



Detergent Industry Network for CLP Classification

CLASSIFICATION RECORD	
Skin/Eye Hazard Classification of Laundry/Home Care Products	
GENERAL INFORMATION	
Company	Company X
Mixture Name	General Purpose Cleaner
Product category	All purpose cleaner
Mixture number	APC001
PHYSICAL/ CHEMICAL PROPERTIES	
Physical form	Free flowing liquid
pH ¹	3.5
Acid / Alkaline reserve ²	Not needed since pH is not extreme
Other relevant information ³	Young et al.: no data
CLASSIFICATION	
Classification according to CLP criteria (skin/eye hazards)	Skin: Skin Irritation Cat. 2 Eye: Eye Irritation Cat. 2
Method used to derive Classification	Skin: CLP additivity approach Eye: Weight of Evidence with Expert Judgement
APPROVAL	
Classification derived by	O. Popolga
Classification completed	2016-09-29
Classification logged on DetNet website	2016-09-29
Classification logging number	DetNet/1234 (logging number as an example only)

1. neat liquid or 10% solution powders

2. Young et al method; expressed as grams NaOH [equivalent] per 100g test material

3. e.g. result of Young et al method calculation if applicable

Supporting Data / Justification Skin

Additivity approach: assessment of new mixture APC001 on the basis of existing toxicological information on data on for the individual ingredients.

The pH of the new mixture APC001 is in the range: $2 < \text{pH} < 11.5$; therefore the pH is not extreme and no need to determine the acidic reserve of the new mixture.

The new mixture APC001 does not contain any ingredient classified as Skin Corrosion Cat. 1 exceeding the cut-off for Skin corrosion cat 1 as such or in additivity with other substances thus the mixture itself is not classified as Skin Corrosion Cat. 1.

The classification of the new mixture APC001 is based on the CLP calculation method (additivity approach). It contains 10% Sulfuric acid, mono-C12-18-alkyl esters, sodium salts classified as Skin Irritation Cat. 2 and therefore is classified as Skin Irritation Cat. 2 (H315).

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Mixture Comparison Chart Skin

ID	Ingredient	CAS numbers	Skin Classification	Untested Mixture	TM Example2
Anionic surfactant					
6	Sulfuric acid, mono-C12-18-alkyl esters, sodium salts	68955-19-1	Skin Irritation Cat. 2	10	12
Nonionic surfactant					
1085	D-Glucopyranose, oligomeric, decyl octyl glycosides	68515-73-1	Not classified as hazardous to skin	4	6.4
Organic acid					
242	Citric acid	77-92-2	Not classified as hazardous to skin	2	0
332	Formic acid	64-18-6	Skin Corrosion Cat.1A	0	2
Alcohol/ Solvent					
286	Ethanol	64-17-5	Not classified as hazardous to skin	3	0
361	1-butoxypropan-2-ol	5131-66-8	Skin Irritation Cat. 2	0.3	3.3
Polycarboxylate/ Polymer					
246	Poly Acrylic Acid-Maleic Anhydride (PAA-MA) copolymer	52255-49-9	Not classified as hazardous to skin	0	2.2
Perfume					
2221	Perfume (not classified as hazardous for skin & eye)	n.a.	Not classified as hazardous to skin	0.15	0.2
Preservative					
203	2-bromo-2-nitropropane-1,3-diol	52-51-7	Skin Irritation Cat. 2	0.02	0
200	1,2-Benzisothiazol-3-one	2634-33-5	Skin Irritation Cat. 2	0.005	0.003
Minor					
1029	Water	7732-18-5	Not classified as hazardous to skin	80.525	73.897

Notes:

A table to justify Skin Irritation Cat. 2 by CLP additivity approach is not part of a DetNet classification record (as no Tested Mixtures is selected)

The Specific concentration limits (SCL) are not part of a DetNet classification record.

