ECHA
EUROPEAN CHEMICALS AGENCY

Biocidal Products Committee (BPC)

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

Product used for temporary preservation of human corpses

ECHA/BPC/208/2018

Adopted

28 June 2018

Opinion of the Biocidal Products Committee

on a product used for temporary preservation of human corpses

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, the Biocidal Products Committee (BPC) has adopted this opinion on a product used for temporary preservation of human corpses.

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

Process for the adoption of the opinion

A request by Commission was received by ECHA on 16 February 2018. ECHA was appointed as the rapporteur at BPC-24. The rapporteur presented the draft opinion to the BPC at its meeting of 27-28 June 2018.

Adoption of the opinion

Rapporteur: European Chemicals Agency (ECHA)

The BPC opinion on a product used for temporary preservation of human corpses was adopted on 28 June 2018.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including their grounds are published on the ECHA webpage at:

https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-other-requests-under-the-biocidal-products-regulation.

1. Further details of the opinion and background

1.1. Introduction

Article 3(3) of Regulation (EU) No 528/2012 empowers the Commission at the request of a Member State to decide whether a specific product or group of products is a biocidal product or a treated article or neither.

On 14 June 2017, Spain requested the Commission to decide, pursuant to Article 3(3) of Regulation (EU) No 528/2012, whether a product used for temporary preservation of human corpses, Bio Sac 200, is a biocidal product or a treated article or neither.

The request from Spain was discussed in the 73rd and 74th meeting of the Member States' Competent Authorities responsible for the implementation of Regulation (EU) No 528/2012 of July and September 2017, respectively. During the 74th meeting, it was agreed that Commission would consider requesting a formal Article 75(1)(g) opinion to ECHA, in order to be able to decide whether Bio Sac 200 is a biocidal product.

1.2. Background

(1) Bio Sac 200 ("the product") is used for temporary preservation of human corpses by placing it between the shroud and the coffin and/or between the shroud and the corpse. The product consists of a porous polypropylene bag containing a mixture of substances, whose function is the adsorption of gaseous compounds:

(a) Activated carbon;

(b) Natural clays (zeolites and sepiolites);

(c) Potassium permanganate impregnating the natural clays.

(2) Potassium permanganate was identified as an existing active substance with the intention to submit a dossier for use in product type 5. However, since no dossier for this active substance was submitted, a non-inclusion decision was taken in 2008 (Commission Decision 2008/809/EC), and subsequently it is not included in the Review Programme, and cannot be used as an active substance in biocidal products.

(3) Taking into account the definition of a biocidal product in Article 3(1)(a) of the BPR, it is important to consider a number of elements in order to conclude whether the product meets that definition. Particularly for the reason mentioned above, it is important to conclude on the role that potassium permanganate might play as an active substance by exerting any direct or indirect controlling effect on the harmful organisms responsible for the putrefaction of corpses, and whether this controlling effect is achieved by means other than mere physical or mechanical action.

(4) In this context, also the outcome of the Söll Case[1] has to be considered. Here it was concluded that "*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, the objective of which is to produce an inhibiting effect in relation to those organisms*".

---

[1] Case C-420/10: Judgment of the Court (Third Chamber) of 1 March 2012 (reference for a preliminary ruling from the Landgericht Hamburg — Germany) — Söll GmbH v Tetra GmbH.

1.3. Questions addressed in the opinion

The following questions are addressed in the opinion:

(a) What is the mode of action of the product Bio Sac 200? Discussion should take into account on whether the mode of action involves:

1. a mere physical or mechanical action, or
2. by indirect means, a chemical action that forms an integral part of a causal chain, the objective of which is exerting a controlling effect of the harmful organisms responsible for the putrefaction of corpses.

(b) On account of its mode of action, does potassium permanganate act as an active substance in the product Bio Sac 200?

2. Summary of information supporting the request for the opinion

2.1. General considerations

The opinion is based on the information provided by ES CA and the producer of Bio Sac 200. Additionally information from public scientific literature was considered.

Considering the BPR definition of a ‘biocidal product’ [Article 3(1)(a)], there must (1) be an active substance, (2) that substance must be intended to destroy, deter, render harmless or prevent the action of a harmful organism, or otherwise exert a controlling effect over it; and (3) this action must be chemical or biological.

2.2. Product Bio Sac 200

The product Bio Sac 200 filter bag, hereinafter being referred to as the product, is a polypropylene bag used for (as claimed by the producer) “temporary preservation” of human corpses. According to the provided information, each 250 g bag contains 90 g activated carbon and 160 g of natural clays (zeolites and sepiolites), impregnated with 2.6% potassium permanganate as injectable solid. According to the producer gaseous molecules are trapped inside the activated carbon by Van der Waals forces, and potassium permanganate, together with the other compounds, helps to generate the physical adsorption power.

