



DUCC



Downstream Users of Chemicals Co-ordination group

Mixture classification and concentration ranges in safety data sheets

**Forum Open Session
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About DUCC

- DUCC is the **D**ownstream **U**users of **C**hemicals **C**oordination Group
- Founded in **2001**, DUCC is a platform of 11 European associations representing industry sectors that **formulate mixtures** (for consumers, professional or industrial users)
- DUCC members collectively represent:
 - more than **9000** companies in Europe
 - most of which are SMEs
 - a collective turnover > **€ 215 billion** (calculated value)

MAIN OBJECTIVE

To contribute, with a **common voice**, to the **successful** implementation of the requirements of the **REACH** and **CLP** Regulations



Who are we?

Adhesives &
Sealants



Detergents



Aerosols



Fragrances



Chemical
Distributors



Lubricants



Construction
Chemicals



Inks & Toners



Cosmetics



Paints



Crop Protection



10 ECHA Accredited Stakeholder Organisations.

Enforcement project findings

In the REF-6 project **17%** of inspected mixtures were reported as having an incorrect classification.

For 90% of mixtures inspectors used the composition in the safety data sheet to check the classification of the mixtures.

Forum enforcement projects have also regularly identified shortcomings in the quality of SDS checked, e.g.:

- 52% non-compliance in REF-2 (2013)
- 50% in joint Forum-ASO project (2019)
- 33% in REF-6 (2019)



Concentration ranges

Although not explicitly mentioned in the REF-6 report, the use of **concentration ranges** in section 3.2 of the SDS has been highlighted as a common issue by Forum members.

Companies are allowed to use ranges in their SDS, but may calculate the mixture classification using the actual concentration (lying within the range).

It is suggested that companies should use ranges that “do not span over several hazard classes and categories”.



However the problem is not usually quite so straightforward.

“This is problematic since inspectors often only have access to concentration ranges in safety data sheets and make their calculations based on the ‘worst case scenario’, so they might end up with a different classification than the owner of the data.”

Forum WG chair, ECHA Newsletter Feb 2020

Additivity in mixture classification

Percentage ranges are commonly used by industry in SDS s.3.2

- To accommodate inherent variability (natural, production, raw material ranges)
- To protect proprietary information (exact recipes)

The ranges used are typically pre-defined in the company's IT system and respect classification boundaries for the individual substance

For some hazard classes however, **additivity applies** and summation of relevant ingredients is required to classify the mixture correctly





- Unless using mixture test data or other methods such as weight of evidence

→ A mixture classification based on the sum of the actual concentrations might not reflect the worst-case sum of the ranges

Example

Detergent containing two surfactants classified as Eye Damage Cat. 1

Ingredient and classification	Actual concentration in mixture	Range specified in Section 3.2
Surfactant A Eye Cat. 1, no SCL	1.51%	1 – 2.5%
Surfactant B Eye Cat. 1, no SCL	1.01%	1 – 2.5%
Total	<i>Total concentration:</i> 2.52%	<i>Total of highest concentrations:</i> 5%
Classification and labelling based on calculation method¹:	Eye Cat. 2 Warning H319 Causes serious eye irritation 	Eye Cat. 1 Danger H318 Causes serious eye damage 

¹ Generic concentration limit for classification of mixture as Eye Cat.1 based on substances classified as Eye Cat.1 is 3%.
Generic concentration limit for classification of mixture as Eye Cat.2 based on substances classified as Eye Cat.1 is 1%.

Can this be fixed?

Adapting the ranges displayed in the SDS to enable correct summation would:

- Often require case-by-case manual intervention – difficult and impractical in a production environment
- Disclose proprietary recipe information
- Render the use of ranges redundant (top of range = actual concentration)



Is that necessary / appropriate?

Industry's view is that it is not, for several reasons:

- The purpose of the SDS is to communicate information on safe use to the recipient - not to audit the classification
- Suppliers can provide further information to inspectors (or downstream formulators) by agreement
- In the case of a mixture classified by testing or via bridging principles, the classification does not reflect the sum of the ranges → *acknowledged in GHS/REACH text*

GHS and REACH texts

GHS Annex 4:

“When using a proportion range, the health and environmental hazard effects should describe the effects of the highest concentration of each ingredient, provided that the effects of the mixture as a whole are not available.”

REACH Annex II (2020/878):

“When using a range of percentages, if the effects of the mixture as a whole are not available, the health and environmental hazards shall describe the effects of the highest concentration of each ingredient.

If the effects of the mixture as a whole are available, the classification determined from this information shall be included under section 2.”

Industry has raised this issue at UNSCEGHS* for consideration of a more practical wording...

* See [UN/SCEGHS/36/INF.20](https://www.unsceg.org/DocStoreDefault.aspx?DocId=1327)

Industry suggestion

“When using a range of percentages, the range for each substance should reflect relevant classification thresholds. The health and environmental hazards of the mixture should however describe the effects of the mixture as a whole **or the effects based on the actual concentration of each ingredient**, as appropriate.”

(Thought-starter, for discussion)

Questions to the Forum members

- Have you experienced such cases involving additivity? What was the outcome of your discussions with the supplier?
- Industry would prefer to be compliant!
Could you support a change to the REACH (and GHS) text to address this issue?
- In the meantime, can we find a pragmatic solution for enforcement?
 - e.g. a note in the SDS (section 2, 3 or 16), and follow-up dialogue between authorities and suppliers as required?