MEMORANDUM

To: CIR Expert Panel and Liaisons

From: Lillian C. Becker, M.S.
Scientific Analyst and Writer

Date: May 13, 2016

Subject: Safety Assessment of Alkoxy Alkyl Silanes as Used in Cosmetics

Attached is the draft report of Alkoxy Alkyl Silanes as used in cosmetics. [alalsi062016Rep]

A Scientific Literature Review (SLR) was issued in January, 2016 with a request for any additional data. These four ingredients are grouped because they are structurally related as silanes bearing both simple alkyl and simple alkoxy groups. These ingredients function as binders, skin-conditioning agents – miscellaneous, and skin-conditioning agents – emollient.

According to the *International Cosmetic Ingredient Dictionary and Handbook*, surface modifier is a possible function of Trimethoxycaprylsilane. Unlike ingredients in the Polymerized Tetramethylcyclotetrasiloxane safety assessment, the Alkoxy Alkyl Silanes do exist independently and as surface modifiers (coating metal oxide particles). The only data in support of the Alkoxy Alkyl Silanes as surface modifiers are inhalation toxicity studies of Triethoxycaprylsilane-coated titanium dioxide particles.

Concentration of use information and unpublished data (including impurity data, dermal penetration, oral toxicity, and mutagenicity) on a trade name mixture that contains Bis-Stearoxydimethylsilane have been submitted by the Council and are incorporated into the report. [alalsi062016Data_1,2,3]

Council comments have been addressed. [alalsi062016PCPC]

If no further data are needed, the Panel should develop the basis for the Discussion and issue a Tentative Report. If more data are required, the Panel should list the data that are needed for the Panel to come to a conclusion of safety, and issue an Insufficient Data Announcement.
History – Alkoxy Alkyl Silanes

**June, 2015** – Added to the Priority List.

**January, 2016** – SLR posted.

**June, 2016** – Panel examines draft report.
<table>
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<tr>
<th>Alkoxy Alkyl Silanes Data Profile for June, 2016. Writer – Lill Becker</th>
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<td>Triethoxycaprylylsilane-coated titanium oxide particles</td>
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<td>Triethoxycaprylylsilane-coated zinc oxide particles</td>
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**SciFinder Group Links:**
Compounds searched by identifiers (text and structure):
29043-70-7 – 5 hits. 0 useful.

18748-98-6 – 79 hits. Filtered for adverse effects/toxicity, biological studies, properties, and additional related refs - 56 hits. Removed Patents – 8 hits, 0 useful.

3069-40-7 – 1163 hits. Filtered for adverse effects/toxicity, biological studies, properties, and additional related refs - 189 hits. Removed patents – 107 hits, 1 useful.

2943-75-1 – 2115 hits. Filtered for adverse effects/toxicity, biological studies, properties, and additional related refs - 532 hits. Removed patents – 180 hits, 2 useful.

References from text and structures searches:

How toxic is Bis-Stearoxydimethylsilane 29043-70-7 – 5 hits for “stearoxydimethylsilane or 29043-70-7, 0 useful.
How toxic is Stearoxytrimethylsilane 18748-98-6 – not useful
How toxic is Triethoxycaprylylsilane 2943-75-1 – 1 hit, retrieved.
How toxic is Stearoxytrimethylsilane 18748-98-6 – not useful
How toxic is Trimethoxycaprylylsilane 3069-40-7 – not useful

**Cosing** – No restrictions, no opinions.

**HPVIS** – no hits.

**ECHA** - Bis-Stearoxydimethylsilane 29043-70-7 – no hits; Stearoxytrimethylsilane 18748-98-6 – hits; Triethoxycaprylylsilane 2943-75-1 – Data available; Trimethoxycaprylylsilane 3069-40-7 Data available. The same data sets were in both ECHA profiles.

**PUBMED** – ingredient names and tox* - 2 hits, already had 1, acquired the other.
CAS no. and tox* - 0 hits
Minutes of PEG Propylene Glycol Esters

December 2-3, 1998
PEG-25, -75, and -120 Propylene Glycol Stearate,
PEG-10 Propylene Glycol, PEG-8 Propylene Glycol Cocoate, and PEG-55 Propylene Glycol Oleate
Dr. Schroeter stated that the following data were received in response to the Tentative Report that was issued at the December 2-3, 1998 Panel meeting: (1) Concentration of use data on PEG-55 Propylene Glycol Oleate, (2) Method of manufacture of PEG-55 Propylene Glycol Oleate, (3) Impurities data on PEG-55 Propylene Glycol Oleate, (4) Ocular irritation test (rabbits) on PEG-25 Propylene Glycol Stearate, (5) Two skin irritation tests (rabbits) on PEG-25 Propylene Glycol Stearate, (6) Guinea pig maximization test on PEG-25 Propylene Glycol Stearate, and (7) Human skin irritation test on PEG-25 Propylene Glycol Stearate.

Dr. Schroeter noted that the Panel's data needs have now been met and that the available data are sufficient for arriving at a “safe as used” conclusion on all ingredients included in this review. He added that the data on PEG-55 Propylene Glycol Oleate and PEG-25 Propylene Glycol Stearate that were submitted address the Panel's data needs on all other ingredients in the group.

Dr. Carlton proposed that a statement indicating that cosmetic formulations containing either of the PEG Propylene Glycol ethers included in this review should not be used on damaged skin should be added to the report discussion. The Panel's concern about use of these ingredients on damaged skin is based on positive patch tests and incidences of nephrotoxicity in burn patients treated with an antimicrobial cream that contained PEG-6, PEG-20, and PEG-75. PEG was the causative agent in both animal and human studies; no evidence of systemic toxicity or sensitization was found in studies with intact skin.

Dr. Bergfeld agreed with Dr. Carlton's proposal.

The Panel voted unanimously in favor of issuing a Final Report with the following conclusion: Based on the available animal and clinical data included in this report, the CIR Expert Panel concludes that PEG-25 Propylene Glycol Stearate, PEG-75 Propylene Glycol Stearate, PEG-120 Propylene Glycol Stearate, PEG-10 Propylene Glycol, PEG-8 Propylene Glycol Cocoate, and PEG-55 Propylene Glycol Oleate are safe as used in cosmetic products.

May 18-19, 1998
PEG-25, -75, and -120 Propylene Glycol Stearate,
PEG-10 Propylene Glycol, PEG-8 Propylene Glycol Cocoate, and PEG-55 Propylene Glycol Oleate
The Panel voted unanimously in favor of issuing a Tentative Report with an insufficient data conclusion on these ingredients. The data needed in order for the Panel to complete its safety assessment are listed in the discussion section of the Tentative Report as follows:

(1) Current concentration of use
(2) Method of manufacture and impurities analysis

December 8-9, 1997
PEG-25, -75, and -120 Propylene Glycol Stearate,
PEG-10 Propylene Glycol, PEG-8 Propylene Glycol Cocoate, and PEG-55 Propylene Glycol Oleate
Dr. Belsito said that his Team determined that the following data are needed in order to complete this safety assessment: (1) Current concentration of use and (2) Method of manufacture and impurities analysis.
Dr. Schroeter said that his Team determined that the components of all of the ingredients in this report have been reviewed by the Expert Panel and were found to be safe as used. With this in mind, Dr. Schroeter suggested that the three ingredients reviewed in this report are safe as used.

Dr. Belsito noted that the methods of production for most of the ingredients being reviewed are missing from the Draft Report. Thus, the Panel does not know which impurities remain at the end of the production process.

Dr. Shank said that he has no problems with the purity of these cosmetic ingredients. Furthermore, he said that he is willing to accept this document on the basis of toxicological data on the component parts.

Dr. Klaassen said that he generally agrees with the preceding statement by Dr. Shank. However, he said that the problem is that there is no quality control for knowing whether what should be the end product in the production process is the same as what was tested in toxicology studies. He said that there is no reason why industry cannot provide the Panel with the methods of production.

The Panel voted unanimously in favor of issuing an Insufficient Data Announcement with the following data requests:

1. Current concentration of use
2. Method of manufacture and impurities analysis
Safety Assessment of Alkoxyl Alkyl Silanes as Used in Cosmetics

Status: Draft Report for Panel Review
Release Date: May 13, 2016
Panel Meeting Date: June 6-7, 2016
INTRODUCTION

This is a review of the scientific literature and unpublished data relevant for assessing the safety of the alkoxyl alkyl silanes as used in cosmetics. The ingredients in this report are structurally-related silanes bearing both simple alkyl and simple alkoxy groups. The 4 ingredients in this report are:

- Bis-Stearoxydimethylsilane
- Stearoxytrimethylsilane
- Triethoxycaprylylsilane
- Trimethoxycaprylylsilane

According to the Cosmetic Ingredient Dictionary and Handbook (Dictionary), the functions of these polymerized tetramethylcyclotetrasiloxane ingredients include: binder, skin-conditioning agent – miscellaneous, skin-conditioning agent – emollient, and surface modifier (Table 1).1

The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) reviewed other siloxane polymers, such as Methicone and other related methicone-containing ingredients, and concluded that those ingredients were safe as used in cosmetic products.2 The Panel also reviewed other cyclicsiloxanes, the cyclomethicones, and concluded that they were safe as used in cosmetic products.3

Trimethoxycaprylylsilane is reported to function as a surface modifier; therefore toxicity studies of particles coated with alkoxyl alkyl silanes are included in this safety assessment.

Some of the data included in this safety assessment were found on the European Chemicals Agency (ECHA) website.4 In this safety assessment report, ECHA is cited as the reference for summaries of information from industry obtained from the ECHA website.

CHEMISTRY

Definition and Structure
The ingredients in this report are structurally-related silanes bearing both simple alkyl and simple alkoxy groups (Figure 1).

\[(RO)_{m} \text{Si} \text{R'}_{n}\]

Figure 1. Alkoxyl Alkyl Silanes, where m+n=4 and R & R’ are methyl or alkyl groups

Physical and Chemical Properties
These ingredients are liquids that work well as dispersants for substances such as titanium dioxide. Triethoxycaprylylsilane and Trimethoxycaprylylsilane are clear and colorless (Table 2).4,5

Triethoxycaprylylsilane in air is not expected to undergo direct photolysis, but may undergo indirect photolysis through hydroxyl radical oxidation.5

Method of Manufacture
The alkoxyl alkyl silanes can be synthesized via hydrosilation of the appropriate alkoxyl silane with an olefin (e.g., Triethoxycaprylylsilane may be synthesized via hydrosilation of 1-octene with triethoxysilane and a platinum catalyst).6 Alternatively, these ingredients may be synthesized via silation of appropriate alcohols with a disilazane (e.g., Stearoxytrimethylsilane may be synthesized via silation of octadecanol with hexamethyldisilazane and an organocatalyst).7

Impurities
A product mixture containing Bis-Stearoxydimethylsilane (approximately 75%), stearyl alcohol (approximately 16%), and dimethicone (approximately 9%), may contain <0.1% octamethylcyclotetrasiloxane as a manufacturing impurity.8 Analysis of three batches of this mixture showed that Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cu, Fe, Hg, Mn, Mo, Ni, Pb, Sb, Sn, Sr, Ti, V, W, Zn, and Zr were not present (detection level < 2 ppm); trace levels (<0.1%) of cyclotetrasiloxanes, cyclopentasiloxane, and cyclohexasiloxane were present.

Triethoxycaprylylsilane is reported to be 95%-100% pure.5 Impurities are reported to include ethanol (0.2%), octane (<1.5%), siloxanes (<2%), and branched octyltriethoxysilanes (<2%).
USE
Cosmetic

The safety of the cosmetic ingredients included in this safety assessment is evaluated based on the expected use of these ingredients in cosmetics. The Panel evaluates 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 through the FDA’s Voluntary Cosmetic Registration Program (VCRP), and include the use of individual ingredients in cosmetics by cosmetic product category. The data received from the cosmetic industry are collected by the Council in response to a survey of the maximum reported use concentrations by category.

According to 2016 VCRP survey data, Triethoxycaprylylsilane is reported to be used in 417 formulations, 413 leave-on formulations and 4 rinse-off formulations (Table 3). Stearoxytrimethylsilane and Trimethoxycaprylylsilane are reported to be used in 10 and 4 formulations, respectively. The results of the concentration of use survey conducted by the Council in 2015 indicate that Triethoxycaprylylsilane has the highest reported maximum concentration of use; it is used at up to 2.6% in suntan products. The other three ingredients are reported to be used at 0.77% or lower.

