# Safety Assessment of Alkonium Clays as Used in Cosmetics

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*All interested persons are provided 60 days from the above date to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available at the CIR office for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Director, Dr. Lillian J. Gill.*


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# INTRODUCTION

This is a review of the available scientific literature and unpublished data provided by industry relevant to assessing the safety of the alkonium clays as used in cosmetics. These 8 ingredients are:

- benzalkonium montmorillonite
- benzalkonium sepiolite
- hydrogenated tallowalkonium bentonite
- quaternium-18/benzalkonium bentonite
- quaternium-90 bentonite
- quaternium-90 montmorillonite
- quaternium-90 sepiolite
- stearalkonium bentonite

In cosmetics, these ingredients are reported to function as dispersing agents-nonsurfactant; emulsion stabilizers; and viscosity increasing agents-nonaqueous (Table 1).[1]

Alkonium clays are derived from a group of phyllosilicate, layered, clay-based minerals (known as smectites), the most prominent of which are montmorillonite, beidellite, nontronite, saponite, and hectorite. These ingredients are grouped together because of their similarities in structure, chemical composition, exchangeable ion type, and the small crystal size of these minerals.

Ingredients similar to the alkonium clays have been reviewed by the Cosmetic Ingredient Review (CIR) Expert Panel (Panel; Table 2). Ammonium hectorites (final 2012; 2013), hectorite (final 2000; 1983, 2003), and quaternium-18 hectorite and quaternium-18 bentonite (re-review 2001; 1982, 2003) were found to be safe as used.[2-6] Relevant data from the safety assessment of ammonium hectorites are presented *in italics* in the appropriate sections below.

Components of the alkonium clays in this safety assessment have been reviewed by the Panel. Tallow and hydrogenated tallow (re-review 2006; 1990, 2008), quaternium-18 (final 2000; 1983, 2003), and elaeis guineensis (palm) oil (a component of quaternium-90; final 2011) were determined to be safe as used, and benzalkonium chloride is safe up to 0.1% (re-review 2006; 1989, 2008).[7-10] Quaternium-90 has not been reviewed by the Panel. However, quaternium-90 and quaternium-18 are structurally very similar; thus, information on quaternium-18 is relevant for the determination of the safety of ingredients containing quaternium-90.

# CHEMISTRY

## Definition and Structure

Alkonium clays are derived from a group of phyllosilicate, layered, clay-based minerals, the general term for which is smectites, and the most prominent of which are montmorillonite, beidellite, nontronite, saponite, and hectorite.[5] These clays are differentiated by variations in chemical composition involving substitutions of aluminum for silicon in tetrahedral cation sites and for aluminum, iron, magnesium, and lithium in octahedral cation sites (Figure 1).

