

Introduction:

Afri-Davidson intends to import the following products and place them on the EU market as products to remediate and condition eutrophic water bodies and the soil profile.

- OxyTurf: For soil profiles
- OxyFlow: For reticulation systems and pipelines
- OxyCure: For larger water bodies
- Sludge Buster: For dam and canal sludge substrate (Only plant fibres)

The invention (patent nr. WO2011061596A3) provides a composition suitable for the in-situ treatment and prevention of eutrophication of water bodies. The composition includes extracts from a variety of naturally occurring plants including plants from the genera Eucalyptus, Poaceae, Carpobrotus, Aloe and Sutherlandia.” Additionally, a small amount of hydrogen peroxide is present in the product.

As an importer of mixtures or formulations containing these substances in quantities higher than 1 ton/year Afri-Davidson has to comply with EU REACH regulation and need to assess if the substances in the mixture fall under the registration requirements REACH imposes on substances placed on the market.

REACH regulation background

REACH is the main EU chemical regulation. It stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. The REACH Regulation places responsibility on industry (manufacturers and importers) to manage the risks from chemicals and to provide safety information on the used substances.

An important principle in REACH is "No data no market" (Article 5): Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and in many cases to register the information in a central database of the [European Chemicals Agency \(ECHA\)](#).

This means that to be in compliance with the REACH regulation, regardless of the registration requirement, the company placing the substance on the EU market should have full knowledge of the imported contents, and the hazard and safety information available to guarantee safe use for human and environment.

Substances naturally occurring in nature

The products, falling under patent number WO2011061596A3 consist for a large part of natural-based-substances. Under REACH they largely fall under the category “Natural Complex Substances (NCS)”. According to Annex V of REACH these substances are under certain conditions exempted from registration.

Three main conditions need to be met for this exemption to be justified.

- The substance occurs in nature’ according to the definition in Article 3(39)
“According to Article 3(39), ‘substances which occur in nature’ means ‘a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means’.”
Whole branches, leaves, flowers etc. are outside the scope of REACH.
- The substance is not chemically modified according to the definition in Article 3(40)
“According to Article 3(40), a ‘not chemically modified substance’ means ‘a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities’

- They don't meet the criteria for classification as dangerous according to CLP (Classification, labelling and packaging), or meet the criteria for being persistent, bio-accumulative and toxic or very persistent and very bio-accumulative.
Many essential oils for example, although being a naturally occurring substance, do not fulfil the conditions for being exempted since they have skin/eye irritating properties or show liver toxicity when ingested.

It should be noted that the companies benefiting from an exemption must provide the authorities (on request) with appropriate information to show that their substances qualify for the exemption.

In all cases, the burden of proof rests with the manufacturer/importer that wishes to use this exemption for his substance. **An absence of information on the properties of a substance cannot be equated to the absence of hazardous properties.** To provide some context, it can occur that substances fall into the 'substances which occur in nature' category but have insufficient information available on them to be able to conclude that they are not dangerous, and thus still need to provide this information. To exempt such substances would undermine the aims of REACH to gather information on substances in order to determine their potential hazards.

Illustrative example natural substance:

Example 1:

A substance is obtained in accordance with a steam distillation process of the leaves from *Mentha arvensis*. The chemical analysis of the *Mentha arvensis* extract thus manufactured indicates that this substance consists of several stereo-isomers including the constituent (-)-menthol (i.e. (1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexanol). All the constituents in the substance were originally present in the leaves. This substance fulfils the requirements for substances which occur in nature, if they are not chemically modified.

Example 2:

The substance isolated in example 1 is further processed by crystallisation in water and ethanol to isolate (-)-menthol and to remove other constituents. Although this process did not result in the chemical modification of the substance within the meaning of Article 3(40), the substance does nevertheless not fulfil the requirements for substances which occur in nature, if they are not chemically modified (because of the use of ethanol). Therefore, the substance does not fulfil the requirements for substances which occur in nature, if they are not chemically modified.

Example 3:

The substance isolated in example 1 is heated solely to remove water. Upon heating the substance isolated in example 1 under vacuum it is converted into a mixture of different constituents including (-)-menthol. Although the isolated substance fulfils the definition of a substance which occurs in nature, it has been chemically modified and therefore does not fulfil the requirements for substances which occur in nature, if they are not chemically modified.

Example 4:

A multi-step synthesis is used for the manufacturing of (-)-menthol. Although this substance consists of the same constituent as the one found in the leaves of *Mentha arvensis*, it is not a substance which occurs in nature and does therefore not fulfil the requirements for substances which occur in nature, if they are not chemically modified.

Hydrogen Peroxide

Hydrogen peroxide (EC 231-765-0) is a substance that needs to be registered when imported in a quantity of more than 1 ton per year.

The composition of Patent WO2011061596A3 shows that Hydrogen peroxide (EC 231-765-0) is present at max. 2 % of the total mixture volume. This means that when 50 ton of the total mixture is imported the registration requirement applies. If two different products are imported each with 2 % Hydrogen peroxide than the total

amount of hydrogen peroxide is relevant. Thus, importing 25 ton of each mixture containing 2 % hydrogen peroxide triggers the registration requirement.

In this case, registration of this substance means joining the existing registration dossier. Except for a set of analytical data Afri-Davidson does not have to generate additional toxicity data, but buys access to the current registration dossier, and the associated information on hazard and toxicity of the imported substance.

Conclusion

The natural components of your product can be exempted from registration under annex V of REACH when the above-mentioned conditions are met regarding hazard information and extraction methods.

Based on the extraction method described by Afri-Davidson the conditions for being a natural substance are met. To benefit from the exemption however, information about potential hazards and safety information is to be provided by Afri-Davidson.

For hydrogen peroxide the registration obligation applies as soon as a company imports more than 1 ton/year.

Disclaimer:

The information in this report was compiled with the greatest care; nevertheless, no rights may be derived from this publication. Information on the composition was provided by Afri-Davidson and was considered to be complete and true.

Marco Mense
Consultant Sustainability and Chemical Safety
Ecomatters

Museumlaan 2
3581 HK Utrecht
The Netherlands

M +31 (0)6-18193259
E marco.mense@ecomatters.nl
W www.ecomatters.nl

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