Supporting Data / Justification Eye

- The pH of the new mixture APC001 is in the range: $2 < \text{pH} < 11.5$; therefore the pH is not extreme and no need to determine the acidic reserve of the new mixture.
- The classification of formula APC001 is following CLP regulation EU No. 1272/2008 (article 9(3) and 1.1.1. Annex I), by determining the weight of evidence and applying expert judgement comparing it to tested mixture example 2 with validated in-vitro test OECD TG 438 (Isolated Chicken Eye test) with additional histopathological assessment of tissues), in-vivo test "Low Volume Eye test" and human data.
- The surfactants (Sulfuric acid, mono-C12-18-alkyl esters, sodium salts and D-Glucopyranose, oligomeric, decyl octyl glycosides) in the new mixture APC001 and the tested mixture are the same. The surfactants are in the same hazard category for effects on eyes. The ratio of anionic and non-ionic surfactant in the new mixture and the tested mixture is not identical, but similar. The total surfactant concentration in the new mixture is lower compared to the tested mixture - the new mixture APC001 is therefore less concentrated with respect to the surfactant content compared to the tested mixture.
- The tested mixture example 2 contains formic acid which is classified as Skin Corrosion Cat. 1A (and therefore Serious Eye Damage Cat. 1 also) in concentrated form. A concentration of only 2% is considered to be irritant to eyes (Eye Irritation Cat. 2) according to the specific concentration limits (SCL) for formic acid in Table 3.1. of CLP, annex VI. The new mixture contains citric acid, which requires a classification as Eye irritant Cat. 2 at a concentration of 10%. Although the amount of acid in the new mixture is the same as the acid in the tested mixture (i.e. 2%), the eye irritation potential of the formic acid contained in the tested mixture is higher (as indicated by the SCL).
- Both the new mixture APC001 and tested mixture example 2 contain equivalent amounts of solvents, which are in the same hazard category for effects on eyes. The solvent in the new mixture APC001 is Ethanol which possesses a lower irritation potential (Eye Irritation Cat. 2 > 50%) compared to the solvent contained in the tested mixture example 2 (1-butxypropan-2-ol, Eye Irritation Cat. 2 > 20%), which can be derived from the concentration limits for classification.
- All other ingredients contained are either not relevant to this toxicological endpoint or below the generic cut off values.
- For above mentioned reasons, the new mixture is less concentrated with regards to the amount of surfactants. Furthermore, the irritation potential of the contained acid as well as of the solvent is lower compared to the tested mixture. The new mixture APC001 is therefore assumed not to exceed the hazard category as the tested mixture example 2.
- Tested Mixture example 2 is classified as Eye Irritation Category 2. The new mixture APC001 is classified as Eye Irritation Cat. 2 (H319) based on the weight of evidence with expert judgement.

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Mixture Comparison Chart Eye

ID	Ingredient	CAS numbers	Eye Classification	Untested Mixture	TM Example 2
Anionic surfactant					
6	Sulfuric acid, mono-C12-18-alkyl esters, sodium salts	68955-19-1	Serious Eye Damage Cat. 1	10	12
Nonionic surfactant					
1085	D-Glucopyranose, oligomeric, decyl octyl glycosides	68515-73-1	Serious Eye Damage Cat. 1	4	6.4
Organic acid					
242	Citric acid	77-92-2	Eye Irritation Cat. 2	2	0
332	Formic acid	64-18-6	Serious Eye Damage Cat. 1	0	2
Alcohol/ Solvent					
286	Ethanol	64-17-5	Eye Irritation Cat. 2	3	0
361	1-butoxypropan-2-ol	5131-66-8	Eye Irritation Cat. 2	0.3	3.3
Polycarboxylate/ Polymer					
246	Poly Acrylic Acid-Maleic Anhydride (PAA-MA) copolymer	52255-49-9	Not classified as hazardous to eyes	0	2.2
Perfume					
2221	Perfume (not classified as hazardous for skin & eye)	n.a.	Not classified as hazardous to eyes	0.15	0.2
Preservative					
203	2-bromo-2-nitropropane-1,3-diol	52-51-7	Serious Eye Damage Cat. 1	0.02	0
200	1,2-Benzisothiazol-3-one	2634-33-5	Serious Eye Damage Cat. 1	0.005	0.003
Minor					
1029	Water	7732-18-5	Not classified as hazardous to eyes	80.525	73.897

Note:
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Summary of data for TM example 2:

Product Form: Free flowing liquid	Product Category: All-purpose cleaner
pH: 3.0	Acid/Alkaline Reserve: 0
Skin Classification: Not Tested	Eye Classification: eye irritation cat. 2 AISE_example 2_summary_OECD438 plus histopath.pdf AISE_example 2_summary_LVET.pdf Supportive: human data