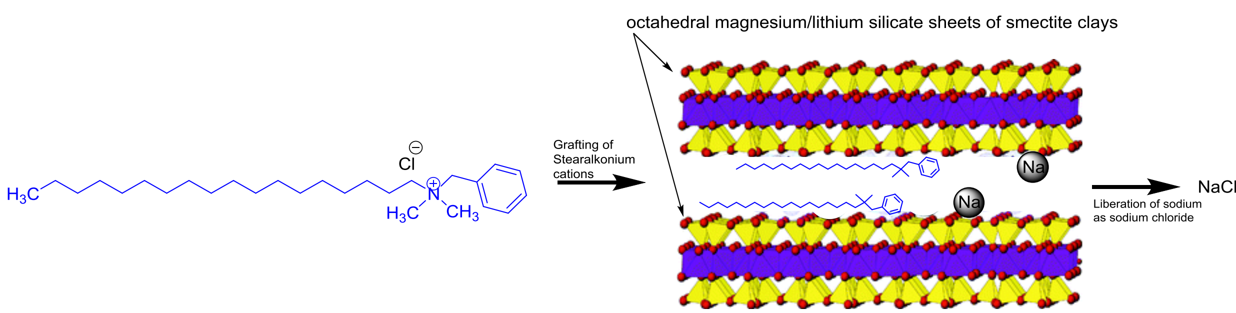


**Figure 1.** Synthesis of alkonium clays.

Smectite minerals, a subset of clays that include alkomium clays, that have a variable net negative charge, which is balanced by sodium, calcium, or magnesium ions adsorbed externally on interlamellar surfaces.[5] The structure, chemical composition, exchangeable ion type, and small crystal size of smectite minerals are responsible for several unique properties, including a large chemically active surface area, a high cation exchange capacity, interlamellar surfaces having unusual hydration characteristics, and the ability to strongly modify the flow behavior of liquids. Because of isomorphous substitution of cations in the octahedral sheet during hectorite formation, the surfaces of these minerals have a delocalized net negative charge in the lattice. Cations located between 2 consecutive layers (octahedral sheets) contribute to compensate for the structural charge and to keep the layers bound. Thus, cations like sodium are attracted to the mineral surface to counterbalance the interlayer charge. These cations can easily be exchanged, because they are retained in the mineral structure by electrostatic attractions.

The structure of alkonium clays depend on the charges of the layers and the lengths of the alkyl chains. Short-chain alkylammonium ions are monolayered. Long-chain alkylammonium ions are bilayered.[11,12] Smectities are highly charged and are composed of 3 kinked alkyl chains.[13] The basal spacing of alkylammonium smectites increases, in steps, with the alkyl-chain length.[14]

NATURAL SMECTITE CLAYS

Smectites (aka organoclays) are closely related and the names have been used interchangeably to describe structurally similar clay minerals in the literature.[15] Natural deposits in which one of these clay minerals predominate are more commonly referred to by the predominant clay mineral's name. Thus, considering the similarity in the clay minerals of this category, the defining differentiation between the groups is the cation that is reacted with the clay.

Bentonite is a widely distributed natural material consisting predominantly of the clay mineral montmorillonite, a smectites mineral.[15,16] Bentonite is formed of highly colloidal and plastic clays, and is produced by in situ devitrification of volcanic ash.[17] Natural bentonite may contain feldspar, cristobalite, and crystalline quartz.[18]

Montmorillonite occurs abundantly as dust at and near surface deposits of bentonite and is dispersed widely by air and moving water.[17] Montmorillonite is thus ubiquitous in low concentrations worldwide in soil, in the sediment load of natural waters, and in airborne dust. In geology, the term "montmorillonite" is ambiguous, and is used to refer to both a group of related clay minerals (where smectite is a more appropriate term) and to a specific member (montmorillonite) of that group.[19]

In structure, sepiolite can be considered to be transitional between the chain-structured and layer-structured silicates.[20,21] Sepiolite is found in sedimentary strata in arid and semi-arid climates around the world.[22] Deposits of sepiolite have been reported in China, France, Japan, Madagascar, the Republic of Korea, Spain, Turkey, the United Republic of Tanzania, and the United States.[20,23,24]

Clays contain trace elements (ie, antimony, arsenic, cadmium, cobalt, copper, lead, mercury, nickel, selenium, tellurium, thallium, zinc) in concentrations that are widely variable, depending on their geological origin. These trace elements may be in the clay mineral structure as well as adsorbed on clay particles, which plays the most important role in controlling the distribution and abundance of these elements within these clays. Chemical elements in crystalline positions are usually locked in the clay, whereas those adsorbed may be mobilized and transferred to leaching solutions.[25]

In an analysis of natural sepiolite samples from Japan, Spain, China, and Turkey, only the sample from China has small amounts of talc and calcite.[26]

## Physical and Chemical Properties

Chemical and physical properties of stearalkonium bentonite are presented in Table 3. Stearalkonium bentonite particle sizes were reported to be: <100 µm, approximately 90%; < 10 µm, 30%; and < 0.5 µm, 0.02%.[27] Chemical and physical properties of the other ingredients in this safety assessment were neither discovered in the literature nor submitted for review.

