

ALINA LIFE – EUROPEAN REGULATORY GUIDANCE

1. Summary

ALINA LIFE is a natural mineral, surface-treated with a quaternary ammonium compound which leads to many potential uses and benefits. Under EU-REACH, the organoclay product requires no submission of a REACH registration dossier, but there are some other requirements. ALINA LIFE is a non-hazardous product which does not fall under the Biocidal Products Regulation. Our own research, as well as data in the public domain, shows that ALINA LIFE does not pose a human health or environmental risk in normal use. Its physico-chemical properties are demonstrated in the paint and coating product development as multifunctional filler material. Also suggesting applications in paper and board, potentially as a Food Contact Material, where compliance can be assured. Though risk is minimal, national legislation needs to be followed. Regulations evolve, and Alina is committed to supporting its customers. We assure customers of this commitment and invite dialogue.

2. ALINA LIFE and organoclays

ALINA LIFE is an organoclay, a naturally occurring clay mineral (phyllosilicates), surface-treated specifically to obtain a positive charge and to change the hydrophilic into a hydrophobic surface, without changing the structure of the clay mineral. The main surface treatment agents used in production are quaternary amines.

Due to their physico-chemical properties, organoclays have a wide range of end-uses, from paints and coatings, cosmetics and personal care to lubricating grease and foundry washes and for environmental clean-up and as rheological additives for drilling fluids.

3. European Reach Regulation

The EU-REACH Regulation^[1] brought in EU-wide standardisation of the regulatory status of organoclays. The EU-REACH status of 1) natural minerals, 2) surface treatment chemicals and 3) organoclays is discussed here.

3.1 Natural minerals

REACH Annex V^[2] explicitly exempts from registration certain categories of “substances which occur in nature, if they are not chemically modified”, including minerals. The Guidance document on Annex V further explains: “Minerals which occur in nature are covered by the exemption if they are not chemically modified. This applies to naturally occurring minerals, which have undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities, provided that

none of the constituents of the final isolated substance has been chemically modified. Synthetic minerals are not covered by this exemption.”

Therefore, the clay substrates used in ALINA LIFE are exempted from registration under EU-REACH, as they are naturally occurring minerals and are not chemically modified.

3.2 Surface treatment agents

Substances used to make organoclays are salts of quaternary ammonium cations with an anion. Quaternary ammonium cations are positively charged ions of the structure NR₄⁺ with R, in the case of organoclays, usually being alkyl (or aryl) groups. Within the meaning of REACH these materials are “substances”, which require registration. Furthermore, quaternary ammonium compounds on their own have been shown to have the potential to cause toxic effects depending on the exposure level. However, when associated with clay minerals, the compounds do not maintain the same toxicological profile and are rendered non-hazardous. The quaternary ammoniums are not released from the organoclay substrate in the same chemical form.

3.3 Surface-treated minerals

The regulatory status of surface-treated substances was clarified by ECHA in their document “Frequently Asked Questions on REACH by industry” first published in June 2008 and updated most recently in June 2015^[3]. This FAQ (Do I have to register chemically surface treated substances?) stated the following:

“The surface treatment of a substance is a “two dimensional” modification of macroscopic particles. A “two dimensional” modification means a chemical reaction between the functional groups only on the surface of a macroscopic particle with a substance which is called a surface treating substance.

By this definition, it becomes clear that this kind of modification means a reaction of only a minor part (surface) of a macroscopic particle with the surface treating substance, i.e. most of the macroscopic particle is unmodified.

Therefore a chemically surface treated substance cannot be regarded as a preparation nor be defined by the criteria of the “Guidance for identification and naming of substances under REACH”^[4].

With the same reasoning, a chemically surface treated substance could not be reported for EINECS nor be notified according to Directive 67/548/EEC because it was covered by the separate EINECS entries of both the basis substance (macroscopic particle) and the surface treating substance.”

Organoclays meet fully the FAQ definitions in these ways:

- In organoclays, the surface-treatment substance is only treating the surface of the substrate and not penetrating through to the inside of the particle.
- Chemically absorbed quaternary ammoniums are difficult to remove from the clay surface and extreme conditions such as solvent extraction need to be employed in order to remove such chemisorbed chemical from an organoclay. Removal of any remaining chemical is for all purposes not possible without total destruction of the organoclay material.
- It is for this reason that hazards associated with neat quaternary ammonium do not carry over to ionically and/or chemisorbed substance when organoclays are concerned. Thus, an organoclay cannot be regarded as a preparation nor be defined as a substance by the criteria of the "Guidance for identification and naming of substances under REACH".