No uses were reported in the VCRP for Bis-Stearoxydimethylsilane, but concentration of use data were received from industry; it was reported to be used in a foundation in the Council survey. Therefore, it can be assumed that there is at least one use for this ingredient.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Dermal

Triethoxycaprylylsilane

New Zealand White rabbits (n=5/sex/dose) were dermally exposed to Triethoxycaprylylsilane (2000, 4000 or 8000 mg/kg) under occlusion for 24 h. The study protocol followed the Environmental Protection Agency’s (EPA) Toxic Substances Control Act (TSCA) Health Effects Test Guideline,[40 CFR 798.1100] The rabbits were observed for 14 days following exposure. One female and three male rabbits died in the 8000 mg/kg group; one male rabbit died in the 4000 mg/kg group. Signs of toxicity were transient, involved the central nervous system, and included limb paresis or paralysis.
Other clinical signs included labored breathing, iritis, slight wetness of the perinasal fur, and weight loss (some with emaciation). Necropsy of the rabbits that died revealed hemorrhaged intestines and a small amount of blood in the urine. Gross pathologic examination of all survivors revealed dark or bright red lungs. One rabbit exhibited intestines partially filled with gas, an enlarged spleen, and a raised tan nodule on one kidney. There were no treatment-related microscopic lesions in selected tissues (including spinal cord, sciatic nerve, kidneys and urinary bladder). The acute dermal LD50 in male rabbits was 6730 mg/kg and in female rabbits > 8000 mg/kg.

**Trimethoxycaprylylsilane**

When Trimethoxycaprylylsilane (0.5 mL) was applied to the shaved dorsal skin of white Russian rabbits (n=3) under occlusion for 4 h, no systemic effects were detected.4

**Oral**

**Bis-Stearoxydimethylsilane**

When a product mixture (2000 mg/kg) containing Bis-Stearoxydimethylsilane (concentration approximately 75%, dosage approximately 1500 mg/kg), stearyl alcohol, and dimethicone was orally administered to rats (n=5/sex), none of the rats died, there were no clinical signs of toxicity, and the necropsies were unremarkable.8,20 There were no effects on body weight changes during the 14-day observation period.

**Triethoxycaprylylsilane**

Triethoxycaprylylsilane (7280, 10,300 and 14,600 mg/kg in a 0.25% aqueous methyl cellulose solution) was administered by gavage to Sprague-Dawley rats (n=5/sex), and the rats were observed for 14 days.5 The study protocol followed EPA TSCA Health Effects Test Guideline.[40 CFR 798.1175] The predominant signs of toxicity included effects on the central nervous system (sluggishness, aggressive behavior, and unsteady gait with limb paresis or paralysis, loss of righting reflex, and prostration). Other clinical signs included an unkempt and/or moribund appearance, emaciation, a red crust on the perinasal and periocular fur, and a moderate amount of blood in the urine. All deaths occurred within 4-9 days after dosing (total deaths not specified); three moribund female rats in the 14,600 mg/kg group were killed early for humane reasons. Necropsy of the rats that died during treatment or observation period revealed discolored lungs, livers, stomachs and intestines, small stomachs, hemorrhaged or gas-filled intestines, bladders distended with red liquid or urine (males); a large amount of blood was present in the urine of three males. The rats that survived the observation period had no gross lesions at necropsy. Selected tissues (brain, spinal cord, sciatic nerve, lungs, kidneys and urinary bladder) from eight male and seven female rats were examined microscopically; the only lesions that were considered to be treatment-related were tubular dilation of the kidneys, renal mineralization and hemorrhages of the urinary bladder. The LD50 was 12,200 mg/kg for male rats, 11,500 mg/kg for female rats, and 11,800 mg/kg for the combined sexes.

Triethoxycaprylylsilane (5110 mg/kg in peanut oil) was administered by gavage to Bor: WISW (SPFCpb) rats (n=5/sex) and the rats were observed for 14 days.5 The study protocol followed Organisation for Economic Co-operation and Development Test Guideline (OECD TG) 401. The predominant clinical signs of toxicity were effects on the central nervous system (incoordination, stilted gait, labored breathing, sunken sides and vocalization on handling). Other signs of toxicity included hypokinesia, diarrhea, piloerection, red encrusted snout and body weight reduction. One female died on day 7 after dosing; at necropsy, the gastrointestinal tract was severely autolytic. At necropsy no abnormalities were detected in the animals that survived until the end of the study. The LD50 was >5110 mg/kg for male and female rats.

**Trimethoxycaprylylsilane**

The reported oral LD50 for Trimethoxycaprylylsilane in Wistar rats (n=10/sex) was >3500 mg/kg for both males and females.4 After a dosage of 3236 mg/kg, there were coordination disturbances, piloerection, chromodacryorrhea, increased salivation, and red nasal discharge. At 4752 mg/kg, there was additional decreased muscle tone, loss of righting reflexes, and increased diuresis. Other clinical signs included tremors, vocalization on handling, lacrimation, opacity of the cornea, and green discolored urine. The development of toxic effects was not always immediate; coordination disturbances were observed 2 h after administration of the test material, and the other clinical signs occurred between days 2 and 5. All clinical signs resolved by day 21 of the observation period.

**Inhalation**

**Trimethoxycaprylylsilane**

In a study conducted in a manner similar to OECD TG 403, Crl:CD (R) BR, VAF (R) PLUS, Sprague-Dawley rats (n=5/sex) were exposed to a saturated vapor concentration of Trimethoxycaprylylsilane in air (approximately 248 mg/m3) in a whole-body inhalation chamber for 4 h and then observed for 14 days.5 There were no deaths during the exposure or the observation period. Hyperactivity during the exposure period was observed in one rat. No exposure-related effects were noted on body weights and no abnormal gross lesions were noted at necropsy. The LC50 was greater than the saturated vapor concentration.
Trimethoxycaprylylsilane

Wistar rats (n=5/sex) were exposed to aerosolized Trimethoxycaprylylsilane in a whole-body chamber (duration not specified); because the concentration of the test material did not reach the desired levels (actual concentrations achieved not specified and no further information was provided), a nose-only apparatus was used to expose the rats. It is not clear if the same or new rats were used when the authors switched methods of exposure. The rats were exposed for 4 h in the nose-only apparatus and observed for 14 days thereafter. The mean actual concentrations of exposure in the nose-only apparatus were 0.9, 2.36, 2.53, and 6.2 g/m³ (corresponding nominal concentrations: 3.5, 9.8, 15.4, and 27.6 g/m³, respectively).

None of the rats died in the 0.9 g/m³ group, one male and three female rats died in the 2.36 g/m³ group, no males and four females died in the 2.53 g/m³ group, and one male and all five females died in the 6.2 g/m³ group.

During exposure to 0.9 g/m³ in the nose-only apparatus, the rats had a hunched appearance, piloerection, and mostly closed eyes. Breathing patterns were superficial and irregular during the first hour of exposure; breathing patterns became more regular concomitant with a decreased breathing frequency (1-2 breaths/sec vs 3-4 breaths/sec normally). Directly after exposure, breathing frequency was irregular in rats exposed to 0.9 g/m³. No abnormalities were observed 4 days after exposure to 0.9 g/m³. However, exposure to 0.9 g/m³ resulted in reduced body weight gain in male rats measured 14 days after exposure, and reduced body weight or body weight gain in female rats 7 and 14 days after exposure.

Piloerection was observed during the first 4 days of observation in one female rat exposed to 2.36 g/m³. Superficial breathing patterns and wet heads were observed in rats exposed to 2.36 or 2.53 g/m³, and labored breathing was observed in four female rats exposed to 2.53 g/m³. Rats in the 2.36 g/m³ group showed drowsiness shortly after the end of exposure. Body weight gain of the surviving rats exposed to 2.36 or 2.54 g/m³ was generally not affected. No abnormalities were observed after 4 days in rats exposed to 2.53 g/m³.

Exposure to 6.2 g/m³ in the nose-only apparatus resulted in a very low, deep or superficial, irregular breathing frequency (<1 breath/sec) 30 min after the start of exposure. In general, breathing patterns became more stable thereafter (1-2 breaths/sec). The rats exhibited wet heads 2 h after the start of the exposure. Directly after exposure, breathing frequency was labored in rats exposed to 6.2 g/m³. The rats with labored breathing were lethargic. The first 4 days of the observation period revealed piloerection, wet noses, drowsiness, and tightly closed eyes in surviving rats exposed to 6.2 g/m³. Piloerection remained until day 7 post exposure. Dyspnea was observed in one male 14 days after exposure; its limbs were blue, the rat was skinny and showed piloerection and signs of ataxia. All four surviving rats exposed to 6.2 g/m³ showed severe body weight reduction 7 days after exposure; body weight gain was observed 14 days after exposure in 3 of these rats.

At necropsy, red discolored lungs were found in rats exposed to 2.36 g/m³. Rats exposed to 2.53 g/m³ had rusty-brown discolored lungs. Dark-red discolored, and sometimes swollen or darkly spotted, and/or edematous lungs were found in the rats that died, or were killed in extremis after exposure to 6.2 g/m³. Furthermore, grey-white spots were observed on the lung lobes of three female rats. In the other rats in the 6.2 g/m³ group that were killed in extremis, no other abnormalities were observed. In all surviving rats necropsied at the end of the 14-day observation period, no abnormalities were found, except for spotted lungs in one male exposed to 6.2 g/m³. The LC₅₀ for Trimethoxycaprylylsilane was 7.5 and 1.9 g/m³ for male and female rats, respectively. The combined LC₅₀ was 3.9 g/m³.

Triethoxycaprylylsilane - Coated Particles

In a pulmonary toxicity study, Triethoxycaprylylsilane-coated titanium dioxide particles (2 and 10 mg/kg) were instilled into the lungs of male Crl:CD (SD)IGS BR rats (n=6/group/recovery time) with and without Tween 80 (1%). The Triethoxycaprylylsilane-coated titanium dioxide particles were 230 μm (assumed diameter; mean or median not reported), with a particle size range of 0.1–0.9 μm, and a surface area of 8.2 m²/g; these particles were hydrophobic. Saline was the control substance. After saline instillation (2 from each group) and at 24 h, 1 week, 1 month, and 3 months (4 from each group), the rats were then killed, their lungs were lavaged with warm phosphate-buffered saline, and the lungs were examined. The numbers of cells recovered by bronchoalveolar lavage from the lungs of any of the Triethoxycaprylylsilane-coated titanium dioxide particles-exposed groups were not different from saline-instilled controls at any post-exposure time point. Histopathological analyses of a lung tissue section of rats in the high dose groups at 1 month post-exposure showed normal pulmonary architecture and, other than a few particle-laden macrophages, were not very different from a saline-instilled lung section at 1 month post-exposure. The authors concluded that the Triethoxycaprylylsilane-coated titanium dioxide particles did not cause pulmonary toxicity.

Zinc oxide particles coated with Triethoxycaprylylsilane (1, 4, 8, 16, 32, 64, or 128 μg) suspended in water with 2% mouse serum were intratracheally instilled into the lungs of C57BL/6N mice (n=3). The particles were 130 nm in diameter; when analyzed in suspension, the median diameter was 208±74 nm and mean diameter was 225±32, indicating agglomeration and an asymmetrical particle-size distribution. The mice were killed and necropsied 24 h after instillation. Acute pulmonary inflammation was observed (marked by polymorphonuclear neutrophil influx) with cell damage (marked by increased lactate dehydrogenase and total protein) in broncho alveolar lavage fluid (BALF) in the 64 and 128 μg groups. Systemic inflammation was indicated by increased blood neutrophils and decreased blood lymphocytes in the lung tissue. These signs were not observed in the 1-32 μg groups.
Short-Term Toxicity Studies

Animal

Bis-Stearoxydimethylsilane

In a 28-day oral study (administered by gavage) conducted in accordance with OECD TG 407, a product mixture (50, 200, 1000 mg/kg) containing Bis-Stearoxydimethylsilane (approximately 75%) was reported to have a no-observed-adverse-effect level (NOAEL) of 1000 mg/kg/d (approximately 750 mg/kg/d Bis-Stearoxydimethylsilane) in SPF-bred Wistar rats.1,2,3 None of the rats died and there were no clinical signs during the test period. There were no adverse effects observed in the grip strength test and locomotor activity test during week 4 of the test period. Feed consumption and body weight changes were similar to the control group (vehicle only). Hematology and clinical biochemistry parameters of blood collected at the end of treatment were similar in the test and control groups. Macroscopic and microscopic findings at necropsy were unremarkable; organ weights were similar in the control and treatment groups.

Triethoxycaprylylsilane

In a combined repeated-dose/reproductive/developmental toxicity screening test following OECD TG 422, Triethoxycaprylylsilane (0, 100, 300 or 1000 mg/kg/d in dried, de-acidified peanut oil) was administered 7 days a week by gavage to Sprague-Dawley rats (n=10/sex).4 There was a group of females evaluated for repeated-dose toxicity and another group evaluated for reproductive toxicity. The same males were used in both the toxicity and reproductive phases of the study. Males and females of the repeated-toxicity group were treated for 28 and 29 days, respectively. Females of the reproductive-toxicity group were treated with the same dose rates for up to 45 days (prior to mating through post-partum day 4). Animals were observed twice daily for mortality, morbidity, and moribundity. Clinical examinations were performed daily following dosing. Functional observational battery (FOB) and motor activity evaluations were performed on males and females of the repeated-dose toxicity group. Detailed physical examinations and body weight measurements were performed weekly. Individual feed consumption was recorded weekly, except during the cohabitation period. Blood samples for hematology and serum chemistry evaluations were collected at the scheduled necropsy. Complete necropsies were performed, and selected organs were weighed. Microscopic examination was performed on protocol-specified tissues from the control and high-dose males, and females of the repeated-dose toxicity and reproductive-toxicity groups. Based on clinical and histopathology findings in the high dose group, various target tissues of the males and females of the repeated-dose toxicity and reproductive-toxicity groups were examined at the mid and low dose groups. [See results specific to reproduction in the Reproductive and Developmental Toxicity section.]