Alkonium clays have a high capacity for expansion and swelling and can be easily hydrated and dehydrated.[28] They are excellent absorbents.

SMECTITE CLAYS

Bentonite has the ability to form thixotrophic gels with water, and absorb large quantities of water, and a high cation exchange capacity.[16] The absorption of water causes an accompanying increase in volume of as much as 12–15 times its dry bulk, and a high cation exchange capacity. Freshly exposed bentonite is white to pale green or blue and, with exposure, darkens in time to yellow, red, or brown.[17]

Montmorillonite clay is composed of minute particles that, under electron microscopy, appear as aggregates of irregular or hexagonal flakes or, less commonly, thin laths.[29] Differences in substitution affect, and in some cases control, morphology.

## Method of Manufacture

Clay minerals, such as the alkonium clays, are synthesized by grafting cationic surfactants to clay (ie, exchanging the interlayer sodium cations with a cationic surfactant). These cationic surfactants are quaternary ammonium compounds with the template formulae $[(CH_3)_3NR]^+$, $[(CH_3)_2NRR']^+$, and $[CH_3NRR'R'']^+$, where R, R', and R'' are alkyl or aromatic hydrocarbons. For instance, in stearalkonium bentonite some of the inorganic cations of bentonite have been replaced by $[(CH_3)_2NRR']^+$, where R and R' are an octadecyl alkyl chain (ie, stearyl group) and a benzyl group, respectively. The exchange is typically performed by the addition of the appropriate ammonium chloride (eg, stearalkonium chloride) to an alcohol/water slurry of the clay.[30] The major by-products are inorganic chlorides (eg, sodium chloride), which are removed during processing. This cation exchange shifts the nature of these minerals from hydrophilic to lipophilic.[30]

### Impurities

Stearalkonium bentonite may contain quartz up to 5% and benzenemethanol up to 0.005%.[27]

## USE

### Cosmetic

The Panel assesses the safety of cosmetic ingredients based on the expected use of these ingredients in cosmetics. The Panel reviews data received from the Food and Drug Administration (FDA) and the cosmetics industry to determine the expected cosmetic use. The data received from the FDA are collected from manufacturers on the use of individual ingredients in cosmetics, by cosmetic product category, through the FDA Voluntary Cosmetic Registration Program (VCRP), and the data from the cosmetic industry are submitted in response to a survey of the maximum reported use concentrations, by category, conducted by the Personal Care Products Council (Council).

According to the 2015 VCRP survey data, stearalkonium bentonite had the most reported uses at 423, including 420 leave-on uses and 3 rinse-off uses (Table 4).[31] Most of these uses were in nail products, but this ingredient was also used in lipstick (64 uses) and in products used around the eye (7 uses). Quaternium-90 bentonite was reported to be used in 64 leave-on products, including products used around the eye and lipstick.

In the survey conducted by the Council of the maximum use concentrations of ingredients in this group, stearalkonium bentonite was reported to be used at concentrations up to 6.5% in nail basecoats and undercoats, 2.4% in lipstick, and 2.5% in eye shadow.[32] Quaternium-90 bentonite was reported to be used up to 6.1% in mascara, 2.2% in face powder, and 6.1% in lipstick.

For 2 ingredients, no uses were reported to the VCRP, but a use concentration was provided in the industry survey. The VCRP did not report any uses for quaternium-90 montmorillonite, but the industry survey indicated that it is used in 2 types of leave-on formulations at concentrations up to 0.8%. No uses were reported by the VCRP for quaternium-90 sepiolite, as well. However, the Council reported that it was used in 2 types of leave-on products at concentrations up to 3.2%. It should be presumed that both of these ingredients are used in at least 2 cosmetic formulations.

