Biocidal Products Committee (BPC)

Opinion on a request according to Article 75(1)(g)

of Regulation (EU) No 528/2012

HeiQ AGS-20

ECHA/BPC/001/2014

Adopted

10 April 2014

Opinion of the Biocidal Products Committee

on HeiQ AGS-20

In accordance with Article 75(1)(g) of Regulation (EU) No 528/2012 (BPR) of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on HeiQ AGS-20

This document presents the opinion adopted by the BPC, having regard to the conclusions of the rapporteur.

1. Process for the adoption of opinions

A request by the Commission was received by ECHA on 26 November 2013. The request was confirmed by ECHA to be passed to the BPC with the meeting documents for the BPC-4 meeting of 11-12 February. The BPC appointed the rapporteur at BPC-4. Following a consultation round with BPC members, the rapporteur presented the second draft opinion at the BPC-5 meeting of 8-10 April 2014, where the opinion was adopted. Following the adoption of the opinion at BPC-5, the opinion was amended and finalised according to the outcome of the discussion.

2. Adoption of the opinion

Rapporteur: BPC member for Sweden

The BPC opinion was adopted on 10 April 2014.

The BPC opinion was adopted by consensus.

3. Further details of the opinion and background

3.1 Request for the opinion and background

The Commission has requested an opinion of ECHA on a biocidal product of the company HeiQ Materials AG (hereafter HeiQ), one of the participants in the European Silver Task Force which is the notifier for several silver containing active substances (SCAS) currently under review for substance approval under Regulation (EU) No 1451/2007 (the Review Regulation), 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 the BPR?

3. Finally, if this active substance meets the definition of a nanomaterial what should be its specifications?

3.2 Summary and evaluation of information supporting the request for the opinion

3.2.1 Summary of information supporting the request for opinion

In HeiQ's request for an opinion (McKay, 2013), the company presents their position in the matter. In brief they claim that:

1. The biocidal product HeiQ AGS-20 (hereafter AGS-20) is a composite material consisting of micrometre sized silicon dioxide powder with physically bound elemental silver crystallites. The elemental silver crystallites span from sub 100 nm range to larger than 100 nm. AGS-20 is a composite of two chemically and physically distinct phases (silver and silicon dioxide).

2. The composite is not a reaction mass nor is it a simple mixture. It is a complex multi-component structure – a composite material.

3. The composite material should be regarded as the active substance.

4. As AGS-20 must be considered as a composite, it is currently not covered by the scope of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU) with reference to recital 14. Recital 14 outlines that "…..materials with internal structure or surface structure in the nanoscale such as complex nano-component nano-materials including nano-porous and nano-composite materials…." are currently not covered by the definition.

5. As outlined by 2, AGS-20 should not be classified as a nanomaterial. The elemental metallic silver contained in AGS-20 is not manufactured separately and so fundamentally cannot be characterised alone without its inert silica support. The composite must be assessed as a whole.

Furthermore, information on method of manufacture and characterisation data of AGS-20 submitted to the evaluating Competent Authority (eCA) during the review for substance approval, is relevant to this opinion.

3.2.2 Evaluation of information supporting the request for the opinion

Question 1

Generally, when defining the identity of biocidal active substances the "Guidance for identification and naming substances under REACH and CLP, version 1.3, ECHA, February 2014" (hereafter "the Guidance") should be applied. This document contains quite limited guidance on the definition of inorganic mixtures other than minerals. Nevertheless, the BPC agrees with HeiQ that the composite material should be defined as the active substance given that the material is the result of a combustion synthesis process and not just a simple mixing of the two components (with reference to footnote 12 on page 21 of the Guidance).