Clinical signs included an increase in soiling of the head (around the nose, chin, and muzzle) in the mid- and high-dose males and females of the repeated-dose toxicity groups, and in the females of the high-dose reproductive-toxicity group. Clinical observations consistent with neuromuscular toxicity (decreased activity, dragging of the hind limbs and/or uncoordinated gait) occurred only in the high-dose reproductive toxicity group, and were not observed in the males or females of the repeated-dose toxicity group. Due to the severity of these clinical signs, three females of the high-dose reproductive-toxicity group were killed prior to scheduled necropsy. There were no changes observed during FOB and motor activity tests conducted with males and females of the repeated-toxicity group (no clinical signs before termination), most likely due to the shorter duration of exposure compared to the females of the reproductive-toxicity group (29 days for females of the repeated-dose toxicity group vs up to 45 days for females of the reproductive-toxicity group). Treatment-related decreases in group mean body weights and/or body weights gains were observed in all rats in the high-dose groups with associated decreases in feed consumption in the females of the repeated-dose and reproductive-toxicity groups. There were no treatment related clinical pathology findings.

There was an increase in mean absolute and relative liver weights of males and toxicity group females in the high-dose group. Histopathological findings were identified in the liver as dose-related increases in the incidence of centrilobular hypertrophy in the mid- and high-dose repeated toxicity groups and reproductive-toxicity groups, which was associated with an increase in mean absolute and relative liver weights; these liver effects were not considered adverse because these changes are consistent with common adaptive changes that occur in the liver upon xenobiotic administration. Histopathological findings were identified in the bladder as diffuse epithelial hyperplasia in all rats in the high-dose repeated-toxicity groups. Other unspecified histopathological findings were also identified in the kidneys, adrenal glands, thymus, spleen, brain, spinal cord, peripheral nerves, and skeletal muscles in the high-dose groups. In the brain, 40% and 80% of the high-dose repeated-toxicity group and reproductive-toxicity group females, respectively, exhibited white matter degeneration. Degeneration of spinal cord occurred in 50% and 90% of the females of the high-dose repeated-toxicity and reproductive-toxicity groups, respectively. The peripheral nerves (sciatic and tibial) also showed minimal to severe degeneration and demyelination in the high-dose repeated-toxicity and reproductive-toxicity groups, with less incidence and severity occurring in the repeated-toxicity group females. Based on the bladder epithelial hyperplasia in males and the neuromuscular findings in the females of the repeated-toxicity and reproductive groups at 1000 mg/kg/d, the NOAEL for systemic toxicity was 300 mg/kg/d.5 6

Fischer 344 rats (n=5/sex, 10/sex in high-dose and control group) were administered Triethoxycaprylylsilane (200, 2000, and 10,000 ppm) in the diet for 28 days.7 The study protocol was similar to that of OECD TG 407. Mean test substance consumption values for males were 12.2, 114.4, and 592.2 mg/kg/d for the 200, 2000, and 10,000 ppm target concentrations, respectively. Mean test substance consumption for females was 13.4, 122.6, and 639.6 mg/kg/d for the 200, 2000, and 10,000 ppm target concentrations, respectively. Following termination of dosing, 5 rats/sex from the high-dose and control groups were allowed a 2-week recovery period. Clinical signs, feed consumption, body and organ weights,
DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART)

Triethoxycaprylylsilane

As stated previously, Triethoxycaprylylsilane (0, 100, 300 or 1000 mg/kg/d in dried, de-acidified peanut oil) was administered 7 days a week by gavage to 10 rats/sex/group for up to 45 consecutive days in a combined repeated-dose/reproductive/developmental toxicity screening test. The study followed OECD TG 422. Females were divided into a repeated-toxicity group and a reproductive-toxicity group. The same males were used for both the repeated-toxicity and reproductive-toxicity phases of the study. Males were treated for 28 days. Reproductive-toxicity group females were treated for up to 45 days (14 days prior to mating, during mating, gestation, and up to and including postpartum day 4). Mating was initiated after 2 weeks of dosing. Reproductive-toxicity group females cohabitated with males of the same treatment group until positive evidence of mating occurred. A maximum of 14 days were allowed for mating. Reproductive parameters evaluated included evidence of mating, pregnancy, duration of gestation, mean number of corpora lutea and mean number of uterine implantation sites, mean mating and fertility indices and evaluation of loss of offspring (pre-implantation and postnatal loss). [See results specific to toxicity in the Repeated Dose Toxicity section.]

Changes in reproductive parameters were observed in the high-dose group and were associated with marked maternal toxicity. Mating and fertility were unaffected by treatment. The mean duration of gestation was increased (5.6%) compared to the control group. Of the seven dams that successfully initiated parturition, four exhibited dystocia (difficult/prolonged labor). The authors concluded that it was not possible to determine with confidence if 1000 mg/kg/d represents the NOAEL. Therefore, the reproductive toxicity NOAEL was considered to be >300 mg/kg/d.

To evaluate the developmental toxicity of Triethoxycaprylylsilane, dams and pups were killed on postpartum day 4 and examined for external gross lesions. Developmental parameters evaluated included total litter size, mean litter size, mean live litter size, mean litter weight, mean ratio of live births/litter size, sex ratio, pup viability, pup body weight, and body weight gain. Changes in developmental parameters were observed in the high-dose group and were associated with marked maternal toxicity; the total litter sizes in this group were unaffected by treatment but the mean number of live male and female pups/dam at first litter check on post-natal day (PND) 0 was decreased (39.3%) compared to controls. PND 0 mean litter weights, average pup body weights and body weight gains were similar to controls. By PND 4, several dams in the high-dose group had been killed due to the severity of various clinical signs and/or difficulty during labor. Only 4 dams survived to PND 4. Of these litters, the total viable pups on PND 4 were decreased compared to controls, resulting in a 25.2% decrease in percent viability of pups/dam on PND 4 compared to controls. This decrease was due to a single dam with a 14.3% post-natal loss of offspring. The remaining dams had no post-natal loss of pups between Days 0-4. PND 4 mean litter weights, average pup body weights and body weight gains in the high-dose group were also decreased compared to controls. External gross lesions were not observed for treated dams or pups. The authors concluded that it was not possible to determine with confidence if 1000 mg/kg/d represents the NOAEL. Therefore, they considered the developmental toxicity NOAEL to be >300 mg/kg/d.

GENOTOXICITY STUDIES

In Vitro

Genotoxicity studies are summarized in Table 4. In multiple genotoxicity assays, Bis-Stearoxydimethylsilane (up to 5000 µg/plate) and Triethoxycaprylylsilane (up to 10,000 µg/plate) were negative for genotoxicity. Trimethoxycaprylylsilane was not cytotoxic.

CARCINOGENICITY STUDIES

Carcinogenicity data were not found in the published literature and no unpublished data were provided.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

Animal

Bis-Stearoxydimethylsilane

A product mixture containing Bis-Stearoxydimethylsilane (approximately 75%) was reported to be non-irritating in rabbits. No further information was provided.

Triethoxycaprylylsilane

Triethoxycaprylylsilane (0.5 mL) was applied under occlusion for 4 h to the intact skin of New Zealand White rabbits (n=3/sex). The study protocol followed EPA TSCA Health Effects Test Guideline. [40 CFR 798.4470] The rabbits were restrained for the 4-h contact period; when the coverings were removed, excess test substance was removed. Moderate erythema (grade 2) and moderate edema (grades 2-3) were observed in all rabbits at the 1-h observation time; this was
resolved on day 7. At day 7, desquamation was observed on two animals. The Primary Irritation Index (PII) was 3.041 (3=primary skin irritant; 4=corrosive to the skin). The substance was considered to be moderately irritating to the skin.

Triethoxycaprylylsilane (100%; 0.5 mL) was applied to the skin of Russian white rabbits ($n=2$ male, 1 female) for 4 h under occlusion in a study following OECD TG 404. The coverings were removed and the test substance was not washed off. Moderate erythema (grades 2-3) and moderate-to-severe edema (grades 3-4) were observed in all three rabbits at 1 h. Desquamation was observed in all animals beginning on day 7. All skin effects had completely resolved on day 10. The Primary Dermal Irritation Index (PDII) was 5.1 in a scale of 0 to 8. The substance was considered to be highly irritating to the skin.

In a toxicological study described previously, New Zealand White rabbits ($n=5$/sex) were dermally exposed to Triethoxycaprylylsilane (2000, 4000 or 8000 mg/kg) under occlusion for 24 h. The study protocol followed EPA TSCA Health Effects Test Guideline. [40 CFR 798.1100] Dermal reactions included erythema, edema, necrosis, fissuring, desquamation and alopecia; it was not specified which dose level(s) caused these reactions.

**Trimethoxycaprylylsilane**

Trimethoxycaprylylsilane (assumed 100%; 0.5 mL) was administered to the shaved dorsal skin of white Russian rabbits ($n=3$) under occlusion for 4 h. The test location was observed at 1, 24, and 72 h, then daily for 14 days. Moderate to severe erythema was observed in all three rabbits immediately after removal of the patches, which resolved by day 10 of observation. Slight edema in one rabbit and moderate edema in the other two rabbits was observed immediately after the end of exposure, which was resolved by day 9. All rabbits showed eschar formation from the middle of the first observation week, which had not completely peeled off in two rabbits until the end of the observation period. The mean PDII was 4.9 in a scale of 0 to 8; the mean value for erythema/eschar was 2.42, and the mean value for edema was 2.5. Trimethoxycaprylylsilane was considered irritating to rabbit skin.

**Sensitization**

**Animal**

**Bis-Stearoxydimethylsilane**

In a Magnusson/Kligman assay conducted according to OECD TG 406 using guinea pigs ($n=20$, control=10) and a product mixture containing Bis-Stearoxydimethylsilane (75%), the test group was intradermally injected with the test substance (10%, 7.5% Bis-Stearoxydimethylsilane; with and without Freund’s complete adjuvant). One week later, the test substance was dermally administered (75% in Alembicol D, 52.50% Bis-Stearoxydimethylsilane). Two weeks later, the guinea pigs were challenged with the test substance (50%, 37.5% Bis-Stearoxydimethylsilane). There was no sensitization response observed.

**OCULAR IRRITATION STUDIES**

**Animal**

**Triethoxycaprylylsilane**

A single instillation of Triethoxycaprylylsilane (assumed 100%; 0.1 mL) was made into one eye of each New Zealand White rabbit ($n=3$/sex) and the eyes were not rinsed. The study protocol followed EPA TSCA Health Effects Test Guideline. [40 CFR 798.4500] The untreated eyes served as controls. Irritation was scored according to the Draize method at 1, 24, 48 and 72 h after administration. Transient iritis (grade 1) was apparent in 4 treated eyes at 1 h, but had resolved at 24 h. Minor to moderate conjunctival irritation characterized by redness and swelling (grades 1-2) with a moderate amount of ocular discharge (grades 1-2) was observed in all treated eyes. All of the rabbits had a normal ocular appearance by day 7. The maximum average score (MAS) was 12.33 (in a scale of 0 to 110) at 1 h; the scores at 72 h and day 7 were <0. Triethoxycaprylylsilane was considered slightly irritating.

In an acute eye irritation/corrosion study conducted in accordance with OECD TG 405, a single instillation of Triethoxycaprylylsilane (0.1 mL) was applied to the conjunctiva of one eye of albino Russian white rabbits ($n=1$ male, 2 female). The untreated eyes served as controls. The eyes were not rinsed. Diffuse redness of the conjunctiva (grade 2) seen in all three rabbits resolved by 48 h. Slight swelling (grade 1) was observed in all three rabbits at 1 h; discharge was also noted in one rabbit at this time point. No effects on the cornea or iris were observed. The irritation index was 2.0 (in a scale of 0 to 110). Triethoxycaprylylsilane was considered slightly irritating.

**Trimethoxycaprylylsilane**

In a Draize test using white Russian albino rabbits ($n=1$ male, 2 females), Trimethoxycaprylylsilane (0.1 mL) was instilled in one eye of each rabbit. The test substance was not rinsed and the eyes were observed for 3 days. There were no effects observed on the corneas and irises. The conjunctiva reacted with hyperemia (grade 1) in one rabbit and a diffuse crimson or beefy discoloration (grade 2 or 3) was observed in two rabbits. In addition, slight swelling (grade 1) or swelling
with partial eversion of lids (grade 2) was observed. Swelling had completely disappeared at 24 h and redness was not observed 48 or 96 h after instillation. Discharge with moistening around the eye was recorded for two rabbits only at the 1-h observation time. The mean irritation score was 4 out of a possible 80. It was concluded that Trimethoxycaprylylsilane was not irritating to the eyes of rabbits.