There were no reported uses for:

- hydrogenated tallowalkonium bentonite
- quaternium-18/benzalkonium bentonite
- benzalkonium montmorillonite
- benzalkonium sepiolite

Quaternium-90 montmorillonite is used in aerosol suntan products at concentrations up to 0.8% and quaternium-90 sepiolite is used in aerosol suntan products up to 3.2%. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm.[33-36] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (ie, they would not enter the lungs) to any appreciable amount.[33,36]

None of the alkonium clays named in this report are restricted from use in any way under the rules governing cosmetic products in the European Union.[37]

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia concluded that stearalkonium bentonite did not pose an unreasonable risk to public health when used in cosmetic products at concentrations up to 5% concentration.[27]

### Non-Cosmetic

Large volumes of smectite clay minerals are used as a binder in foundry sand; a filter/clarifier/decolorizer; pet waste/odor absorbent; oil/grease absorbent; and pesticide carrier.[38] Smaller volumes are used in medical and pharmaceutical applications, building products, radioactive waste disposal, lubricants, detergents, seed coating, and water purification.

The European Food Safety Authority (EFSA) approved bentonite as an additive to complete feed for ruminants up to 0.5% for the reduction of contamination by mycotoxins.[39,40]

NATURAL SMECTITE CLAYS

Bentonite is considered generally recognized as safe (GRAS) by the FDA. [21 CFR 184.1155]

For occupational exposures, sepiolite is regulated by the United States Occupational Safety and Health Administration (OSHA) with the inert or nuisance dust standard (permissible exposure limits, 15.0 mg/m$^2$ total dust and 5.0 mg/m$^2$ respirable fibers).[29CFR1910.1000]

## TOXICOKINETICS

### Absorption, Distribution, Metabolism, and Excretion

Data on toxicokinetics of the alkonium clays in this safety assessment were not found in the published literature, nor were unpublished data submitted. Because of the chemical nature of alkonium clays, it may be that toxicokinetic assays are not possible.

## TOXICOLOGICAL STUDIES

### Single Dose (Acute) Toxicity

***Dermal – Non-Human***

The dermal $LD_{50}$ of stearalkonium bentonite was > 2000 mg/kg (in deionized water) in Sprague-Dawley rats (n=5/sex).[27] The test was conducted according to the Organization for Economic Cooperation and Development (OECD) Test Guideline (TG) 402.

***Oral – Non-Human***

The oral $LD_{50}$ of stearalkonium bentonite was > 5000 mg/kg (in corn oil) in albino Wistar rats (n=5/sex).[27] Clinical signs included matted fur and unkempt appearance on days 1 and 2 of observation. One male animal showed slight depression on day 4 prior to its death on day 5. At necropsy, a slightly reddened gastric mucosa was noted in a single rat. The test was conducted in a manner similar to the OECD TG 401.

***Inhalation – Non-Human***

Data on the acute inhalation toxicity of the alkonium clays in this safety assessment were not found in the published literature, nor were unpublished data submitted.

### Repeated Dose Toxicity

***Dermal***

New data on the repeated dose dermal toxicity of the alkonium clays in this safety assessment were not found in the published literature, nor were unpublished data submitted.

*AMMONIUM HECTORITE*

*QUATERNIUM-18 HECTORITE - Quatemium-18 hectorite (up to 50%) applied, unoccluded, to the exposed skin of rabbits 3 times per day for 5 days per week for 3 weeks caused no toxic effects.[41,42] There was mild drying and scaling of the upper layers of the skin during the early days of the study.*

*STEARALKONIUM HECTORITE - There were no toxic effects observed when stearalkonium hectorite (12.5% to 50%) was dermally applied to rabbits twice per day, unoccluded over 3 weeks.[43]*

