1.1.3.4)?

If YES and can apply interpolation, classify accordingly

If NO, go to step 7

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Step 7: Is there a possible tested mixture which could be used for 'substantially similar mixtures'⁵ Bridging Principle (as strictly defined in CLP Annex 1, 1.1.3.5)?

If YES and can apply Bridging Principles, classify accordingly

If NO, go to step 8

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Step 8: Is (are) there possible tested mixture(s) which could be used for read-across based on Weight of Evidence using Expert Judgement⁶?

If YES and can apply Weight of Evidence with Expert Judgement, classify accordingly

If NO, apply summation method and classify accordingly (see ECHA guidance¹ for further details) or consider generating new data according to alternative test methods (e.g. in vitro) and classify accordingly.

⁵ See section 3 of body text: '3. Assessment of new mixtures on the basis of existing toxicological information on similar mixtures'

⁶ See section 4.5 of the body text: '4.5. Use of expert judgement', including '4.5.1.Expert qualification', and section '4.6.Weighing of information'