**SUMMARY**

This is a review of the available scientific literature and unpublished data relevant to assessing the safety of the alkoxyl alkyl silanes as used in cosmetics. The ingredients in this report are structurally-related silanes and bear both simple alkyl and simple alkoxyl groups. The functions of these polymerized tetramethyldicyclosiloxane ingredients include skin-conditioning agent – miscellaneous, skin-conditioning agent – emollient, binder, and surface modifier.

According to 2015 VCRP survey data, Triethoxycaprylylsilane is reported to be used in 417 formulations, 413 in leave-on formulations and 4 rinse-off formulations. Stearoxytrimethylsilane and Trimethoxycaprylylsilane are reported to be used in 10 and 4 formulations, respectively. Bis-Stearoxydimethylsilane had no reported uses in the VCRP.

The 2015 Council survey reports that Triethoxycaprylylsilane has the highest reported maximum concentration of use; it is used at up to 2.6% in suntan products. The other three ingredients are reported to be used at 0.77% or lower.

A product mixture containing Bis-Stearoxydimethylsilane (approximately 75%) did not penetrate porcine skin in an in vitro assay.

The acute dermal LD$_{50}$ of Triethoxycaprylylsilane was 6730 mg/kg in male rabbits and >8000 mg/kg in female rabbits. When Trimethoxycaprylylsilane was administered to the skin of rabbits under occlusion for 4 h, there were no systemic effects observed.

When a product mixture containing Bis-Stearoxydimethylsilane (approximately 1500 mg/kg) was orally administered to rats, none of the rats died, there were no clinical signs of toxicity, and the necropsies were unremarkable. The LD$_{50}$ was 12,200 mg/kg for Triethoxycaprylylsilane for male rats, 11,500 mg/kg for female rats, and 11,800 mg/kg for the combined sexes. In another assay, the LD$_{50}$ value was >5110 mg/kg for male and female rats. The reported oral LD$_{50}$ for Trimethoxycaprylylsilane in rats was >3500 mg/kg for both males and females; after a dose of 3236 mg/kg, there were coordination disturbances, piloerection, chromodacryorrhea, increased salivation, and red nasal discharge.

There were no deaths during exposure or the observation period when rats were exposed to a saturated vapor of approximately 248 mg/m$^3$ of Triethoxycaprylylsilane in a whole body inhalation chamber for 4 h.

The inhalation LC$_{50}$ for Trimethoxycaprylylsilane following a 4 h exposure was 7.5 and 1.9 g/m$^3$ for male and female rats, respectively; the combined LC$_{50}$ was 3.9 g/m$^3$. Clinical signs included superficial and irregular breathing during the first hour of exposure, wet heads, lethargy, piloerection, tightly closed eyes. Body weight gains were reduced during the observation period. The lungs of the rats that died or were killed in extremis were discolored and had spots.

Triethoxycaprylylsilane-coated titanium oxide particles at 10 mg/kg did not cause pulmonary toxicity when instilled into the lungs of rats. Zinc oxide particles coated with Triethoxycaprylylsilane caused acute pulmonary inflammation with cell damage in BALF at 64 and 128 µg in mice but not at 1-32 µg.

In a 28-day oral study, a product mixture containing Bis-Stearoxydimethylsilane at approximately 75% was reported to have a NOAEL of 1000 mg/kg/d (approximately 750 mg/kg/d Bis-Stearoxydimethylsilane) in rats. In a repeated-dose/reproductive/developmental toxicity screening test, the NOAEL for systemic toxicity was 300 mg/kg/d Triethoxycaprylylsilane when administered for 28-29 days. Clinical signs at 300 and 1000 mg/kg/d included an increase in soiling around the nose, chin, and muzzle. Neuromuscular toxicity was observed at 1000 mg/kg/d. Treatment-related decreases in group mean body weights and/or body weights gains were observed in all rats in the high-dose groups with associated decreases in feed consumption in the toxicity group females and reproductive group females. There were no treatment related clinical pathology findings. The NOAEL was >10,000 ppm (the highest dose tested), corresponding to dosages of approximately 592.2 and 639.6 mg/kg/d for male and female rats, respectively, when Triethoxycaprylylsilane was administered in the diet for 28 days.

The reproductive and developmental toxicity NOAELs were >300 mg/kg/d for orally administered Triethoxycaprylylsilane in female rats; Triethoxycaprylylsilane was administered from 14 days prior to mating through 4 days postpartum. Reproductive effects only occurred in the 1000 mg/kg/d group in association with marked maternal toxicity.

A product mixture containing Bis-Stearoxydimethylsilane (approximately 75%) was reported to not be mutagenic at doses up to 5000 µg/plate in an Ames assay. In two separate assays, Triethoxycaprylylsilane was negative for mutagenicity in bacterial reverse mutation assays with *Salmonella typhimurium* and *Escherichia coli*, with and without metabolic activation at up to 10,000 µg/plate. In an *in vitro* chromosome aberration assay, Triethoxycaprylylsilane was cytotoxic to CHO cells with metabolic activation at 50 µg/mL and without metabolic activation at 20 µg/mL. In an *in vitro* chromosome aberration assay, Triethoxycaprylylsilane was negative for the induction of chromosome aberrations and was not clastogenic up to 1570 µg/mL. In an Ames tests, Trimethoxycaprylylsilane was not mutagenic to *S. typhimurium* up to 5000 µg/plate.

A product mixture containing Bis-Stearoxydimethylsilane (approximately 75%) was reported to be non-irritating in rabbits. The PII was 3.041 when Triethoxycaprylylsilane (assumed 100%) was administered to rabbits; the substance was considered as moderately irritating to the skin. In another assay (assumed 100%), the PDI was 5.1 and the substance was considered to be highly irritating to rabbit skin. When rabbits were dermally exposed to Triethoxycaprylylsilane at 2000-8000 mg/kg under occlusion for 24 h, dermal reactions included erythema, edema, necrosis, fissuring, desquamation and
alopecia; it was not specified which dose level(s) caused these reactions. Trimethoxycaprylylsilane was considered irritating to rabbit skin at 100%.

A product mixture containing 75% Bis-Stearoxydimethylsilane was reported to be non-sensitizing in a Magnusson/Kligman assay using guinea pigs.

A product mixture containing Bis-Stearoxydimethylsilane at approximately 75% was reported to be non-irritating in the eyes of rabbits. After a single instillation of Triethoxycaprylylsilane, the MAS was 12.33 at 1 h; the scores at 72 h and day 7 were <0; Triethoxycaprylylsilane was considered slightly irritating. In an acute eye irritation/corrosion study, the irritation index was 2.0 for Triethoxycaprylylsilane and was considered slightly irritating. In a Draize test using rabbits, Trimethoxycaprylylsilane, there were no effects observed on the corneas and irises and was considered to be non-irritating.

**DISCUSSION**

[To be determined]

**CONCLUSION**

[To be determined]
**Table 1. Definitions, CAS Nos., idealized structures, and functions of the alkoxy alkyl silane ingredients in this safety assessment.**

<table>
<thead>
<tr>
<th>Ingredient CAS No.</th>
<th>Definition &amp; Structures</th>
<th>Function(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis-Stearoxydimethylsilane 29043-70-7</td>
<td>Bis-Stearoxydimethylsilane is the silicon compound that conforms to the formula. [Bis-Stearoxydimethylsilane is an organo-silicon compound, Si-substituted with 2 octadecyoxyl groups and 2 methyl groups.]</td>
<td>Skin-conditioning agent - miscellaneous</td>
</tr>
<tr>
<td>Stearoxytrimethylsilane 18748-98-6</td>
<td>Stearoxytrimethylsilane is the organo-silicon compound that conforms to the formula. [Stearoxytrimethylsilane is an organo-silicon compound, Si-substituted with 1 octadecyoxyl group and 3 methyl groups.]</td>
<td>Skin-conditioning agent - emollient</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane 2943-75-1</td>
<td>Triethoxycaprylylsilane is the siloxane ether that conforms to the formula. [Triethoxycaprylylsilane is an organo-silicon compound, Si-substituted with 3 ethoxy groups and 1 octyl group.]</td>
<td>Binder</td>
</tr>
<tr>
<td>Trimethoxycaprylylsilane 3069-40-7</td>
<td>Trimethoxycaprylylsilane is the siloxane ether that conforms to the formula. [Trimethoxycaprylylsilane is an organo-silicon compound, Si-substituted with 3 methoxy groups and 1 octyl group.]</td>
<td>Binder; surface modifier</td>
</tr>
</tbody>
</table>
### Table 2. Chemical and physical properties of alkoxy alkyl silane ingredients.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bis-Stearoxydimethylsilane</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Weight g/mol</td>
<td>597.13</td>
<td>27</td>
</tr>
<tr>
<td><strong>Stearoxytrimethylsilane</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Weight g/mol</td>
<td>342.68 est</td>
<td>*</td>
</tr>
<tr>
<td>Density/Specific Gravity</td>
<td>0.8±0.1 est.</td>
<td>*</td>
</tr>
<tr>
<td>Vapor pressure mmHg@ 25 °C</td>
<td>0.6±0.9 est.</td>
<td>*</td>
</tr>
<tr>
<td>Boiling Point °C</td>
<td>387.1±10.0 est.</td>
<td>*</td>
</tr>
<tr>
<td>logP</td>
<td>10.65 est.</td>
<td>*</td>
</tr>
<tr>
<td><strong>Triethoxycaprylylsilane</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Weight g/mol</td>
<td>376.49 est</td>
<td>*</td>
</tr>
<tr>
<td>Physical Form</td>
<td>Liquid</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>Clear/colorless</td>
<td></td>
</tr>
<tr>
<td>Density/Specific Gravity g/cm³ @ 23°C</td>
<td>0.876</td>
<td>*</td>
</tr>
<tr>
<td>Vapor pressure mmHg@ 25°C</td>
<td>0.1±0.4 est.</td>
<td>*</td>
</tr>
<tr>
<td>Melting Point °C</td>
<td>-46</td>
<td>*</td>
</tr>
<tr>
<td>Boiling Point °C</td>
<td>257</td>
<td>*</td>
</tr>
<tr>
<td>Water Solubility g/L @ 22.8°C</td>
<td>&lt;0.13</td>
<td>*</td>
</tr>
<tr>
<td>log Kow @ 23°C</td>
<td>-3.7</td>
<td>*</td>
</tr>
<tr>
<td>logP</td>
<td>5.45 est.</td>
<td>*</td>
</tr>
<tr>
<td><strong>Trimethoxycaprylylsilane</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Form</td>
<td>Liquid</td>
<td>*</td>
</tr>
<tr>
<td>Color</td>
<td>Clear/colorless</td>
<td></td>
</tr>
<tr>
<td>Molecular Weight g/mol</td>
<td>231.11</td>
<td>*</td>
</tr>
<tr>
<td>Viscosity kg/(s m)@ °C</td>
<td>0.10</td>
<td>*</td>
</tr>
<tr>
<td>Vapor pressure mmHg@ 20°C</td>
<td>157.5</td>
<td>*</td>
</tr>
<tr>
<td>Boiling Point °C</td>
<td>227</td>
<td>*</td>
</tr>
<tr>
<td>Water Solubility g/L @ 20°C</td>
<td>0.0133</td>
<td>*</td>
</tr>
<tr>
<td>log P&lt;sub&gt;ow&lt;/sub&gt;</td>
<td>3.9±0.2</td>
<td>*</td>
</tr>
</tbody>
</table>

* Estimated by Chem Draw
* Estimated by ACD/Labs Percepta Platform - PhysChem Module
* The water solubility and log K<sub>ow</sub> values may not be accurate because the chemical is hydrolytically unstable.
* est. = estimated
Table 3. Frequency of use according to duration and exposure of alkoxyl alkyl silanes.9,10

<table>
<thead>
<tr>
<th>Use type</th>
<th>Uses</th>
<th>Total/range</th>
<th>Duration of use</th>
<th>Triethoxycaprylylsilane</th>
<th>Bis-Stearoxydimethylsilane</th>
<th>Stearoxytrimethylsilane</th>
<th>Trimethoxycaprylylsilane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye area</td>
<td>120</td>
<td>0.005-2.5</td>
<td></td>
<td>541</td>
<td>0.000001-2.6</td>
<td>NR</td>
<td>0.1</td>
</tr>
<tr>
<td>Incidental ingestion</td>
<td>15</td>
<td>0.0024-1</td>
<td></td>
<td>10</td>
<td>0.1-0.55</td>
<td>4</td>
<td>0.1-0.77</td>
</tr>
<tr>
<td>Incidental Inhalation-sprays</td>
<td>9; 36</td>
<td>0.011-0.021; 14</td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Incidental inhalation-powders</td>
<td>40; 14</td>
<td>0.006-2; 0.000001-2.4</td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dermal contact</td>
<td>386</td>
<td>0.000001-2.6</td>
<td></td>
<td>10</td>
<td>0.1-0.55</td>
<td>4</td>
<td>0.1-0.77</td>
</tr>
<tr>
<td>Deodorant (underarm)</td>
<td>NR</td>
<td>NR</td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Hair-noncoloring</td>
<td>4</td>
<td>0.8</td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
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<tr>
<td>Hair-coloring</td>
<td>5</td>
<td>NR</td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Nail</td>
<td>2</td>
<td>0.18-0.15</td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Mucous Membrane</td>
<td>19</td>
<td>0.001-1</td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Baby</td>
<td>NR</td>
<td>NR</td>
<td></td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>NR = Not Reported; Totals = Rinse-off + Leave-on + Diluted for Bath Product Uses.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d It is possible these products may be powders, but it is not specified whether the reported uses are powders.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4. In vitro genotoxicity studies of alkoxyl alkyl silanes.