***Oral – Non-Human***

In a 28-day oral toxicity test conducted according to OECD TG 407 of stearalkonium bentonite (100, 316, and 1000 mg/kg in 0.1% aqueous solution of Na-carboxymethylcellulose) in Fischer CDF(F344)/CRLBR, SPF rats (n=5/sex), the no-observed-effect-level (NOEL) was 1000 mg/kg/d, based on the absence of test substance related toxicological effects at any of the doses administered.[27] Clinical signs were similar between the treatment and control groups. Chromodakryorrhoea was observed occasionally in both the control and treatment groups. There were no differences in feed consumption or body weight gain in males. Decreased body weights were recorded for females in the high dose recovery group (duration of recovery period not specified) but these were considered by the study authors to be of no toxicological relevance. There were no differences in hematology or clinical biochemistry parameters. There were no differences or dose-related trends observed at necropsy or by histopathology examination. There were no spontaneous lesions observed. There were no organ weight changes in the males. The organ weight decreases in the females (heart and brain) at the end of recovery period were noted by the study authors to be of no toxicological relevance, because there were no corresponding differences observed at the end of the exposure period.

***Inhalation – Non-Human***

Data on the repeated dose inhalation toxicity of the alkonium clays in this safety assessment were not found in the published literature nor were unpublished data provided.

## REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

Data on reproductive and developmental toxicity of the alkonium clays in this safety assessment were not found in the published literature, nor were unpublished data submitted.

*AMMONIUM HECTORITE*

*DIHYDROGENATED TALLOW BENZYLMONIUM HECORITE - Orally administered dihydrogenated tallow benzylmonium hectorite had a no effect level of 1000 mg/kg to Sprague Dawley rats.[44] The test material was administered throughout the complete reproductive cycle for 1 generation. No further information was provided.*

## GENOTOXICITY

### In Vitro

Stearalkonium bentonite (3.16, 10, 31.6, 100, and 316 µg/plate, with and without metabolic activation, in dimethyl sulfoxide) was not genotoxic to *Salmonella typhimurium* (strains TA1535, TA1537, TA98, TA100, and TA102).[27] The positive control yielded the expected results. Pronounced cytotoxicity was noted in all test strains at 316 µg/plate, with and without metabolic activation. In the assays without metabolic activation, cytotoxicity was also noted in several strains at 31.6 and/or 100 µg/plate. The test was performed according to the OECD Test Guideline 471.

### In Vivo

In a micronucleus assay, conducted according to the OECD TG 474, stearalkonium bentonite (1000, 1500, and 2000 mg/kg in 0.1% aqueous solution of Na-carboxymethylcellulose) was not clastogenic in Crl:NMRI BR mice (n=5/sex) when administered by gavage.[27] There were no mortalities prior to scheduled killing. The ratios between the polychromatic and normochromatic erythrocytes in the female mice at all doses were similar to that of the control data. However, the ratios were greater in males at all doses at 24 h. Because the values were within the historical negative control data ranges, the differences were not considered by the study authors to be attributable to the test substance. The number of micronucleated polychromatic erythrocytes in the high dose groups (both sexes) was higher than that of the corresponding negative control group 48 h after administration. However, all counts were within the range of historical negative control data, thus the study authors considered effect to be unrelated to the treatment. The concurrent negative and positive controls produced the expected results.

## CARCINOGENICITY

Data on carcinogenicity of the alkonium clays in this safety assessment were not found in the published literature, nor were unpublished data submitted.

## IRRITATION AND SENSITIZATION

### Irritation

***Dermal – Non-Human***

Stearalkonium bentonite (100%) was not irritating to the intact or abraded skin of New Zealand White rabbits (n=6) when applied under occlusion for 24 h.[27] The mean erythema/eschar and edema scores for the intact sites were 0; the mean erythema/eschar score for the abraded sites was 0.3, and the edema score was 0.25. The test was conducted in a manner consistent with the OECD TG 404. The test sites were examined at 24 and 72 h after patch removal.

Stearalkonium bentonite injected intradermally was not irritating at a concentration of 1.25% in distilled water and applied topicallyto the skin; this ingredient was not irritating at 60% in distilled water, as tested in albino Hartley guinea pigs.[27] No further details were provided.

