



## Request for an ECHA opinion

### Background

- 1) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (the "BPR") introduces specific provisions concerning active substances that are nanomaterials. In particular, the approval of an active substance will not include its possible nanomaterial forms unless explicitly mentioned.
- 2) These new provisions could have important consequences for those companies which are waiting for the conclusions of evaluations of existing active substances currently under assessment under the review programme established under Regulation (EC) No 1451/2007.
- 3) In view of these new provisions and possible consequences, and with the objective of providing legal certainty to all interested parties, the Commission services invited all participants in the review programme to clarify whether they support or not a nanomaterial form of the substances included in the programme.
- 4) The company HeiQ Materials AG provided the information included in Annex and is seeking clarification as to whether HeiQ AGS-20, a material that is placed on the market for treatment of textiles to inhibit microbial colonisation of textiles, is a nanomaterial or not.
- 5) According to the information provided, HeiQ AGS-20 is composed of crystallites of metallic silver immobilised on an amorphous silicon dioxide carrier substrate, with ca. 20:80 elemental silver to silicon dioxide. HeiQ AGS-20 is to be used for the treatment of textile. Under moist conditions, silver ions are reported to be released from HeiQ AGS-20, and to inhibit microbial colonisation of the treated textiles.
- 6) HeiQ AGS-20 therefore fulfils the definition of a biocidal product as it is a substance or mixture, in the form in which it is supplied to the user, consisting of, [or] containing one [...] active substance [...], with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.
- 7) It should however be clarified whether the active substance is silver on its own or crystallites of metallic silver immobilised on an amorphous silicon dioxide carrier substrate, with ca. 20:80 elemental silver to silicon dioxide.
- 8) In this respect, the fact that silver is immobilised on an amorphous silicon dioxide carrier substrate could be considered as irrelevant in the substance evaluation, and

hence a matter of product authorisation, as the amorphous silicon dioxide is not supposed to have activity on or against the harmful organisms targeted (i.e. microbial contamination).

- 9) Then for the purpose of the original objective, the question to be addressed is whether the form of the active substance used by HeiQ in its biocidal product HeiQ AGS-20 meets the definition of a nanomaterial provided in Article 3(1)(z) of Regulation (EU) No 528/2012.

### **Terms of reference**

Taking into consideration this background information and the supporting documents provided in annex, pursuant to Article 75(1)(g) of the Regulation (EU) No 528/2012, ECHA is requested to formulate an opinion on the following questions:

1. With regard to the biocidal product HeiQ AGS-20, should silver or silver adsorbed on silicon dioxide be considered as the active substance?
2. Would this active substance meet the definition of a nanomaterial, as provided in Article 3(1)(z) of Regulation (EU) No 528/2012?
3. Finally, if this active substance meets the definition of a nanomaterial what should be its specifications?

In case further information should be provided concerning the supporting documents, ECHA is invited to request this information directly from HeiQ Materials AG.

### **Deadline**

30 June 2014.

### **Supporting documents**

See Annex.

## Annex

### HeiQ input



HeiQ input.pdf