Biocidal Products Committee (BPC)

Opinion on a request according to Article 75(1)(g)
of Regulation (EU) No 528/2012 on

Polymeric binder

ECHA/BPC/005/2014

Adopted

9 April 2014

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on polymeric binder

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

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 2 February 2014**.** The BPC members appointed the rapporteur at the BPC-4 meeting of 11-12 February 2014. The rapporteur presented the draft opinion to the BPC-5 meeting of 8-10 April 2014. 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 Germany

The BPC opinion was adopted on 9 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

A company is placing AM Polymers (antimicrobial polymers based on quaternary ammonium compounds) / polymeric binder on the market for use in paints to confer anti-microbial properties to finished and dried paint surfaces. The company is claiming that the modified surface of the paint is responsible for mechanically destroying bacteria or fungi touching it and would therefore not meet the definition of a biocidal product as provided in Article 3(1)(a) of the BPR.

The Netherlands requested a decision from the Commission as to whether AM Polymers are biocidal products or not. The request from the Netherlands was discussed on the occasion of the 54th meeting of representatives of Members States Competent Authorities. However no clear conclusions could be reached regarding the mode of action of this technology and whether it involved or not an active substance in the meaning of Article 3(1)(c) of the BPR.

Therefore, the Commission has requested ECHA to formulate an opinion via the BPC on the following questions:

1. With regard to the polymeric binder, does it contribute to the anti-microbial properties of paints in which it may be incorporated?

2. If so, do these properties result from the action of an active substance in the meaning of Article 3(1)(c) of the BPR?

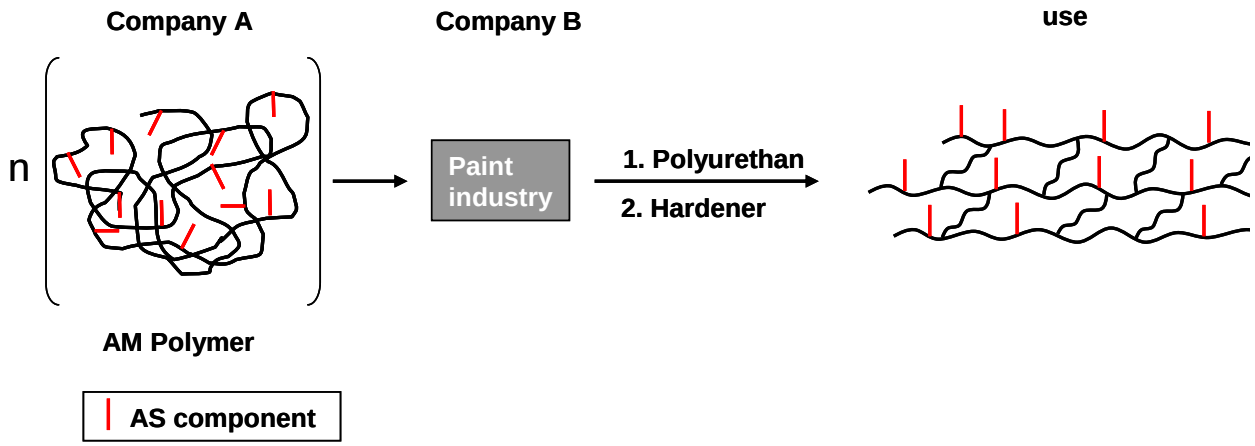
3. If so, what is the identity of that active substance?

3.2 Summary of information supporting the request for the opinion

The company provided a report and general information on bactericidal mechanisms of antimicrobial polymers based on quaternary ammonium salts.

According to the provided information, AM polymers consist of polymers modified with quaternary ammonium groups that are produced using different polymers depending on the request of customers (the manufacturers of antimicrobial paints). The company then sells the customised AM polymers (that themselves do not have an antimicrobial activity) to the manufacturer of the paint. The paints' manufacturer mixes the AM polymers with the polymers used for the paint and a hardener thereby cross-linking both polymers. The cross-linked polymers form a cationic surface in the finished painted coating exerting the antimicrobial effect.

Figure 1: Use of the polymeric binder



In contrast to other surfaces which show a mechanical mode of action due to surface texture (e.g. spikes or smoothness), it is described that the cross-linked polymers containing AM polymers work via electrostatic attractions leading to death of the target organism. The exact working mechanism is not known, however it is proposed that AM molecules enhance the adhesion forces between a micro-organism and a substrate surface to a lethally strong attraction causing reduced growth, stress de-activation and removal of membrane lipids and eventually leading to death (so called "Biomechanical stress model").

Further Information used by the Biocidal Products Committee:

1. Manual of Decision (https://circabc.europa.eu/sd/d/d0155521-069e-4e8c-91cc-126006d32a83/MoD_17_01_14.pdf, page 41/42):

The mode of action of an anti-microbial high molecular weight polymer, where a strong electric field along the polymer chain interferes with micro-organism leading to inhibition of growth, was considered a biochemical and thus a biocidal mode of action.