The product is placed between the shroud and the coffin and/or between the shroud and the corpse. The ES CA notes that according to the submitted efficacy studies (Galach 2012, Moreno 2012, Naves 2016) no external signs of putrefaction were observed after 72 h once the product was applied. The efficacy studies provided describe delayed signs of putrefaction (e.g. foul odour, skin colour and texture, appearance of insects) on the corpses at a period of up to 12 days.

Mode of action described/presented by the producer:

Activated carbon and natural clays have a high surface area due to their microporous structure, being thus ideal for physical adsorption of various substances.

Permanganate, on the other hand, is a strong oxidant. The example given in the background information is oxidation of hydrogen sulfide gas into solid substances:

$8\ KMnO_4 + 3\ H_2S \rightarrow 2\ H_2O + 3\ K_2SO_4 + 2\ KOH + 8\ MnO_2$

The producer claims that the principle action is *"cleaning the air of signals that can be used by bacteria and fungi to develop"*, and that the *"beneficial effect observed in corpse preservation is due to the fact that bacteria use these gaseous signals in their biological function"*. The producer also states that the preservation is achieved solely by a physical modification of the corpse's environment, and that the product cannot therefore be considered as a biocide.

2.3. Human decomposition

Human decomposition begins some minutes after death has occurred and passes through several stages as the decomposition progresses: autolysis, early stages of decomposition, active decay, late decomposition, and the final stages of decomposition (Vass 2001, Hyde et al. 2013, Hyde et al. 2015). Although continuous, these stages may in most instances be assessed visually.

After death has occurred cells are deprived of oxygen, carbon dioxide increases, pH decreases and waste accumulates, and the cellular enzymes dissolve the cells by autolysis, eventually causing them to rupture, and release nutrient-rich fluids (Vass 2001). During early decay, intrinsic bacteria begin to digest the intestines from inside out, eventually resulting in the catabolism of tissues into gases, liquids and simple molecules (Hyde et al. 2013). During putrefaction bacteria undergo anaerobic respiration and produce various gases, such as hydrogen sulfide, carbon dioxide, methane, ammonia, sulfur dioxide and hydrogen, especially in the bowels, but also in other parts of the body. This is associated with anaerobic fermentation, primarily in the gut, releasing volatile fatty acids, mainly butyric acid and propionic acids. The microbial diversity in the decomposition process is high, and involves a succession from aerobic (e.g. *Staphylococcus* and Enterobacteriaceae) to anaerobic (e.g. *Clostridia, Bacteroides*) species (Hyde et al. 2013, Pechal et al. 2014). The build-up of gases creates pressure, eventually causing a purging event forcing the fluids out, and marking the shift from early decomposition to late decomposition. The final stages of decomposition last through to skeletonization and are the driest stages.

A wide spectrum of volatile organic compounds have been shown to be emitted in the environment during human decomposition (Statheropoulos et al. 2007, Rosier et al. 2015). Almost every chemical class is represented: alkanes, alkenes, aromatic compounds, cyclic compounds, ethers, alcohols, ketones, aldehydes, acids, esters, sulphur-, nitrogen- and halogen-containing compounds. The most common inorganic gases determined are CO_2, CO, NH_3 and H_2S (Statheropoulos et al. 2007).

2.4. Action of potassium permanganate

Potassium permanganate ($KMnO_4$) is an inorganic chemical commonly used as an oxidising agent. In aqueous solutions, it completely dissociates to K^+ and MnO_4^-. It is used for water disinfection in some parts of the world (Hobbs et al. 2006).

The combination of powdered activated carbon and $KMnO_4$ is used for removal of natural organic matter in water treatment (Gifford et al. 1989, Zhang et al. 2013). Granular activated carbon impregnated with $KMnO_4$ is also widely used in special air filters aimed at, in addition to removal of particles, to removal of odorous gases (e.g. www.americanfiltration.com, www.jasfiltration.com).

2.5. Evaluation of information supporting the request for the opinion

The product Bio Sac 200 contains activated carbon and natural clays, which have due to their microporous structure high surface areas, and absorb molecules via van der Waals forces, which is considered as physical adsorption, leaving the chemical species of the adsorbate and surface intact.

Potassium permanganate, occurring in the Bio Sac 200 product in solid form impregnated in the clay, is a strong oxidant and the example given by the producer in the background information (see chapter 2.2) indicates a chemical transformation of hydrogen sulfide gas into solid substances. This reaction is defined as chemisorption, which involves a chemical reaction between the surface and the adsorbate.

In the product Bio Sac 200 the mixture of potassium permanganate impregnated in natural clay and activated carbon are wrapped in a polypropylene bag. The compounds have therefore no direct contact to the bodies resulting in lack of direct microbicidal effect of permanganate by its oxidising mode of action. The relevant mode of action can be considered solely via adsorption of gaseous substances from the proximity of the body.

Since many of the organic and inorganic gaseous compounds produced have a characteristic foul odour (Statheropoulos et al. 2007), the reduction of these compounds would inevitably facilitate easier storage of the body. This mere effect of reducing bad odour could be by the user taken as a preservative function, even though a biocidal action is thereby not exerted.

