

Minority opinion of the German CA on granulated copper (PT 08) discussed at BPC-13

The German Competent Authority identified the following concerns with regard of the opinion for granulated copper which was adopted by majority at BPC-13:

The reference product is a dummy formulation of copper, monoethanolamine, carbon dioxide, oxygen and water. However, according to the information given the resulting product is not a mixture of the aforementioned constituents but the following chemical reaction takes place where a copper ethanolamine complex is generated:



On the basis of this reaction **the active substance is $[\text{Cu}(\text{MEA})_{3.5}]^{2+} \cdot (\text{CO}_3^{2-}) \cdot 2(\text{OH}^-)$ and not copper**. It is not clarified if this reaction is a complete transformation of copper to the copper complex or an equilibrium between the copper complex and the starting materials. Depending on this information there are two possible options for the definition of the active substance based on the reference product assessed:

1. $[\text{Cu}(\text{MEA})_{3.5}]^{2+} \cdot (\text{CO}_3^{2-}) \cdot 2(\text{OH}^-)$
2. copper/ $[\text{Cu}(\text{MEA})_{3.5}]^{2+} \cdot (\text{CO}_3^{2-}) \cdot 2(\text{OH}^-)$.

But in both cases the active substance is neither copper nor granulated copper.

In addition to the questions of the identity of the active substance, there are severe doubts that the properties of the copper complex have been evaluated in relation to efficacy, hazard as well as risk assessment.

The German CA is of the opinion that either the reference product does not suit for the active substance which shall be approved or the active substance is not the correct one for the reference products assessed.

Since the BPC decided that this concern cannot be clarified at that late stage of the approval process and adopted the opinion by majority, the German CA submits this minority opinion.