



## Request for an ECHA opinion

### "Product used for temporary preservation of human corpses"

#### 1.- Background

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

- (a) Activated carbon.
- (b) Natural clays (zeolites and sepiolites).

These natural clays are also impregnated with potassium permanganate, which seems to act converting the gases in different substances.

(3) Potassium permanganate was identified as existing active substance in Annex I of the Commission Regulation (EC) No 2032/2003, of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, and amending Regulation (EC) No 1896/2000. However, since no dossier for this active substance was submitted, this active substance was not included in Regulation (EU) No 1451/2007 and cannot be used as an active substance in biocidal products.

(4) Taking into account the definition of a biocidal product in Article 3(1)(a) of the BPR, it is therefore important to consider a number of elements in order to conclude whether the product meets that definition. Particularly, 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.

(5) In this context, it is also important to consider the outcome of the Söll Case<sup>1</sup>, following to which products which act only by indirect means on the target

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<sup>1</sup> 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 (Placing on the market of biocidal products — Directive 98/8/EC — Article 2(1)(a) — Concept of 'biocidal products')

harmful organisms, as 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, must be interpreted as included in the concept of biocidal product.

## 2.- Available technical information for consideration by ECHA

- (6) Documents submitted in the initial request submitted by Spain:



Request for decision  
from the European C



Technical report of  
the company .pdf

- (7) Additional information submitted by Spain for the 74<sup>th</sup> CA meeting:



BIO SAC 200 (2).pdf

- (8) Additional information provided by the applicant:



2. Product currently  
in use .pdf



3. BioSac200  
technical report (Engl



4. BENEFITS BIOSAC  
200.pdf

## 3.- The questions to be addressed by the ECHA opinion:

- (9) Taking into consideration this background information, as well as the enclosed documents, ECHA is requested to formulate an opinion on the following questions:
- (a) What is the mode of action of the product Biosac 200? In particular, it should be discussed and a conclusion presented 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 Biosac 200?

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— Product causing flocculation of harmful organisms without destroying or deterring them or rendering them harmless).

#### **4.- Deadline for the ECHA opinion**

- (10) The ECHA opinion should be submitted to the Commission by the end of July 2018 at the very latest.