Whether AGS-20 should be named chemically as silver adsorbed on silicon dioxide or silicon dioxide /silver composite seems to be outside the scope of this request for an opinion. However, it should be noted that the Guidance does not contain the term 'composite' and it should be noted that composite is a very general term with the following meaning (ASTM D3878-07) "a substance consisting of two or more materials, insoluble in one another, which are combined to form a useful engineering material possessing certain properties not possessed by the constituents". It is noted that the purpose of adding elemental silver on the surface of silicon dioxide is to obtain a system that delivers active silver ions in sufficient amounts and which is also easy to handle and safe to use. This may not be achievable through the use of nanosilver alone and therefore it could be considered that AGS-20 qualifies as a composite material.

During the BPC-5 meeting the naming of the substance was discussed further in order to have a name to be included in the Commission Regulation on the work programme for examination of all existing substances foreseen by the BPR which will replace the Review Regulation. The BPC concluded that the name 'silver adsorbed on silicon dioxide' should be used for now. The applicant agreed to this proposal and will work on having a CAS number assigned to this name. The naming and further specification of this active substance may be subject to further technical discussions at a BPCWorking Group meeting in the future.

To further specify the active substance a range for the silver content (and silicon dioxide content) should be added.

Question 2

From the characterisation data it seems clear that the aggregate consisting of primary particles of silicon dioxide and elemental silver conforms to the provisions in Article 3(1)(z) of the BPR:

"'Nanomaterial' means a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm."

Moreover, the BPC interpretation of recital 14 to Commission Recommendation 2011/696/EU, is that this refers to complex heterogeneous material not being particles having surface structures, pores or particulate zones in the nanoscale; thus the BPC concludes that the purpose of recital 14 is not to exclude purely particulate materials like AGS-20.

The BPC conclusion is thus that AGS-20 shall be regarded as a nanomaterial as defined in BPR.

Question 3

The BPC opinion is that it is premature to discuss the specification prior to the evaluation phase of the active substance under the Review Regulation i.e. limitations related to the identity may be triggered by the risk assessment. However, in line with the earlier approval of silicon dioxide as a nanomaterial under the BPR, the specification for silver adsorbed on silicon dioxide could outline that it is a stable aggregate with particle size 1-50 µm, containing primary particles in the nanoscale (the particle size could possibly be added) and a volume specific surface area > 60 m^2/cm^3 (or the measured surface area could be added).

3.3 Overall conclusions

The BPC has reached the following conclusion with respect to the three questions in the request for an opinion:

1. The material AGS-20 should be regarded as the biocidal active substance as it is the result of a combustion synthesis process and not just a simple mixing of the two components.

It is agreed that the chemical name for the active substance should be silver adsorbed on silicon dioxide. A range for the silver content (and silicon dioxide content) should be added.

2. AGS-20 meets the definition of a nanomaterial as provided in Article 3(1)(z) of the BPR as it is a stable aggregate with primary particles complying with the number size distribution provision.

It is proposed that the derogation in recital 14 to Commission Recommendation 2011/696/EU does not apply to AGS-20 as the purpose of recital 14 is to outline that more complex heterogeneous nanomaterials are currently not covered by the definition.

3. It is premature to discuss a possible (nano) specification of AGS-20 prior to the evaluation phase of the active substance under the Review Regulation. However, as for the approval of (nano) silicon dioxide under the BPR (Implenting Regulation (EU) No 408/2014), it could be outlined that AGS-20 is a stable aggregate with primary particles in the nanoscale with additional specification of particle size and volume specific surface area.

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4. References

Glover, R.D., Miller, J.M., Hutchison, J.E. Generation of metal nanoparticles from silver and copper objects: nanoparticle dynamics on surfaces and potential sources of nanoparticles in the environment. American Chemical Society, 5 (11), 8950-8957. Non-GLP (2011).

Height, M. Release of silver from textiles. Empa, Swiss Federal Laboratories for Materials Science and Technology, HeiQ Study Number HQE-A-005 Not GLP (2013). Unpublished.

McKay, M. HeiQ letter to the European Commission (Aug 2013).

ASTM D3878-07. Standard Terminology for Composite Materials (2007)

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