***Ocular***

Stearalkonium bentonite (100%; 0.1 g) was severely irritating when administered into the eyes of New Zealand White rabbits (n=7).[27] The test was conducted in a manner similar to the OECD TG 405 and the rabbits were observed for 7 days after exposure. If the test substance was still present in the eye at 24 h after exposure, the eye was rinsed with distilled water. The most severe observation for conjunctiva/redness was grade 3 (diffuse beefy red) in all rabbits 24 h after instilling the test substance. One rabbit still exhibited a grade 2 response (more diffuse, crimson red, individual vessels not easily discernible) on day 7. The most severe observation for conjunctiva/chemosis was grade 4 (swelling with lids about half-closed to completely closed) in 5 of 6 rabbits examined 24 h post exposure. One rabbit still exhibited a grade 2 response (obvious swelling with partial eversion of the lids) on day 7. The highest score for conjunctiva/discharge was grade 3 (discharge with moistening of the lids and hairs and of a considerable area around eye) in 2 of 6 rabbits at 24 h post exposure. This was resolved by day 7. The most severe observation for corneal opacity was grade 2 (easily discernible translucent areas, details of iris slightly obscured) in 2 of 6 rabbits at 24 h post exposure. The highest score was grade 3 (opalescent areas, no details of iris visible, size of pupil barely discernible) was observed in 1 of 6 animals at 48 h post exposure. One rabbit still exhibited the highest grade 4 for opaqueness, the iris was invisible on day 7. Five of 6 rabbits exhibited a grade 1 iridial inflammation response (sluggish reaction) with the effect persisting in 1 rabbit through day 7.

Stearalkonium bentonite (31-36 mg in 0.1 mL; vehicle not specified) was slightly irritating to the conjunctiva of female New Zealand White rabbits (n =3).[27] Neither cornea nor irises were affected. Slight conjunctiva redness was observed in 2 rabbits 1 through 48 h after exposure. Slight-to-moderate chemosis of the conjunctiva was observed in 2 rabbits at 1 through 48 h after exposure. Ocular discharge was noted in 2 rabbits from 1 to 24 h after administration. The test was conducted according to the OECD TG 405.

### Sensitization

***Dermal – Non-Human***

Stearalkonium bentonite was not sensitizing to albino Hartley guinea pigs (n=20) when topically applied at 60% (in distilled water) during the induction phase and topically at 30% and 60% during the challenge phase.[27] There were no signs of sensitization at 24 and 48 h after the challenges. The test was conducted according to the OECD TG 406. The test sites were treated with 10% lauryl sodium sulfate in petroleum jelly prior to the induction phase.

## SUMMARY


This is a review of the available scientific literature and unpublished data submitted by industry for assessing the safety of alkonium clays as used in cosmetics. Alkonium clays are derived from a group of phyllosilicate, layered, clay-based minerals, including montmorillonite, saponite, and hectorite. These ingredients are grouped together because of the similar chemical structures, chemical composition, exchangeable ion type, and small crystal size of these minerals.

In cosmetics, these ingredients are reported to function as dispersing agents-nonsurfactant; emulsion stabilizers; viscosity increasing agents-nonaqueous.

Stearalkonium bentonite had the most reported uses at 423 including 420 leave-on uses and 3 rinse-off uses; it was reported to be used up to 6.5% in nail basecoats and undercoats, 2.4% in lipstick, and 2.5% in eye shadow. Quaternium-90 bentonite was reported to be used in 64 leave-on products; it was reported to be used up to 6.1% in mascara, up to 2.2% in face powder, and up to 6.1% in lipstick.

The dermal $LD_{50}$ of stearalkonium bentonite was > 2000 mg/kg in rats. The oral $LD_{50}$ of stearalkonium bentonite was > 5000 mg/kg in rats. In a 28-day oral toxicity test of stearalkonium bentonite, the NOEL was 1000 mg/kg/d in rats.

Stearalkonium bentonite was not genotoxic to *S. typhimurium* (strains TA1535, TA1537, TA98, TA100, and TA102). It was cytotoxic at 316 µg/plate, without and with metabolic activation. In the tests without metabolic activation, cytotoxicity was also noted in several strains at concentrations of 31.6 and/or 100 µg/plate. In a micronucleus assay, stearalkonium bentonite was not clastogenic in mice up to 2000 mg/kg.