2. Judgement of the Court of Justice of the EU (Söll GmbH v Tetra GmbH, Case C-420/10, Judgment of the Court (Third Chamber) of 1 March 2012):

An anti-algae product that is poured into the pond water leading to a chemical action (hydrolysis) thereby forming a precipitate which is designed subsequently to gather the algae on the surface of the water by a mechanical and physical action (flocculation) was considered a biocidal product as "the concept of 'biocidal products' […] must be interpreted as including even products which act only by indirect means on the target harmful organisms, so long as they contain one or more active substances provoking a chemical or biological action which forms an integral part of a causal chain".

3.3 Evaluation of information supporting the request for the opinion

1. With regard to the polymeric binder, does it contribute to the anti-microbial properties of paints in which it may be incorporated?

It is suggested that AM polymers work via electrostatic attractions leading to death of the target organism. Although the first step of this cascade might be mere physical, the latter steps seem to involve physiological and thus biochemical steps (e.g. involving bacterial signal transduction systems). Similar mode of actions were also discussed on EU level, see MoD (Manual of Decisions, https://circabc.europa.eu/sd/d/d0155521-069e-4e8c-91cc-126006d32a83/MoD_17_01_14.pdf, page 41/42) and the judgement of the Court of Justice of the EU (Söll GmbH v Tetra GmbH, Case C-420/10, Judgment of the Court (Third Chamber) of 1 March 2012) clearly indicates that a chemical or biological action as part of a causal chain (that in the end leads to an effect on a harmful organism) is sufficient to be considered a biocidal effect. Therefore, cross-linked AM polymers contribute to the anti-microbial properties of paints in which it may be incorporated and should be regarded as exerting a biocidal effect.

2. If so, do these properties result from the action of an active substance in the meaning of Article 3(1)(c) of the BPR?

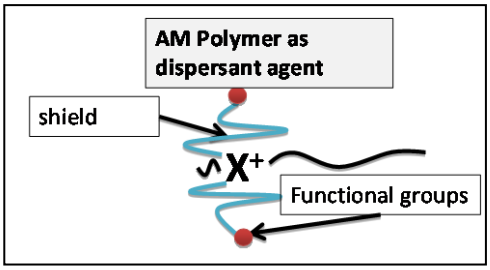
According to Article 3 (1)(c) of the BPR an active substance is defined as "a substance…that has an action on or against harmful organisms". A polymer is a substance which in the case of the cross-linked AM polymer has a biocidal effect. It is therefore proposed that the cross-linked polymer fulfills the definition of an active substance.

3. If so, what is the identity of that active substance?

The product consists of the following components:

- AM Polymer: A cationic, polymeric binder, with quaternary ammonium groups, variable chain length and equipped with hydroxyl as functional group. Other functional groups are proposed however we limit our comment to only one functional group.
  The polymer shows no anti-microbial activity due to the steric hindrance as illustrated in the figure below:

Figure 2: Illustration of the steric hindrance by the AM polymer.



- A polymeric dispersion (e.g. polyurethane) equipped with the same hydroxyl functional groups as the cationic, polymeric binder.
- A polymeric hardener for cross-linking the above mentioned polymeric constituents.

In the process of hardening and cross-linking, the constituents form covalent bonds and the quaternary ammonium groups with the alkyl chain are positioned at the surface of the coating enabling the anti-microbial activity. Consequently the three constituents react to one newly formed cross-linked polymer which is a prerequisite to obtain the anti-microbial activity by a specific steric configuration of the ammonium group.

It is proposed to define the active substance for the process of the active substance approval as follows (the specification of a definite identity of the active substance will be a matter of the active substance approval):

The active substance is formed in-situ in the paint by a chemical reaction of all three constituents. By this reaction a spatial configuration is generated which enables the anti-microbial activity. That means that the active substance is the cross-linked polymer generated in situ from AM Polymer, hardener (chemical name) and the second polymer (e.g. polyurethane). The active substance could therefore be defined as:

Cross-linked polymer of (definition of the AM polymer) and (definition of the hardener) and (definition of the second polymer) including quarternary ammonium groups causing a cationic surface.

4. Overall conclusions

1. Cross-linked AM polymers contribute to the biocidal properties of antimicrobial paints as the mode of action of the polymers is biocidal and not only physical or mechanical. Consequently the antimicrobial paint is considered a biocidal product as it is a mixture and is intended to have an antimicrobial effect (that is to kill harmful and pathogenic microorganisms on the paint surface).

2. The AM polymer fullfils the definition of an active substance as provided in Article 3(1)(c) of the BPR as a polymer is a substance which in the case of the cross-linked AM polymer has a biocidal effect.

3. The active substance is the cross-linked polymer formed in-situ by the reaction of the AM polymer, the hardener and the second polymer. The specification of a definite identity of the active substance will be a matter of the active substance approval.

5. References

D.P.W. Alkema, J.P. Langenberg: Bactericidal mechanism of antimicrobial polymers based on quaternary ammonium salts. TNO report R10599 (2013),

Manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products. European Commission, version 17 January 2014 which is available at:

https://circabc.europa.eu/w/browse/a512c74d-0c6c-48f7-a539-cbe48f0b31f8

Court of Justice of the EU: Söll GmbH v Tetra GmbH, Case C-420/10, Judgment of the Court (Third Chamber) of 1 March 2012.

o0o