Classification of a mixture for skin corrosion/irritation and serious eye damage/irritation following the tiered evaluation approach using serious eye damage/eye irritation *in vitro* data from a Bovine Corneal Opacity and Permeability (BCOP) test (OECD TG 437)

This example uses Serious Eye Damage/Eye Irritation *in vitro* data from a Bovine Corneal Opacity and Permeability (BCOP) test (OECD TG 437) to illustrate classification of a mixture following the proposed tiered evaluation approach in GHS Chapter 3.3.

Information on Mixture A

pH of mixture (neat liquid): 7 – 8

Mixture is not classified for skin corrosion/irritation based on test data

Composition:

Ingredient	Weight %	Skin/Eye classification
Ingredient 1	22.06	Eye Cat. 1; Skin Cat. 2
Ingredient 2	4.00	Eye Cat. 1; Skin Cat. 2
Ingredient 3	5.50	Eye Cat. 2A
Ingredient 4	8.00	Not classified *
Ingredient 5	0.05	Not classified *
Ingredient 6	0.2	Not classified *
Water	60.19	Not classified

* *Not classified for skin corrosion/irritation or serious eye damage/eye irritation based on test data*

Test data:

BCOP test data			
	Mean opacity value	Mean permeability OD_{490} value	IVIS
Mixture	15	5	90
Concurrent positive and negative controls acceptable			

IVIS: *In Vitro* Irritancy Score

IVIS = mean opacity value + (15 x mean permeability OD_{490} value)

A test sample that induces an IVIS $\geq$ 55.1 is defined as a corrosive or severe irritant to eyes.

Classification of Mixture A

Answer:

Applying the proposed tiered evaluation approach in GHS Chapter 3.3, Mixture A is classified as Serious Eye Damage Category 1 based on test data.

Based on the information of the ingredients of the mixture and generic concentration limits Mixture A is classified as Skin Irritation Category 2.

Rationale:

(a) Classification based on existing human eye data is not possible since such data are not available;

(b) Classification via application of substance criteria in GHS Table 3.3.1 and Table 3.3.2 is not possible since existing animal data are not available;

(c) Test results derived using the BCOP test method indicate Mixture A is a corrosive or severe eye irritant.

(d) Classification of the mixture based on ingredient information should be considered for skin irritation (GHS paragraph 3.2.3.3.2 and Table 3.2.3).

(Ref.Doc: ST/SG/AC.10/C.4/2012/25, Annex 3)