Stearalkonium bentonite was not irritating to intact or abraded skin of rabbits at 100%. Stearalkonium bentonite was not irritating when injected intradermally at 1.25% and was not irritating when topically applied to the skin at a concentration of 60% in guinea pigs.

Stearalkonium bentonite was a severe ocular irritant when administered into the eyes of rabbits at 100%. Stearalkonium bentonite (31-36 mg/ 0.1 mL) was slightly irritating to rabbit eyes. Neither cornea nor irises were affected. 310-360 mg/mL.

Stearalkonium bentonite was not sensitizing to guinea pigs when topically induced with a 60% solution and challenged topically with 30% and 60% solutions.


## DATA NEEDS

CIR is seeking all information pertaining to the safety of these ingredients in a wide range of areas, including:

- Chemical and physical properties;
- Impurities data;
- Toxicokinetics data, specifically dermal absorption of these ingredients; if these ingredients were to have appreciable dermal absorption or if toxicokinetic assays are not possible, oral toxicity data, including reproductive/developmental toxicity and carcinogenicity data, are needed, as are genotoxicity data; these data may not be crucial if these ingredients have no appreciable dermal penetration, however, if they were available, they would improve the resulting safety assessment;
- Oral, inhalation, and/or dermal toxicity data;
- Dermal, ocular, and/or other mucous membrane irritation and sensitization data; and
- Any other relevant safety information that may be available.

Even though there are some data on stearalkonium bentonite, additional supporting data is desired.

## TABLES

**Table 1.** Definitions and functions of the ingredients in this safety assessment.[1]

| Ingredient CAS No. | Definition | Function |
|---|---|---|
| Hydrogenated tallowalkonium bentonite | Hydrogenated tallowalkonium bentonite is the product of the reaction of hydrogenated tallowalkonium chloride and bentonite. | Viscosity increasing agent-aqueous |
| Quaternium-18/benzalkonium bentonite | Quaternium-18/benzalkonium bentonite is a reaction product of bentonite and quaternium-18 and benzalkonium chloride. | Dispersing agent-nonsurfactant |
| Quaternium-90 bentonite 226226-22-8 | Quaternium-90 bentonite is a reaction product of bentonite and quaternium-90. | Dispersing agent-nonsurfactant |
| Stearalkonium bentonite 130501-87-0 | Stearalkonium bentonite is a reaction product of bentonite and stearalkonium chloride. | Dispersing agent-nonsurfactant |
| Benzalkonium montmorillonite | Benzalkonium montmorillonite is the reaction product of benzalkonium chloride and montmorillonite. | Dispersing agent-nonsurfactant; emulsion stabilizer; viscosity increasing agent-nonaqueous |
| Benzalkonium sepiolite | Benzalkonium sepiolite is the product obtained by the reaction of benzalkonium chloride and sepiolite. | Dispersing agent-nonsurfactant; emulsion stabilizer; viscosity increasing agent-nonaqueous |
| Quaternium-90 montmorillonite | Quaternium-90 montmorillonite is the product obtained by the reaction of quaternium-90 and montmorillonite. | Dispersing agent-nonsurfactant; emulsion stabilizer; viscosity increasing agent-nonaqueous |
| Quaternium-90 sepiolite | Quaternium-90 sepiolite is the product obtained by the reaction of quaternium-90 and sepiolite. | Dispersing agent-nonsurfactant; emulsion stabilizer; viscosity increasing agent-nonaqueous |

**Table 2.** Safety assessments by CIR of ingredients relevant to the safety assessment of alkonium clays. These include previous safety assessments of ingredients related to or moieties of ingredients in this report.