The producer states that gases evolving from the decomposing body act *"as signals for other bacteria"*. Bacteria are known to use cell-to-cell signalling, quorum sensing, to coordinate their gene expression with cell density and spatial distribution, but the most well described signalling molecules are soluble diffusible molecules, like acyl-homoserine lactones, peptides and quinolones (Williams 2007). Recently, however, the potential at-a-distance influence of bacterial organic and inorganic volatile compounds on inter- and intraspecies bacterial interactions has also been suggested (Audrain et al. 2015). Thus even if not described, involvement of gaseous substances as signalling molecules in the human decomposition might be envisaged. It is also known that microbial volatile substances attract a variety of insects (Davis et al. 2013). Since the product is considered to adsorb gaseous substances, it may affect the progress of the decomposition, but the nature and extent of this effect cannot be assessed based on the available information. The effect would also depend on the placement of the bags and on how gas-tight the shroud is.

According to the submitted efficacy studies no external signs of putrefaction were observed after 72 h once the product was applied, and in addition to odour, also the appearance of insects and other external signs of putrefaction, like skin discoloration, were controlled by the product up to 12 d. These observations point towards a delaying effect of the actual decomposition process, even though it should be pointed out that there is no comparison to untreated controls mentioned. The described delay might be accomplished by a change in the gaseous atmosphere caused by physical and chemical adsorption of the gases. This effect is indirect, but involving chemical reactions, and should be considered as a biocidal effect, since the action of decomposing organisms would be indirectly controlled by modifying their environment via chemical oxidative reactions of $KMnO_4$.

2.6. Overall conclusions

The efficacy data provided is quite limited, and there is no comparison to untreated controls mentioned. Notwithstanding that the efficacy data has not been scientifically assessed, the producer states that the product acts by modifying the atmosphere inside the coffin and decreasing the concentration of the gases which are used by bacteria and fungi as part of their biological function.

It is thus concluded that the mode of action of the product Bio Sac 200 involves a physical action via activated carbon and natural clays, as well as a chemical action via potassium permanganate. It is also concluded that potassium permanganate as one of the substances included in the product should be considered as an active substance according to the BPR[2]. This conclusion is based on the assumption that the conservation of corpses could be influenced by chemical reactions with gases produced during the decomposition process causing an alteration of the gaseous atmosphere and thereby having an indirect effect on the activity of the decomposing flora.

[2] ‘active substance’ means a substance or a microorganism that has an action on or against harmful organisms

2.7. References

Audrain B, Farag MA, Ruy C-M, Chigo J-M (2015) Role of bacterial volatile compounds in bacterial biology. FEMS Microbiology Reviews 39:222-233

Davis TS, Crippen TL, Hofstetter RW, Tomberlin JK (2013) Microbial volatile emissions as insect semiochemicals. Journal of Chemical Ecology 39: 840-859

Gifford JS, George DB, Adams VD (1989) Synergistic effects of potassium permanganate and PAC in direct filtration systems for THM precursor removal. Water Research 23:1305-1312

Hyde ER, Haarmann DP, Lynne AM, Bucheli SR, Petrosino JF (2013) The living dead: bacterial community structure of a cadaver at the onset and end of the bloat stage of decomposition. PLOS One 8:10 e77733.

Hyde ER, Haarmann DP, Petrosino JF, Lynne AM, Bucheli SR (2015) Initial insights into bacterial succession during human decomposition. International Journal of Legal Medicine 129:661-671

Galach JA (2012) Estudio-CEU-Valencia. http://conserfilnature.com/estudios/estudio-anatomico-forense-valencia.pdf

Moreno CR (2012) Informe de conservación cadavéra del producto CN Sa 200. CEU Universidad Cardenal Herrera, Valencia, Spain. http://conserfilnature.com/estudios/estudio-ceu-valencia.pdf

Naves FJ (2016) Estudio ensayo en cadáveres descongelados. Faculta de Medicina de la Universidad de Oviedo. http://conserfilnature.com/estudios/estudio-universidad-oviedo.pdf

Pechal JL, Crippen TL, Benbow ME, Tarone AM, Dowd S, Tomberlin JK (2014) The potential use of bacterial community succession in forensics as described by high throughput metagenomic sequencing. International Journal of Legal Medicine 128:193-205

Statheropoulos M, Agapiou A, Spiliopoulou C, Pallis GC, Sianos E (2007) Environmental aspects of VOCs evolved in the early stages of human decomposition. Science of the Total Environment 385:221-227

Vass A (2001) Beyond the grave – understanding human decomposition. Microbiology Today Vol 28/Nov01

Williams P (2007) Quorum sensing, communication and cross-kingdom signalling in the bacterial world. Microbiology 153:3923-3938

Zhang Y, Wang Y, Zhou L (2013) Influence of excess $KMnO_4$ on the adsorption of powdered activated carbon. Chemical Engineering Journal 226:279-285

o0o