<table>
<thead>
<tr>
<th>Ingredient/Concentration</th>
<th>Assay</th>
<th>Results</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis-Stearoxydimethylsilane (approximately 75%) with stearyl alcohol and dimethicone; 33.3-5000.0 µg/plate</td>
<td>Ames assay, OECD TG 471; S. typhimurium (TA98, TA100, TA1535, and TA1537) with and without metabolic activation. No controls were specified. The experiment was conducted twice.</td>
<td>Negative. No toxic effects were observed.</td>
<td>8,23,25</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane; up to 10,000 µg/plate</td>
<td>Ames assay, OECD TG 471; S. typhimurium (strains TA98, TA100, TA1535, TA1537, and TA1538) and Escherichia coli (WP2 uvrA) with and without metabolic activation. No controls were specified. The experiment was conducted twice.</td>
<td>Negative. Cytotoxic concentration in both studies was &gt;5000 µg/plate.</td>
<td>3,8,23,25</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane (16-50 µg/mL with metabolic activation, 6.4-35.4 µg/mL without metabolic activation)</td>
<td>Chromosome aberration assay (similar to OECD TG 473). The cells were exposed for 6, 24 and 48 h in the absence of metabolic activation and for 6 h in the presence of metabolic activation.</td>
<td>There were no increases in structural or numerical chromosome aberrations. Cytotoxic to CHO cells with metabolic activation at 50 µg/mL and without metabolic activation 20 µg/mL and higher. The controls had the expected results.</td>
<td>3,8,23,25</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane; 0.016-157 µg/mL in ethanol</td>
<td>Chromosome aberration assay, OECD TG 473, using CHO cells.</td>
<td>Negative with and without metabolic activation. The controls had the expected results.</td>
<td>3,8,23,25</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane; up to 10 mg/plate</td>
<td>Bacterial reverse mutation assay, OECD TG 471; with S. typhimurium (strains TA98, TA100, TA1535, TA1537, and TA1538) and Escherichia coli (WP2 uvrA)</td>
<td>Negative with and without metabolic activation. Not cytotoxic. The controls had the expected results.</td>
<td>3,8,23,25</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane; up to 10 mg/plate</td>
<td>Bacterial reverse mutation assay, OECD TG 471; with S. typhimurium (strains TA98, TA100, TA1535, TA1537, and TA1538) and Escherichia coli (WP2 uvrA)</td>
<td>Negative with and without metabolic activation. Not cytotoxic. The controls had the expected results.</td>
<td>3,8,23,25</td>
</tr>
<tr>
<td>Trimethoxycaprylylsilane; 33.3-5000 µg/plate</td>
<td>Ames test; S. typhimurium (strains TA98, TA100, TA1535, and TA1537)</td>
<td>Negative with and without metabolic activation. Not cytotoxic. The controls had the expected results.</td>
<td>3,8,23,25</td>
</tr>
</tbody>
</table>

CHO = Chinese hamster ovary
OECD TG = Organisation for Economic Co-operation and Development Test Guideline
REFERENCES


2. Andersen, FA. Final report on the safety assessment of stearoxy dimethicone, dimethicone, methicone, amino bispropyl dimethicone, aminopropyl dimethicone, amodimethicone, amodimethicone hydroxyesterate, behenoxy dimethicone, C24-28 alkyl methicone, C30-45 alkyl methicone, C30-45 alkyl dimethicone, cetearyl methicone, cetyl dimethicone, dimethoxysilyl ethylenediaminopropyl dimethicone, hexyl methicone, hydroxypropyl dimethicone, stearamidopropyl dimethicone, stearly dimethicone, stearly methicone, vinyl dimethicone. International Journal of Toxicology. 2003;22(Suppl. 2):11-35.


### 2016 VCRP Data – Alkoxy Alkyl Silanes

<table>
<thead>
<tr>
<th>Category</th>
<th>Silane</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>03D - Eye Lotion</td>
<td>STEAROXYTRIMETHYLSILANE</td>
<td>1</td>
</tr>
<tr>
<td>07C - Foundations</td>
<td>STEAROXYTRIMETHYLSILANE</td>
<td>1</td>
</tr>
<tr>
<td>12D - Body and Hand (exc shave)</td>
<td>STEAROXYTRIMETHYLSILANE</td>
<td>1</td>
</tr>
<tr>
<td>12F - Moisturizing</td>
<td>STEAROXYTRIMETHYLSILANE</td>
<td>4</td>
</tr>
<tr>
<td>12G - Night</td>
<td>STEAROXYTRIMETHYLSILANE</td>
<td>1</td>
</tr>
<tr>
<td>13A - Suntan Gels, Creams, and Liquids</td>
<td>STEAROXYTRIMETHYLSILANE</td>
<td>2</td>
</tr>
<tr>
<td>03A - Eyebrow Pencil</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>2</td>
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<tr>
<td>03B - Eyeliner</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>11</td>
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<tr>
<td>03C - Eye Shadow</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
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<td>03D - Eye Lotion</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>8</td>
</tr>
<tr>
<td>03F - Mascara</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>5</td>
</tr>
<tr>
<td>03G - Other Eye Makeup Preparations</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>20</td>
</tr>
<tr>
<td>04C - Powders (dusting and talcum, excluding aftershave talc)</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>4</td>
</tr>
<tr>
<td>05B - Hair Spray (aerosol fixatives)</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>4</td>
</tr>
<tr>
<td>06E - Hair Color Sprays (aerosol)</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>5</td>
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<tr>
<td>07A - Blushers (all types)</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>21</td>
</tr>
<tr>
<td>07B - Face Powders</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>36</td>
</tr>
<tr>
<td>07C - Foundations</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>102</td>
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<tr>
<td>07D - Leg and Body Paints</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
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<tr>
<td>07E - Lipstick</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
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<tr>
<td>07F - Makeup Bases</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
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<td>07I - Other Makeup Preparations</td>
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<td>08E - Nail Polish and Enamel</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>2</td>
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<tr>
<td>10A - Bath Soaps and Detergents</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>4</td>
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<tr>
<td>12C - Face and Neck (exc shave)</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>13</td>
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<tr>
<td>12D - Body and Hand (exc shave)</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
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</tr>
<tr>
<td>12F - Moisturizing</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>18</td>
</tr>
<tr>
<td>12G - Night</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>7</td>
</tr>
<tr>
<td>12J - Other Skin Care Preps</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>8</td>
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<tr>
<td>13A - Suntan Gels, Creams, and Liquids</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>3</td>
</tr>
<tr>
<td>13B - Indoor Tanning Preparations</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>7</td>
</tr>
<tr>
<td>13C - Other Suntan Preparations</td>
<td>TRIETHOXYCAPRYLYLSILANE</td>
<td>1</td>
</tr>
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</table>

**Total Count:** 417
<table>
<thead>
<tr>
<th>Category</th>
<th>Substance</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>03C - Eye Shadow</td>
<td>TRIMETHOXYCAPRYLYLSILANE</td>
<td>1</td>
</tr>
<tr>
<td>07C - Foundations</td>
<td>TRIMETHOXYCAPRYLYLSILANE</td>
<td>1</td>
</tr>
<tr>
<td>12F - Moisturizing</td>
<td>TRIMETHOXYCAPRYLYLSILANE</td>
<td>1</td>
</tr>
<tr>
<td>12J - Other Skin Care Preps</td>
<td>TRIMETHOXYCAPRYLYLSILANE</td>
<td>1</td>
</tr>
</tbody>
</table>

There were no reported uses in the 2016 VCRP for Bis-Stearoxydimethylsilane.
Memorandum

TO: Lillian Gill, D.P.A.
Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Beth A. Lange, Ph.D.
Industry Liaison to the CIR Expert Panel

DATE: October 9, 2015

SUBJECT: Concentration of Use Information: Alkoxy Alkyl Silanes
### Concentration of Use by FDA Product Category – Alkoxy Alkyl Silanes

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Product Category</th>
<th>Maximum Concentration of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Bubble bath</td>
<td>0.001%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Other bath preparations</td>
<td>0.048%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Eyebrow pencil</td>
<td>0.038-0.22%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Eyeliners</td>
<td>0.0096-1.9%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Eye shadow</td>
<td>0.06-2.5%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Eye lotions</td>
<td>0.006-0.2%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Mascara</td>
<td>0.0068-0.12%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Other eye makeup preparations</td>
<td>0.005-0.86%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Perfumes</td>
<td>0.011%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Powders (dusting and talcum)</td>
<td>0.023%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Tonics, dressings and other hair grooming aids</td>
<td>0.8%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Blushers</td>
<td>0.027-0.6%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Face powders</td>
<td>0.006-2%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Foundations</td>
<td>0.05-1.4%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Lipstick</td>
<td>0.0024-1%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Makeup bases</td>
<td>0.032-0.66%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Makeup fixatives</td>
<td>0.81-1.9%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Other makeup preparations</td>
<td>0.011-0.64%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Nail polish and enamel</td>
<td>0.018-0.15%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Other manicuring preparations</td>
<td>0.011%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Bath soaps and detergents</td>
<td>0.066%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Skin cleansing (cold creams, cleansing lotions, liquids and pads)</td>
<td>0.014%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Face and neck products</td>
<td>0.000001-2.4%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Body and hand products</td>
<td>0.07-2.3%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Moisturizing products</td>
<td>0.012-0.021%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Night products</td>
<td>0.012-0.25%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Paste masks and mud packs</td>
<td>0.0005-0.087%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Skin fresheners</td>
<td>0.0063%</td>
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<tr>
<td>Triethoxycaprylylsilane</td>
<td>Other skin care preparations</td>
<td>0.011-0.5%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Suntan products</td>
<td>0.005-2.6%</td>
</tr>
<tr>
<td>Triethoxycaprylylsilane</td>
<td>Indoor tanning preparations</td>
<td>0.004-0.012%</td>
</tr>
<tr>
<td>Bis-Stearoxydimethylsilane</td>
<td>Foundations</td>
<td>0.38%</td>
</tr>
<tr>
<td>Ingredient</td>
<td>Product Type</td>
<td>Concentration</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Stearyoxytrimethylsilane</td>
<td>Eye shadow</td>
<td>0.36%</td>
</tr>
<tr>
<td>Stearyoxytrimethylsilane</td>
<td>Hair conditioner</td>
<td>0.55%</td>
</tr>
<tr>
<td>Stearyoxytrimethylsilane</td>
<td>Rinses (noncoloring)</td>
<td>0.55%</td>
</tr>
<tr>
<td>Stearyoxytrimethylsilane</td>
<td>Foundations</td>
<td>0.55%</td>
</tr>
<tr>
<td>Stearyoxytrimethylsilane</td>
<td>Other makeup preparations</td>
<td>0.47%</td>
</tr>
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<td>Face and neck products</td>
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<tr>
<td></td>
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<td>Stearyoxytrimethylsilane</td>
<td>Night products</td>
<td>0.28%</td>
</tr>
<tr>
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<td>Stearyoxytrimethylsilane</td>
<td>Suntan products</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Not spray</td>
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</tr>
<tr>
<td>Trimethoxycaprylsilane</td>
<td>Eyeliner</td>
<td>0.1%</td>
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<td>Trimethoxycaprylsilane</td>
<td>Eye shadow</td>
<td>0.14%</td>
</tr>
<tr>
<td>Trimethoxycaprylsilane</td>
<td>Makeup fixatives</td>
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<td>Other makeup preparations</td>
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<tr>
<td>Trimethoxycaprylsilane</td>
<td>Face and neck products</td>
<td>0.6%</td>
</tr>
<tr>
<td></td>
<td>Not spray</td>
<td></td>
</tr>
<tr>
<td>Trimethoxycaprylsilane</td>
<td>Body and hand products</td>
<td>0.6%</td>
</tr>
<tr>
<td></td>
<td>Not spray</td>
<td></td>
</tr>
</tbody>
</table>

Information collected in 2015
Table prepared October 8, 2015
Memorandum

TO: Lillian Gill, D.P.A.
    Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Beth A. Lange, Ph.D.
       Industry Liaison to the CIR Expert Panel

DATE: November 11, 2015

SUBJECT: Bis-Stearoxydimethylsilane

This information is on the trade name material Belsil® SDM 6022 which contains approximately 75% Bis-Stearoxydimethylsilane, 16% Stearyl Alcohol and 9% Dimethicone.


