

Final version – agreed CG-44

Should a co-formulant triggering a supplemental labelling information (e.g. EUH208), but not the classification of the product, be considered as Substance of Concern (SoC) ?

The approach described below has been agreed during the CG-44 following an e-consultation started by Belgium CA the 26th October 2020.

Question 1 : Should a co-formulant triggering a supplemental labelling information (e.g. EUH208), but not the classification of the product, be considered as a SoC?

According article 3 (f) of Regulation (EU) 528/2012, Biocidal Products Regulation (hereafter referred as BPR), a SoC means “... *a substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation, ...*”.

According Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (hereafter referred as CLP regulation), EUH statement is not part of the definition of “Hazardous substances and mixtures”. They are considered as “supplemental information on the label or as special rules for labelling”.

Therefore, due to the definition of SoC in BPR, the EUH sentences that are a translation from classification under Directive 67/548/EEC (R phrases) have to be considered as SoC, for example EUH066.

However, EUH sentences that aren't a translation from the classification under Directive 67/548/EEC should not be considered as SoC, for example EUH208.

In conclusion, the following table is agreed:

EUH statement leading to the identification of a Substance of concern	EUH statement NOT leading to the identification of a Substance of concern
EUH001 (R1)	EUH070
EUH014 (R14)	EUH201
EUH018 (R18)	EUH201A
EUH019 (R19)	EUH202
EUH044 (R44)	EUH203
EUH029 (R29)	EUH204
EUH031 (R31)	EUH205
EUH032	EUH206

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(R32)	
EUH066 (R66)	EUH207
EUH071 (R39-41)	EUH208
	EUH209 EUH209A
	EUH210
	EUH401

Question 2a: if the answer to the first question is yes, then should the co-formulant be allocated to band A following Annex A: Substances of Concern of the Guidance on BPR: Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017?

Question 2b: if the answer to the first question is no, then do you agree no further assessment is required?

For some substance (e.g. leading to the supplementary labelling EUH 066 of the mixture), the co-formulant should be considered a SoC and should be allocated to band A following Annex A: Substances of Concern of the Guidance on BPR: Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017.

For others substances (e.g. leading to the supplementary labelling EUH 208 of the mixture), the co-formulant should not be considered a SoC and therefore, no further assessment should be required.