

ECHA-REACH EU registration rules

The BIOSAFE HM-4005 Silane based antimicrobial substance does meet the exempt criteria set and listed in document 10152/23036412 by the EU chemical authorities.

BIOSAFE® Antimicrobial is a non-leaching silanes-based antimicrobial that imparts bacteriostatic, fungistatic, and algistatic properties to coatings and resins for manufactured goods.

- Used in water based surface treatments and coatings
- Microbiostatic agent that protects articles from deterioration and discoloration
- Leach resistant
- Active against forms of fungi, algae, and bacteria
- High antimicrobial performance in ISO and ASTM testing
- Does not promote development of resistant microorganisms

https://echa.europa.eu/documents/10162/23036412/annex_v_en.pdf/8db56598-f7b7-41ba-91df-c55f9f626545

Guidance for Annex V Exemptions from the obligation to register

Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight. Most substances present a certain level of instability upon exposure to environmental factors such as air, moisture, microbial organisms and the irradiation from sunlight. Any reaction products thus formed do not have to be registered as it would be inappropriate; they are generated incidentally and without the awareness of the manufacturer or importer or downstream user of the original substance. **For example, the reaction products from the incidental hydrolysis of substances (e.g. esters, amides, acryl halides, anhydrides, halogenated organosilanes, etc.) in contact with the moisture from the environment are exempted from registration as they fall within this criterion. Another example is diethyl ether which may form peroxides after exposure to air or light. The peroxides thus formed do not have to be registered by the manufacturer or importer of diethyl ether, or by any downstream user or distributor of the substance on its own, in a preparation or in an article. Note however that the potential risks associated with the reaction products formed in this manner must be taken into account in the assessment of the original substance. Finally, the decomposition products from paint, where the decomposition is caused by the activity of mould and the products from the bleaching of**

coloured textiles, which occurs due to the exposure to sunlight, could also be seen as examples falling under this entry.

ENTRY 2

Subparagraph (a) In section (a) of this entry, a comprehensive list of groups of precursors for substances exempted in accordance with this paragraph is provided. This list of precursors, given in alphabetic order for easy retrieval, includes: Adhesion promoters An adhesion promoter is a substance which is applied to a substrate to improve the adhesion of a product to the substrate. The adhesion is created by the formation of strong bonds (including both covalent and non-covalent bonds) between the adhesion promoter and the surfaces of the products to be bound. In addition, some adhesion promoters in a first step chemically react to generate the adhesion properties. The substances thus formed during the use of an adhesion promoter are exempted from the registration provisions. While the adhesion promoter itself is subject to registration, if it meets the necessary requirements, any substance generated as a result of chemical reaction when the adhesion promoter functions as intended, is exempted from registration, provided it is not itself manufactured, imported or placed on the market. **Example: • Silanes are applied to a substrate and hydrolyse into silanols in contact with moisture. The substance thus obtained acts as adhesion promoter in a second step.**