Wacker Chemie Ag. 2015. Safety data sheet Belsil® SDM 6022.

RCC. 2000. Summary: Skin permeability in vitro absorption through porcine ear skin with Wacker Belsil SDM 6022 (contains approximately 75% Bis-Stearoxydimethylsilane).

Research Toxicology Centre S.p.A. 1996. Summary: Acute oral toxicity study in the rat Belsil SDM 6022 (contains approximately 75% Bis-Stearoxydimethylsilane).

RCC. 1999. Summary: 28-Day oral toxicity (gavage) study in the Wistar rat Wacker-Belsil SDM 6022 (contains approximately 75% Bis-Stearoxydimethylsilane).

RCC. 1996. Summary: *Salmonella typhimurium* reverse mutation assay with Wacker Belsil SDM 6022 (contains approximately 75% Bis-Stearoxydimethylsilane).
PRODUCT DOSSIER

Product Name: BELSIL® SDM 6022

1 General Characterisation:

1.1 Chemical Description:

PCPC: INCI-designation (Proposed) Stearoxy Dimethicone, Dimethicone
JCID-2007 (Japan): None

Chemical description / Product composition:

<table>
<thead>
<tr>
<th>INCI</th>
<th>Chemical description</th>
<th>%</th>
<th>CAS No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stearoxy Dimethicone</td>
<td>Dimethyl bis(octadecyloxy) silane</td>
<td>~75%</td>
<td>29043-70-7</td>
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<tr>
<td>Stearylalcohol</td>
<td>1-Octadecanol</td>
<td>~16%</td>
<td>112-92-5</td>
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<tr>
<td>Dimethicone</td>
<td>Polydimethylsiloxane</td>
<td>~9%</td>
<td>63148-62-9</td>
</tr>
</tbody>
</table>

Primary function of cosmetic ingredient: skin conditioning agent

1.2 Inventory list

Europa, EINECS: registered
USA, TSCA: registered
Japan, ENCS: not registered
Australia, AICS: registered
Canada, DSL: registered
China, IECSC: not registered
Philippines, PICCS registered
South Korea, ECL not registered

REACH compliance status according to Regulation (EC) No 1907/2006
Herewith we confirm that BELSIL® SDM 6022 is in compliance with Regulation (EC) No 1907/2006 (REACH).

REACH compliance means that all substances and monomers contained in BELSIL® SDM 6022 are
- pre-registered or registered by our company and/or our suppliers, and/or
- excluded from the regulation, and/or
- exempted from registration.

We intend to register all phase-in substances contained in BELSIL® SDM 6022 according to the deadlines cited in article 23 of Regulation (EC) No 1907/2006 (REACH).

Herewith we confirm that we intend to register for this product all uses listed on COLIPA's use mapping.

Declaration of compliance with the Regulation (EC) No 1223/2009 on Cosmetic Products
BELSIL® SDM 6022 is suitable for use as a cosmetic ingredient under Regulation (EC) No 1223/2009 (Recast of the Cosmetic Directive 76/768/EC and all its amendments). The product neither contains any of the prohibited or restricted substances included in Annex II and Annex III as per recipe nor are any CMR cat. 1A or 1B compounds intentionally introduced.

Small amounts of octamethylcyclotetrasiloxane (Repr. 2) may be present as an unavoidable impurity (< 0.1%). How-ever, this substance has been evaluated by the SCCS (Scientific Committee on Consumer Products) in 2010 and was considered not to pose a risk to human health when used in cosmetic products.

1.4 Additional Information
Molecular Weight:

Mw = approx. 950 g/mol  Mn = approx. 700 g/mol
PD = 1.4

Shelf Life:

12 months (min.)

Specific requirements to be considered during transport/storage:

none, (see also section 7 of the MSDS)
2 Raw Material Basis:

Animal Origin: Not of animal origin thus infection with Bovine spongiforme Enzephalopathie (BSE) is not possible

Plant Origin: Not of plant origin thus contamination with Genetically Modified Organisms (GMO) is not possible

Synthetic/Mineral Origin: Of synthetic origin

Biotechnological Origin: Not of biotechnological origin

3 Additives, By-products and Contaminants:

Polycyclic aromatic hydrocarbons, organohalogen compounds, nitrosamines: Pahs, pcbs, organohalogen compounds, nitrosamines are not used as ingredients or processing aids during manufacture. We therefore firmly believe that these compounds may not be present — ubiquitous levels exempted.

Preservatives: None

Solvents: None

Antioxidants: None

Pesticides, Mycotoxins None

Metals, Heavy Metals: The results of a three batch analyse proved the absence of following heavy metals including arsenic: Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cu, Fe, Hg, Mn, Mo, Ni, Pb, Sb, Sn, Sr, Ti, V, W, Zn, Zr all < 2 ppm

Traces of: Low molecular weight cyclics: Cyclotetrasiloxane: < 0.1% Cyclopentasiloxane: < 0.1% Cyclohexasiloxane: < 0.1%

Nanoparticles as defined under Commission Recommendation 2011/696/EU None

4 Manufacturing Procedure:

BELSIL® SDM 6022 is a speciality of Wacker Chemie AG. The detailed procedure, however, is considered a trade secret and will only be disclosed to authorities.
5 Toxicological Information:

BELSIL® SDM 6022 has been submitted to toxicological testing. The last test has been carried out in 1999.

Acute Toxicity: Acute oral toxicity (rat) LD₉₀ > 2000 mg/kg
Irritation: Acute skin irritation (rabbit): non irritant
Acute eye irritation (rabbit): non irritant
Sensitisation: Magnusson & Kligman: non-sensitizing
Skin Absorption: No penetration through isolated porcine skin could be detected.
Mutagenicity: Ames test: non-mutagenic
Subacute oral Toxicity: NOAEL (28 d, rat) > 1000 mg/kg/d
Subacute / subchronic Toxicity: No data
Photoirritation/-sensitivity: No data
Last test on animals performed: Last test on BELSIL® SDM 6022 has been carried out in 1999.

6 Microbiological Information:

Number of germs/g: No data
Fungi & Yeasts: No data
Microbiological challenge test performed: No data

7 Eco-toxicological Information:

Water Hazard Class: 1, according to annex 4 of VwVwS
Biodegradability: Not tested, but polydimethylsiloxanes are expected to be non-biodegradable but expected to be eliminated in waste water treatment plants by adsorption to the sludge.
Aquatic toxicity: No data
8 Additional Information:

BELSIL® SDM 6022 is a product of WACKER CHEMIE AG / WACKER SILICONES. WACKER SILICONES' sites are regularly certified by accredited certification bodies to ISO 9001 (since 1994) and ISO 14001 (since 1998). In addition, an industrial and plant safety management system as per OHRIS has been introduced at the Burghausen site. All this is part of WACKER SILICONES' IMS system.
Available ISO Certificates can be downloaded via

Attachments:
Data Sheet (recommended use, recommended levels of usage)
Safety Data Sheet
Specifications

Attention: The information provided in this dossier is not included in the updating service.

Elke Weißkopf
Manager Product Stewardship 3
S-RQ-PS
Wacker Chemie AG

D.: Tassilo Habereder
Technical Manager
Performance Materials
Wacker Chemie AG
Wacker-Belsil SDM 6022  
BIS-STEAROXYDIMETHYSILANE, STEARYL ALCOHOL, DIMETHICONE

Product description

Structural formula:

\[
\begin{align*}
H_{37}C_{18} & \quad O \quad Si \quad O_m \quad C_{18}H_{37} \\
& \quad Me \quad Me
\end{align*}
\]

forms a protective barrier, thereby providing moisturizing benefits. It imparts a non-greasy, soft, velvety feel to the skin and offers excellent compatibility with most cosmetic raw materials. In color-cosmetics formulations, it enhances gloss and brilliance.

Storage

The 'Best use before end' date of each batch is shown on the product label.

Storage beyond the date specified on the label does not necessarily mean that the product is no longer usable. In this case however, the properties required for the intended use must be checked for quality assurance reasons.

Safety notes

Comprehensive instructions are given in the corresponding Material Safety Data Sheets. They are available on request from WACKER subsidiaries or may be printed via WACKER web site http://www.wacker.com.

Application

In skin-care formulations, Wacker-Belsil SDM 6022

Product data

<table>
<thead>
<tr>
<th>Typical general characteristics</th>
<th>Inspection Method</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td></td>
<td>white, opaque, sold</td>
</tr>
<tr>
<td>Density at 50 °C</td>
<td></td>
<td>0.84 g/cm³</td>
</tr>
<tr>
<td>Melting point / Melting range</td>
<td></td>
<td>35 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>ISO 2719</td>
<td>180 °C</td>
</tr>
<tr>
<td>INCI name</td>
<td></td>
<td>BIS-Stearoxydimethylsilane, Stearyl Alcohol, Dimethicone</td>
</tr>
</tbody>
</table>

These figures are only intended as a guide and should not be used in preparing specifications.
### Additional information

#### Solubility

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oils</td>
<td>Emulsifiers / ethoxylated oils</td>
</tr>
<tr>
<td>Mineral oil (high-vis.)</td>
<td>PEG-75 Lanolin oil</td>
</tr>
<tr>
<td>Mineral oil (low-vis.)</td>
<td>PEG-7 Glyceryl Cocoate</td>
</tr>
<tr>
<td>C9-13 Isoparaffin</td>
<td>PPG-5-Laureth-5</td>
</tr>
<tr>
<td>Ester oils / waxes C12-15 alkyl benzoate</td>
<td>Octyl dodecanoal</td>
</tr>
<tr>
<td>Isopropyl myristate</td>
<td>Oleyl alcohol</td>
</tr>
<tr>
<td>Isopropyl palmitate</td>
<td>Propylene glycol</td>
</tr>
<tr>
<td>Decyl oleate</td>
<td>Isopropanol</td>
</tr>
<tr>
<td>Oleyl oleate</td>
<td>Ethanol</td>
</tr>
<tr>
<td>Tiglioglycerides</td>
<td>Glycerin</td>
</tr>
<tr>
<td>Castor oil</td>
<td>Water</td>
</tr>
<tr>
<td>Olive Oil</td>
<td>Silicone fluids</td>
</tr>
<tr>
<td>Wheatgerm oil</td>
<td>Cyclopentasiloxane</td>
</tr>
<tr>
<td>Lanolin Oil</td>
<td>Stearyl Dimethicone</td>
</tr>
<tr>
<td></td>
<td>(Belsil® SDM 5055)</td>
</tr>
<tr>
<td></td>
<td>Trimethylsiloxyphenyl Dimethicone</td>
</tr>
<tr>
<td></td>
<td>(Belsil® PDM 350 VP)</td>
</tr>
</tbody>
</table>

\( \checkmark = \) soluble (> 10\%)  \( \_ = \) partially soluble (1 - 10\%)  \( - = \) insoluble
1. Product and company identification

1.1 Identification of the substance or preparation:

Commercial product name: Wacker-Belsil® SDM 6022
Use of substance / preparation: Industrial
Raw material for: cosmetics

1.2 Company/undertaking identification:

Manufacturer/distributor: Wacker Chemie AG
Hanns-Seidel-Platz 4
81737 München
Germany

Customer information:
Wacker Chemical Corporation
3301 Sutton Road
Adrian, Michigan 49221-9397
USA
InfoLine:
Tel (517) 264-8240, Fax (517) 264-8740
Hours of operation:
Monday - Friday, 8 am to 5 pm (eastern standard time)
Corporate website: www.wacker.com

Emergency telephone no. (24h):
(517) 264-8500
Transportation emergency:
(800) 424-9300 (CHEMTREC, USA)
(703) 527-3887 (CHEMTREC, international)

This SDS was prepared by the Regulatory Affairs and Product Safety Department (RAPS) of Wacker Chemical Corporation.

2. Hazards identification

2.1 Classification of the substance or mixture
Classification (GHS):
Not a hazardous substance or mixture.

2.2 Label elements
Labelling (GHS):
No labeling according to GHS required.

2.3 Other hazards
No data available.

3. Composition/information on ingredients

3.1 Chemical characterization (preparation)
Chemical characteristics
Alkoxysilanes + Polydimethylsiloxane.

3.2 Information on ingredients:
This material does not contain any reportable hazardous ingredients.
Substances listed in the Subsections "HAPS" and "California Proposition 65 Carcinogens / Reproductive Toxins" that are not listed in this section are only present at quantities below 0.1% for California Proposition 65 listed toxins or below 1% for non-carcinogenic HAPS or they are inextricably bound in the product.
4. First-aid measures

4.1 General information:
Get medical attention if irritation or other symptoms occur. Before seeking medical attention remove contaminated clothing and shoes. Take a copy of the Safety Data Sheet when going for medical treatment.