3.4 REACH compliance

The REACH FAQ further states:

"Taking this decision up under REACH means a consequent continuation of former decisions. Using the same line of arguments, chemically surface treated substances should not be registered as such under REACH, but the following requirements should be fulfilled:

- 1. Registration of the basis substance (macroscopic particle), unless exempted*
- 2. Registration of the surface treating substance*
- 3. Description of the use "surface treatment" in the registration dossier of the Surface treating substance and in the registration dossier of the basis substance*
- 4. Any specific hazards or risks of the surface treated substance should be appropriately covered by the classification and labelling and by the chemicals safety assessment and resulting exposure scenarios."*

ALINA LIFE further complies with these requirements. Furthermore, organoclays have been extensively risk assessed under the OECD HPV programme^[5]. It has been shown that organoclays are significantly less toxic to aquatic organisms than the surface treatment chemicals on their own^[6].

4. European Biocidal Products Regulation (BPR)

Biocides are covered under the EU Biocidal Products Regulation^[7] (2012). Article 3(1)(a) of the BPR defines a 'biocidal product' as:

- "any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,
- any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless,

preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.”

As shown above, ALINA LIFE is an organoclay consisting of a naturally occurring clay mineral, surface-treated specifically to obtain a positive charge and to change the hydrophilic into a hydrophobic surface, without changing the structure of the clay mineral. ALINA LIFE has many diverse uses, due to its physico-chemical properties. Some uses include as a formulant in wood primer, paint and stain additive, extending the life of processed surfaces and reducing paint product degradation. The surface treatment chemical used in production is irreversibly linked to the clay substrate and is not biologically available on its own. No claims of mitigating against harmful organisms are made. The quaternary ammonium compound used is chosen for its surfactant properties conferred on the clay and has not separately been applied for approval under the BPR. As such, ALINA LIFE is not a biocidal product and neither are its end-uses. This regulatory status has been confirmed by at least one EU Member State Competent Authority.

5. Food Contact Uses

Due to its properties, ALINA LIFE may attract uses in the manufacture and supply of paper and board. Some applications may come under the definition of a FCM (Food Contact Material). FCMs are regulated under the wider law^[8] on food contact materials. In general, this requires that materials do not:

- Release their constituents into food at levels harmful to human health,
- Change food composition, taste and odour in an unacceptable way.

Primarily, these requirements have been implemented for direct and indirect FCMs in plastics, where the properties of ALINA LIFE would not be of benefit. Though some 10 Member States have regulations for paper and board, these are not yet standardised across the whole of the EU. It can be confirmed that there are no specific restrictions in the Member States or Council of Europe against the use of the components of ALINA LIFE in FCMs. The database suggests that there should be no significant risk in extractables and leachables from ALINA LIFE. As such, it can be determined that ALINA LIFE can be used in paper and board as a FCM, but respecting national MS laws and monitoring future changes in legislation.

6. Cosmetic Uses

Organoclays are permitted for use in cosmetics. In addition, the EU Scientific Committee on Consumer Safety (SCCS) has reviewed the safety of the quaternary ammoniums which are used in organoclays, where the quaternary ammoniums themselves are added to cosmetics for uses other than as a preservative.^[9]

10th January, 2022

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- [1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- [2] Annex V of REACH sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACH because registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH;
- [3] <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/reach>;
- [4] <https://echa.europa.eu/guidance-documents/guidance-on-reach>;
- [5] OECD HPV Programme https://hpvchemicals.oecd.org/ui/SIDS_Details.aspx?id=6640768b-1033-4ab0-a730-3e9cc60c532e;
- [6] Pals, M; Putna-Nimane, I; Kostjukovs, J; Karasa, J; Kostjukova, S & Nakurte, I (2017) Determination and toxicology studies of quaternary ammonium salts in solution after organoclay processing. Key Engineering Materials 762:368-372;
- [7] Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) <https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr>;
- [8] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC;
- [9] SCCS Opinion https://ec.europa.eu/health/scientific_committees/consumer_safety/.../sccs_o_012.pdf.