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Table Example 2: Weight of evidence analyses for classification of All-purpose Cleaner APC001 for effects on eyes (use of testing and non-testing methods)

	Full Reference	Study result	Data quality Klimisch score	Adequacy and relevance	Coverage of relevant parameters/ observations Yes/No	Consistency	Conclusive remark
Existing human data on company-owned mixtures similar to APC001	PCC data collected over a 12 months period	<p>14 cases of mild to moderate eye effects only were reported out of all sold products*. In the cases where follow-up information was available, all ocular effects were fully reversible within a few days.</p> <p><i>*This is an example, in reality the number of cases will need to be identified relative to the number of products sold in a specific geographical area.</i></p>	Klimisch score is a method of assessing the reliability of toxicological studies, and is not applicable to PCC data.	Supportive information, limitation due to unknown dose and exposure duration. No CLP criteria for C&L based on human data.	No, not in every case all relevant parameters/ observations are covered (e.g. exposure conditions, detailed tissue effects).	Consistent with existing <i>in vivo</i> and <i>in vitro</i> studies as well as other human experience, which identify the All Purpose Cleaner A01 as not Cat. 1	Supportive data.
Existing human data on similar mixtures	MAGAM II Multicentre multi-national prospective, study of human eye exposures reported to Poisons Control Centres (PCCs), over a 24 months period (data collection from 6 to 18 months per PCC).	116 reported cases related to all-purpose cleaners: mild to moderate but no severe eye irritation after exposure. In the cases where follow-up information was available, all effects fully recovered within a few days.	Klimisch score is a method of assessing the reliability of toxicological studies, and is not applicable to PCC data.	Supportive information. Scoring based on PCC severity scoring system complemented by MAGAM reported symptoms. No CLP criteria for C&L based on human data. Information provided as a product category containing different products vs an individually named product.	Although not in every case all relevant parameters are available, (e.g. exposure conditions), tissue observations are conducted typically by an ophthalmologist and reported in a standardized way.	Consistent with existing <i>in vivo</i> and <i>in vitro</i> studies, which identify the All Purpose Cleaner A01 as not Cat. 1	Supportive data.

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Existing <i>in vivo</i> study on eye irritation corrosion	Low Volume Eye Test, A.I.S.E DetNet Robust Summary available, 2001	Eye Irrit. 2; H319, all effects reversed within 14 days and scores are not close to the border for classification as Eye Cat. 1, but closer to the border for no classification.	1	Key study similar to OECD 405 and conducted according to GLP: all endpoints covered.	Yes	Consistent with existing <i>in vitro</i> study and human experience data	Key data. LVET data are relevant for the use domain of detergents and cleaning products and to make classification decisions in a WoE approach.
<i>In vitro</i> data on eye irritation corrosion	Isolated Chicken Eye Test OECD 438 with histopathology as an additional endpoint 2015	No Prediction can be Made based on a combination of the endpoint categories of II;II;III. This combination of endpoint categories is much lower than those used to identify classification as Cat. 1. Not Cat. 1 based on criteria developed by Cazelle et al. (2014) for histopathological evaluation of non-pH-extreme detergents and cleaning products.	1	Key study conducted according to GLP. Due to histopathology, severity and persistence of effects are covered.	Yes	Consistent with existing <i>in vivo</i> study and human experience data, which identify the All Purpose Cleaner A01 as not Cat. 1	Key data. OECD 438 study with histopathology as an additional endpoint.
Physico-chemical properties	Determination of pH, acidity and alkalinity measurement according to OECD 122	pH is 3.0, A01 is therefore not pH-extreme	1	Supportive information because pH alone does not allow assessment of the eye irritancy.	Yes		Supportive data.
Overall conclusion	<p>Human experience data indicate only mild to moderate and fully reversible effects. LVET data indicate Cat. 2 hazard (i.e. eye irritation). <i>In vitro</i> data do not indicate the need for Cat. 1 classification (serious eye damage). pH does not indicate corrosion.</p> <p>In conclusion, a WoE evaluation of consistency, quality and relevance of all the available data allows a decision on the eye irritation/serious eye damage potential of the All Purpose Cleaner APC001. The All Purpose Cleaner APC001 should be classified as UN GHS Cat. 2.</p>						

Remark: This example has been developed only to illustrate how the classification of an untested mixture could be derived and justified. This does not contain any recommendation for a testing strategy.