4.2 After Inhalation
No special measures required. Inhalation is not applicable.

4.3 After contact with the skin
For skin contact, immediately wipe away excess material. Use a waterless hand cleaner to remove as much of the remaining material as possible. Wash with soap and water.

4.4 After contact with the eyes
If contact with eyes, immediately hold eyelids apart and flush with plenty of water for at least 15 min.

4.5 After swallowing
For ingestion, if conscious, give several glasses of water but do not induce vomiting. If vomiting does occur, give additional fluids. Get medical attention. Show label if possible.

5. Fire-fighting measures

5.1 Flammable properties:
<table>
<thead>
<tr>
<th>Property:</th>
<th>Value:</th>
<th>Method:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
<td>160 °C (320 °F)</td>
<td>(ISO 2719)</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>not applicable</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit (LEL)</td>
<td>350 °C (662 °F)</td>
<td>(DIN 51794)</td>
</tr>
</tbody>
</table>

5.2 Fire and explosion hazards:
This material does not present any unusual fire or explosion hazards.

5.3 Recommended extinguishing media:
water-spray, water-mist, carbon dioxide, dry chemical or foam-type extinguishing media

5.4 Unsuitable extinguishing media:
sharp water jet

5.5 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases
Hazardous decomposition products: carbon dioxide, carbon monoxide, formaldehyde, silicon dioxide and incompletely burnt hydrocarbons.

5.6 Fire fighting procedures:
Fire fighters should wear full protective clothing including a self-contained breathing apparatus. Use respiratory protection independent of recirculated air. Cool endangered containers with water.

6. Accidental release measures

6.1 Precautions:
No special measures required.

6.2 Containment:
Prevent material from entering sewers or surface waters.

Spills of material which could reach surface waters must be reported to the United States Coast Guard National Response Center's toll free phone number (800) 424-8802.
6.3 Methods for cleaning up
Take up mechanically and dispose of according to local/state/federal regulations.

6.4 Further Information:
None required.

7. Handling and storage

7.1 General information:
No special protective measures required.

7.2 Handling
Precautions for safe handling:
No special protective measures required.

Precautions against fire and explosion:
No special precautions against fire and explosion required.

7.3 Storage
Conditions for storage rooms and vessels:
none known

Advice for storage of incompatible materials:
not applicable

Further information for storage:
Keep container tightly closed.

8. Exposure controls and personal protection

8.1 Engineering controls
Ventilation:
Use with adequate ventilation.

Local exhaust:
No special ventilation required.

8.2 Associate substances with specific control parameters such as limit values
none known.

8.3 Personal protection equipment (PPE)
Respiratory protection:
Respiratory protection is not normally required.

Hand protection:
Recommendation: Any liquid-tight rubber or vinyl gloves.

Eye protection:
Recommendation: Safety glasses with side shields or chemical safety goggles.

Other protective clothing or equipment:
Additional protective clothing or equipment is not normally required. Provide eye bath and safety shower.

8.4 General hygiene and protection measures:
Avoid contact with eyes, skin and clothing. Avoid breathing dust/vapor/mist/gas/aerosol. Do not eat, drink or smoke when handling. Follow standard industrial hygiene practices when using this material. Wash thoroughly after handling.

9. Physical and chemical properties

9.1 Appearance
Physical state / form: solid - compact
Colour: white
9.2 Safety parameters

Property: Melting point / melting range Value: 35 °C (95 °F) at 1013 hPa
Boiling point / boiling range: not applicable
Flash point: 160 °C (320 °F)
Ignition temperature: 350 °C (662 °F)
Lower explosion limit (LEL): not applicable
Vapour pressure: not applicable
Density: 0.84 g/cm³ at 50 °C (122 °F)
Water solubility / miscibility: virtually insoluble
pH-Value: not applicable
Viscosity (dynamic): > 15 mPa.s at 80 °C (176 °F)

9.3 Further Information

Thermal decomposition: not applicable

10. Stability and reactivity

10.1 General Information:
If stored and handled in accordance with standard industrial practices no hazardous reactions are known.

10.2 Conditions to avoid
none known

10.3 Materials to avoid
none known

10.4 Hazardous decomposition products
If stored and handled properly: none known. Measurements have shown the formation of small amounts of formaldehyde at temperatures above about 150 °C (302 °F) through oxidation.

10.5 Further Information:
Hazardous polymerization cannot occur.

11. Toxicological information

11.1 Information on toxicological effects

11.1.1 Acute toxicity
Product details:

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>Result/Effect</th>
<th>Species/Test system</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>oral</td>
<td>LD₅₀ &gt; 2000 mg/kg</td>
<td>rat</td>
<td>test report</td>
</tr>
</tbody>
</table>

11.1.2 Skin corrosion/Irritation

Product details:

<table>
<thead>
<tr>
<th>Result/Effect</th>
<th>Species/Test system</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>not irritating</td>
<td>rabbit</td>
<td>test report</td>
</tr>
</tbody>
</table>

11.1.3 Serious eye damage / eye irritation

Product details:

<table>
<thead>
<tr>
<th>Result/Effect</th>
<th>Species/Test system</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>not irritating</td>
<td>rabbit</td>
<td>test report</td>
</tr>
</tbody>
</table>

11.1.4 Respiratory or skin sensitization
### Wacker

**Safety Data Sheet**

**Material:** Wacker-Boehl® SDM 6022  
**Version:** 2.0 (US)  
**Date of print:** 10/06/2015  
**Date of last alteration:** 08/04/2015

#### 11.1.5 Germ cell mutagenicity

**Product details:**

<table>
<thead>
<tr>
<th>Result/Effect</th>
<th>Species/Test system</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>negative</td>
<td>mutation assay (in vitro)</td>
<td>test: report</td>
</tr>
<tr>
<td></td>
<td>bacterial cells</td>
<td>OECD 471</td>
</tr>
</tbody>
</table>

#### 11.1.6 Carcinogenicity

**Assessment:**

For this endpoint no toxicological test data is available for the whole product.

#### 11.1.7 Reproductive toxicity

**Assessment:**

For this endpoint no toxicological test data is available for the whole product.

#### 11.1.8 Specific target organ toxicity (single exposure)

**Assessment:**

For this endpoint no toxicological test data is available for the whole product.

#### 11.1.9 Specific target organ toxicity (repeated exposure)

**Product details:**

<table>
<thead>
<tr>
<th>Result/Effect</th>
<th>Species/Test system</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL: 1000 mg/kg</td>
<td>rat</td>
<td>test: report</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OECD 407</td>
</tr>
</tbody>
</table>

#### 11.1.10 Aspiration hazard

**Assessment:**

For this endpoint no toxicological test data is available for the whole product.

#### 11.1.11 Further toxicological information

- No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
- Other information: Product reveals no penetration on isolated animal skin.

#### 12. Ecological information

**12.1 Toxicity**

**Assessment:**

For the product as a whole, no test data is available. According to current knowledge adverse effects on water purification plants are not expected.

**12.2 Persistence and degradability**

**Assessment:**

Elimination by adsorption to activated sludge.

**12.3 Bioaccumulative potential**

**Assessment:**

Bioaccumulation is not expected to occur.
Safety Data Sheet

Material: Wacker-Belsil® SDM 6022

Version: 2.0 (US)  Date of print: 10/06/2015  Date of last alteration: 08/04/2015

12.4 Mobility in soil
   Assessment:
   Separation by sedimentation.

12.5 Other adverse effects
   none known

13. Disposal considerations

13.1 Product disposal
   Recommendation:
   Dispose of according to regulations by incineration in a special waste incinerator. Small quantities may be disposed of by
   incineration in an approved facility. Observe local/state/federal regulations.

13.2 Packaging disposal
   Recommendation:
   Completely discharge containers (no tear drops, no powder rest, scraped carefully). Containers may be recycled or re-used.
   Observe local/state/federal regulations.

14. Transport information

14.1 US DOT & CANADA TDG SURFACE
   Value..............................................: Not regulated for transport

14.2 Transport by sea IMDG-Code
   Value..............................................: Not regulated for transport

14.3 Air transport ICAO-TII/IATA-DGR
   Value..............................................: Not regulated for transport

15. Regulatory Information

15.1 U.S. Federal regulations
   TSCA inventory status and TSCA information:
   This material or its components are listed on or are in compliance with the requirements of the TSCA Chemical Substance
   Inventory.
   TSCA 12(b) Export Notification:
   This material does not contain any TSCA 12(b) regulated chemicals.
   CERCLA Regulated Chemicals:
   This material does not contain any CERCLA regulated chemicals.
   SARA 302 EHS Chemicals:
   This material does not contain any SARA extremely hazardous substances.
   SARA 311/312 Hazard Class:
   This product does not present any SARA 311/312 hazards.
   SARA 313 Chemicals:
   This material does not contain any SARA 313 chemicals above de minimus levels.
   HAPS (Hazardous Air Pollutants):
   This material does not contain any hazardous air pollutants.

15.2 U.S. State regulations
   California Proposition 65 Carcinogens:
   This material does not contain any chemicals known to the State of California to cause cancer.
   California Proposition 65 Reproductive Toxins:
   This material does not contain any chemicals known to the State of California to cause reproductive effects.
Safety Data Sheet

Material: Wacker-Belsil® SDM 6022
Version: 2.0 (US) Date of print: 10/06/2015 Date of last alteration: 08/04/2015

Massachusetts Substance List:
This material contains no listed components.

New Jersey Right-to-Know Hazardous Substance List:
This material contains no listed components.

Pennsylvania Right-to-Know Hazardous Substance List:
This material contains no listed components.

15.3 Canadian regulations
This product has been classified in accordance with the Hazard criteria of the CPR and the SDS contains all the information required by the CPR.

WHMIS Hazard Classes:
None.

Non-DSL Chemicals:
This material does not contain any non-DSL chemicals.

15.4 Details of international registration status
Relevant information about individual substance inventories, where available, is given below.

Japan.................................: ENCS (Handbook of Existing and New Chemical Substances):
   This product is listed in, or complies with, the substance inventory.

Australia.............................: AICS (Australian Inventory of Chemical Substances):
   This product is listed in, or complies with, the substance inventory.

Canada...............................: DSL (Domestic Substance List):
   This product is listed in, or complies with, the substance inventory.

Philippines...........................: PICCS (Philippine Inventory of Chemicals and Chemical Substances):
   This product is listed in, or complies with, the substance inventory.

United States of America (USA).....: TSCA (Toxic Substance Control Act Chemical Substance Inventory):
   This product is listed in, or complies with, the substance inventory.

European Economic Area (EEA)......: REACH (Regulation (EC) No 1907/2006):
   General note: the registration obligations for substances imported into the EEA or manufactured within the EEA by the supplier mentioned in section 1 are fulfilled by the said supplier. The registration obligations for substances imported into the EEA by customers or other downstream users must be fulfilled by the latter.

16. Other information
16.1 Additional Information:
This Safety Data Sheet (SDS) meets the requirements of the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200). This product has been classified according to the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by the CPR. This information relates to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is to the best of our knowledge and belief accurate and reliable as of the date compiled. However, no representation, warranty or guarantee expressed or implied, is made as to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability and completeness of such information for his own particular use. We do not accept liability for any loss or damage that may occur from the use of this information. Nothing herein shall be construed as a recommendation for uses which infringe valid patents or as extending a license under valid patents. This SDS provides selected regulatory information on this product, including its components. This is not intended to include all regulations. It is the responsibility of the user to know and comply with all applicable rules, regulations and laws relating to the product being used.

Vertical lines in the left-hand margin indicate changes compared with the previous version.

All deliveries are subject to the WACKER SILICONES Health Care Policy, which is available at www.wacker.com.
16.2 Glossary of Terms:

ACGIH - American Conference of Governmental Industrial Hygienists

DOT - Department of Transportation

hPa - Hectopascals

mPa·s - Milli Pascal-Seconds

OSHA - Occupational Safety and Health Administration

PEL - Permissible Exposure Limit

Flash point determination methods ............................................ Common name

ASTM D56.............................................................................. Tagliabue (Tag) closed cup

ASTM D92, DIN 51376, ISO 2592 ................................................. Cleveland open cup

ASTM D93, DIN 51758, ISO 2719 ................................................. Pensky-Martens closed cup

ASTM D3278, DIN 55880, ISO 3679 ................................................. Selasflash or Rapid closed cup

DIN 51755.............................................................................. Abel-Pensky closed cup

16.3 Conversion table:

Pressure: ........................................ 1 hPa = 0.75 mm Hg = 1 torr; 1 bar = 1000 hPa

Viscosity: ........................................ 1 mPa·s = 1 centipoise (cP)
Project ID of the Contracting Institute:
RCC PROJECT 712978

RCC - CCR PROJECT 624401

SKIN PERMEABILITY

IN VITRO ABSORPTION THROUGH

PORCINE EAR SKIN

WITH

WACKER BELSIL SDM 6022
contains 75% Bis-(stearyl)dimethylsiloxane

Report

Study Completion Date:
February 04, 2000

RCC
Distributed for Comment Only -- Do Not Cite or Quote

COPY OF GLP CERTIFICATE

GLP-Bescheinigung

Hiermit wird bestätigt, daß die Prüfereinrichtung
RCC Cytotest Cell Research GmbH
in 64380 Rößdorf
In den Leppsteinwiesen 19
(Ort, Anschrift)
der RCC/CCR Nohling Verwaltungs GmbH
(Firma)
am 25./26. Februar 1998
(Datum)

von der für die Überwachung zuständigen Behörde über
die Einhaltung der Grundzüge der Guten Laborpraxis
inspeziert worden ist.