| Ingredients | Conclusion | Highest use concentration | Reference |
|---|---|---|---|
| **Ammonium hectorites -** disteardimonium hectorite, dihydrogenated tallow benzylmonium hectorite, stearalkonium hectorite, and quatemium-18 hectorite | Safe as used. | 28% | 3,5 |
| Quaternium-18, quaternium-18 hectorite, and quaternium-18 bentonite | Safe as used. | 10%, 19% | 2,4 |
| **Hectorite, bentonite, montmorillonite**, aluminum silicate, calcium silicate, magnesium aluminum silicate, magnesium silicate, magnesium trisilicate, sodium magnesium silicate, zirconium silicate, attapulgite, bentonite, fuller's earth, kaolin, lithium magnesium silicate, lithium magnesium sodium silicate, pyrophyllite, and zeolite | Safe as used. | 100% | 6 |
| Benzalkonium chloride | Safe up to 0.1%. | 0.1%; 0.5% in a liquid towelette | 7,9 |
| Elaeis guineensis (palm) oil | Safe as used. | 100% | 8 |
| Tallow, tallow glyceride, tallow glycerides, hydrogenated tallow glyceride, and hydrogenated tallow glycerides | Safe as used. | 78% | 7,10 |

**Table 3.** Chemical and physical properties of stearalkonium bentonite.

| Property | Value | Reference |
|---|---|---|
| **Stearalkonium bentonite** | | |
| Density/Specific Gravity @ 25 ºC | 330-480 | 27 |
| Melting Point ºC | > 390 | 27 |
| Boiling Point ºC | > 500 | 27 |
| Water Solubility g/L @ 20 ºC | < 0.04 | 27 |
| log $K_{ow}$ @ 25˚C | 5.87 (est) | 27 |

**Table 4.** Frequency of use according to duration and exposure of alkonium clays.[31,32]

| Use type | Uses | Maximum Concentration (%) | Uses | Maximum Concentration (%) | Uses | Maximum Concentration (%) | Uses | Maximum Concentration (%) |
|---|---|---|---|---|---|---|---|---|
| | **Quaternium-90 bentonite** | | **Quaternium-90 montmorillonite** | | **Quaternium-90 sepiolite** | | **Stearalkonium bentonite** | |
| **Total/range** | **64** | **0.41-6.1** | **NR** | **0.4-0.8** | **NR** | **1.6-3.2** | **423** | **0.051-6.5** |
| *Duration of use* | | | | | | | | |
| Leave-on | 64 | 0.41-6.1 | NR | 0.4-0.8 | NR | 1.6-3.2 | 420 | 0.19-6.5 |
| Rinse-off | NR | 0.63 | NR | NR | NR | NR | 3 | 0.051 |
| Diluted for (bath) use | NR | NR | NR | NR | NR | NR | NR | NR |
| *Exposure type*[a] | | | | | | | | |
| Eye area | 31 | 0.41-6.1 | NR | NR | NR | NR | 7 | 0.19-2.5 |
| Incidental ingestion | 16 | 6.1 | NR | NR | NR | NR | 64 | 0.5-2.4 |
| Incidental Inhalation-sprays | 2[b] | NR | NR | 0.8 | NR | 3.2 | 1[d] | NR |
| Incidental inhalation-powders | 2[b] | 2.2; 0.88[c] | NR | NR | NR | NR | NR | NR |
| Dermal contact | 35 | 0.41-4 | NR | 0.4-0.8 | NR | 1.6-3.2 | 19 | 0.19-2.5 |
| Deodorant (underarm) | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair-noncoloring | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair-coloring | NR | NR | NR | NR | NR | NR | NR | NR |
| Nail | NR | 0.46-0.5 | NR | NR | NR | NR | 340 | 0.051-6.5 |
| Mucous Membrane | 16 | 6.1 | NR | NR | NR | NR | 66 | 2.4 |
| Baby | NR | NR | NR | NR | NR | NR | NR | NR |

NR = Not Reported; Totals = Rinse-off + Leave-on Product Uses.

Note: Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum total uses.

[a] Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

[b] Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

[c] It is possible these products may be powders, but it is not specified whether the reported uses are powders.

[d] It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

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