



Background:
Interpretation of ‘Complete quantitative composition’

According to Annex III of the BPR, the applicant should provide the following information:

2.3. Complete quantitative (g/kg, g/l or % w/w (v/v)) composition of the biocidal product, i.e. declaration of all active substances and non-active substances (substance or mixture according to Article 3 of Regulation (EC) No 1907/2006), which are intentionally added to the biocidal product (formulation) as well as detailed quantitative and qualitative information on the composition of the active substance(s) contained in the biocidal product. For non-active substances, a safety data sheet in compliance with Article 31 of Regulation (EC) No 1907/2006 has to be provided. In addition, all relevant information on individual ingredients, their function and, in the case of a reaction mixture, the final composition of ...

The Danish CA made an e-consultation on the interpretation of this requirement, especially in relation to the ‘complete quantitative composition’ of “mixtures”.

In the example below, a biocidal product contains 0.4% of mixture A.

Mixture A contains 4 substances and 2 mixtures. The weight % of each ingredient in the biocidal product is listed in the last column.

			Weight % of mixture added	Weight % of individual constituents of mixture
Mixture A added to biocidal product			0.4	
Substance 1 in mixture	Binder			0.0000056
Substance 2 in mixture	Binder			0.00016
Substance 3 in mixture	Water			0.1056744
Mixture 1 in mixture	Binder			0.0176
Mixture 2 in mixture	Binder			0.00456
Substance 4 in mixture	Pigment			0.272

The two mixtures in mixture A are present at concentrations of 0.0176% and 0.00456%, respectively.

Mixtures added at these concentrations; do not have relevance for the product’s classification. If they had relevance, the relevant substances (i.e. those resulting in a classification) would be listed in the SDS for each mixture.

The substances in mixtures 1 and 2 could have relevance for the identification of substances of concern.

The questions to the other member states were:

1: Do you require 'complete quantitative composition' for the mixture(s) in a mixture in a biocidal product?

2: If you require complete quantitative composition, do you have a cut-off level for when this information is not required?

The document was discussed at CG-34 and CG-35, with the following outcome:

The majority of respondents are of the opinion, that the complete quantitative composition of mixtures in mixtures are not required.

However, in case-by-case decision, further information might be required, in order to properly classify the biocidal product, for example in the case of preservatives (CMIT/MIT), fragrances or in order to properly evaluate the function of the mixture.

The respondents, does not use a general cut-off limit, as the decision is made on a case-by-case decision