Es wird hiermit bestätigt, daß folgende Prüfungen in
dieser Prüfereinrichtung nach den Grundzügen der Guten
Laborpraxis durchgeführt werden:

Prüfungen zur Bestimmung der toxikologischen
Eigenschaften
Prüfungen zur Bestimmung der entgiftungsabhängigen
Eigenschaften (in vitro und in vivo)

Im Auftrag

Dr. Fuchs


Certificate

It is hereby certified that the test facility
RCC Cytotest Cell Research GmbH
In 64380 Rößdorf
In den Leppsteinwiesen 19
(location, address)
of RCC/CCR Nohling Verwaltungs GmbH
(company name)
on 25./26. Februar 1998
(date)

was inspected by the competent authority
regarding compliance with the Principles of
Good Laboratory Practice.

It is hereby certified that studies in this
test facility are conducted in compliance with
the Principles of Good Laboratory Practice:

Toxicity studies
Mutagenicity studies
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STATEMENT OF COMPLIANCE

Project Number: 624401
Test Item: WACKER BELSIL SDM 6022
Study Director: Dr. Hans-Eric Wollny
Title: Skin Permeability
       In vitro Absorption through Porcine Ear Skin with WACKER BELSIL SDM 6022

This study performed in the testing facility of RCC Cytotest Cell Research was conducted in compliance with Good Laboratory Practice Regulations.


"OECD Principles of Good Laboratory Practice", as revised in 1997 [C(97)186/Final]

"Good Laboratory Practice (GLP) in Switzerland", Procedures and Principles, March 1986

There were no circumstances that may have affected the quality or integrity of the study.

Study Director

RCC-CCR
Dr. Hans-Eric Wollny

Date: February 10, 2000

A copy of the statement of compliance of the analytical part signed by the principle investigator is attached as annex 1.
SUMMARY

The test item WACKER BELSIL SDM 6022 was assessed for its potential to permeate porcine skin.

The test item was tested at a concentration of 3 mg/ml suspended in ethanol/water (40 %v/v). Each donor chamber was filled with 1 ml of the test item suspended in ethanol/water (40 %v/v).

The same solvent was slowly pumped through the acceptor chambers with a flow rate of 1 to 2 ml per hour. The liquid leaving the acceptor chambers was collected and the fractions were changed following the schedule below:

Exp. I and II: 0; 0.5; 1; 2; 4; 6; 8; and 24 hours following the application of the test item.

The conductivity across the skin samples of each chamber was measured at the same intervals.

The blank samples (at 0 hours) were collected immediately prior to filling the donor chambers at the maximal flow rate of the pump.

Air bubbles were observed in all of the acceptor chambers after 24 hours possibly blocking some of the skin area. However, since the conductivity across the skin was hardly affected even after 24 hours, it was judged that the air bubbles did not have any relevant effect on the skin penetration.

The samples were analysed by atom absorption spectroscopy.

No reproducible permeation of the skin occurred at any time point within the time frame of the experiments.

Conclusion

In conclusion, it can be stated that during the described permeability test and under the experimental conditions reported, the test item did not penetrate the skin.
RESEARCH TOXICOLOGY CENTRE S.p.A.

BELSIL SDM 6022 contains 75% ACUTE ORAL TOXICITY STUDY IN THE RAT 8-is-Stearoyl dimethyl silicone

FINAL REPORT

RTC Study Number: 4977
RTC Report Number: 4977/T/221/95

Seen and approved by:

[Signature]

A. Nunziata
Responsible for Toxicological Experimentation as authorized by the Italian Ministry of Health

[Signature]

A. Marzoli
President
RTC Report Number: 4977/T/221/95

COMPLIANCE STATEMENT

We, the undersigned, hereby declare that this report is a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of this study conducted by Research Toxicology Centre S.p.A. were performed in accordance with:


(Adoption of the Commission Directive of 18th December 1989 adapting to technical progress the Annex to Council Directive 80/320/EEC on the inspection and verification of Good Laboratory Practice (90/18/EEC)).

C. Longobardi, Biol.D
Study Director: 16-04-96

J. Brightwell, Ph.D.
Scientific Director: 16-01-96
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1. **SUMMARY**

The acute oral toxicity of BELSIL SDM 6022 was investigated in the rat.

A single dose of 2000 mg/kg was administered to five male and five female rats. Animals were observed for fourteen days after dosing. All animals were subjected to necropsy examination.

No animal died following treatment.

No significant clinical signs were observed following treatment with the test substance.

Body weight changes were not remarkable.

Necropsy revealed no abnormalities.

Classification based on these results would indicate the following:-

- Classification: Not required
- Symbol: None indicated
- R phrase: None indicated
- S phrase: None indicated

- 1 -
6. CONCLUSION

The results of this study indicate that the test substance, BELSIL SDM 6022, has no toxic effect in the rat following a single administration by the oral route at a dose level of 2000 mg/kg.

Evaluation of acute oral toxicity required by regulations on the classification, packaging and labelling of dangerous substances indicated the following:

- Classification: Not required
- Symbol: None indicated
- R phrase: None indicated
- S phrase: None indicated
RCC PROJECT 712967

WACKER-BELSIL SDM 6022:
Contains 75% Bis-Stearoyl dimethylsilane

28-DAY ORAL TOXICITY (GAVAGE) STUDY IN

THE WISTAR RAT

REPORT

Author: W.H. Braun, H. Luetkemeler,
K. Biedermann, Dr. K. Weber

Sponsor: WACKER-CHEMIE GMBH
Johannes-Hess Str. 24
D-84489 Burghausen

Study Completion Date: May 11, 1999
RCC PROJECT 712967
WACKER-BELLSIL SDM 6022

2 SUMMARY

GENERAL
In this subacute toxicity study, WACKER-BELLSIL SDM 6022 was administered daily by gavage to SPF-bred Wistar rats of both sexes at dose levels of 50, 200 and 1000 mg/kg body weight/day for a period of 28 days. The groups comprised five animals per sex which were sacrificed after 28 days of treatment. A control group comprising five animals per sex was treated concurrently with the vehicle only.

Clinical signs, outside cage observation, food consumption and body weights were recorded periodically during pretest and the treatment periods. Functional observational battery, locomotor activity and grip strength were performed during week 4.

At the end of the dosing, blood samples were withdrawn for hematology and plasma chemistry analyses. All animals were killed, necropsied and examined post mortem. Histological examinations were performed on organs and tissues from all control and high dose animals, and all gross lesions from all animals were evaluated by the study pathologist.

MORTALITY / VIABILITY
All animals survived to scheduled necropsy.

CLINICAL SIGNS
No test article-related clinical signs were noted during daily or weekly observations (performed at pretest and weeks 1-3).

FUNCTIONAL OBSERVATIONAL BATTERY
No test article-related clinical signs were noted during functional observational battery (performed at week 4).

Grip Strength
Minor differences noted in the forelimb and hindlimb grip strength when compared with the control values were considered to be unrelated to the test article.

Locomotor Activity
The locomotor activity of the test article-treated animals was considered to be unaffected when compared with the control values.

FOOD CONSUMPTION AND BODY WEIGHT
The mean daily food consumption, the body weight development and the relative food consumption of test article-treated groups compared favorably with those of the control group.
CLINICAL LABORATORY INVESTIGATIONS

Hematology and Clinical biochemistry
The hematology and clinical biochemistry parameters of the test article-treated groups were generally similar to those of the control group.

ORGAN WEIGHTS
The absolute and relative organ weights of all groups compared favorably.

MACROSCOPIC / MICROSCOPIC FINDINGS
There were no test article-related macroscopic or microscopic findings. All morphologic findings were spontaneous in nature and within the normal range of background alterations which may be recorded in Wistar rats of this age. Toxic manifestations resulting from treatment with WACKER-BELSIL SDM 6022 were not in evidence.
3 ASSESSMENT

WACKER-BELSIIL SDM 6022 was administered by oral gavage to Wistar rats at doses of 50, 200 and 1000 mg/kg/day for 28 days.

All animals survived without test article-related clinical signs, or changes in food consumption or differences in body weight development. There were no quantitative or qualitative differences to control values in weekly detailed clinical observations (weeks 1-4), grip strength (week 4) or locomotor activity (week 4). Hematology and clinical biochemistry parameters were unaffected by the test article and organ weights (absolute and relative) compared favorably with those of the control animals. Test article-related macroscopic or microscopic findings were not evident in any animal.

Based on the results of this study, 1000 mg/kg body weight/day was established as the no-observed-adverse-effect-level (NOAEL).
6 RESULTS

6.1 VIABILITY/MORTALITY
All animals survived until scheduled necropsy.
See pp. 36-43

6.2 OBSERVATIONS

6.2.1 GENERAL CAGESIDE OBSERVATIONS (DAILY)
No test article-related differences to the control animals were noted at any dose level.
Slight alopecia (various locations) was noted from treatment day 21 onwards in two males and five females treated with the test article at 200 mg/kg body weight. This finding was not noted in animals treated with 1000 mg/kg and therefore considered to be incidental.
See pp. 44-51 and 83-122

6.2.2 DETAILED CLINICAL OBSERVATIONS (WEEKLY)
No test article-related differences to the control animals were noted at any dose level.
Slight alopecia (various locations) was noted during treatment week 3 in two males and five females treated with the test article at 200 mg/kg body weight. This finding was not noted in animals treated with 1000 mg/kg and therefore considered to be incidental.
See pp. 52-53 and 123-132

6.2.3 FUNCTIONAL OBSERVATIONAL BATTERY
No quantitative or qualitative differences to the control animals was noted during treatment week 4.

Grip Strength
The hindlimb grip strength of both sexes and the forelimb grip strength of the females treated with 1000 mg/kg was significantly increased (p<0.05) when compared with the control animals. A slight increase in this parameter was not considered to be an adverse effect of treatment.
See pp. 54-55 and 133-134

Locomotor Activity
Females treated with the test article at 50 or 200 mg/kg were significantly more active (p<0.05) than the females of the control group 30-45 minutes after dosing. These findings were considered to be incidental as similar findings were not ascertained in the females treated with 1000 mg/kg.
See pp. 56-57 and 135-136
6.3 FOOD CONSUMPTION
The mean daily food consumption of the test article-treated rats compared favorably with those of the control rats. The relative food consumption of all groups compared favorably.
See pp. 29-30, 33-34, 58-61, 66-69, 137-138 and 141-142

6.4 BODY WEIGHTS
The body weight development of the test article-treated rats compared favorably with those of the control rats.
See pp. 31-32, 62-65 and 139-140

6.5 CLINICAL LABORATORY INVESTIGATIONS
6.5.1 HEMATOLOGY
No test article-related differences to the control values were noted in any of the hematology parameters.
The few incidences of statistical significance were not dose-related and therefore considered to be incidental.
See pp. 70-71 and 144-151

6.5.2 CLINICAL BIOCHEMISTRY
No test article-related differences to the control values were noted in any of the clinical biochemistry parameters.
The few incidences of statistical significance were either not dose-related or restricted to only one sex, and were therefore considered to be incidental.
See pp. 72-73 and 152-159

6.6 PATHOLOGY
6.6.1 ORGAN WEIGHTS
No test article-related differences in organ weights were noted.
The mean absolute and relative thymus weights were reduced in males treated with 50 mg/kg. The thymus weights of males treated with 200 mg/kg and 1000 mg/kg compared favorably with those of the controls.
The mean absolute and relative organ weights of all females compared favorably.
See pp. 76-81 and 168-176
6.6.2 MACROSCOPICAL FINDINGS

The macroscopical findings did not distinguish treated rats from those of the controls. The macroscopical findings were within the range of spontaneous alterations which may be seen in rats of this age and strain. They included dilated renal pelves, discolored foci in various organs, dilated uterine horns filled with fluid and size reduction of testes, epididymides and adrenal glands.

See pp. 74-75 and 160-167

6.6.3 MICROSCOPICAL FINDINGS

A number of microscopical findings were noted. Their type, incidence and severity did not distinguish test article-treated rats from controls.

See pathology report pp. 220-269
CCR PROJECT 522000

SALMONELLA TYPHIMURIUM
REVERSE MUTATION ASSAY

WITH

WACKER BELSIL SDM 6022
contains 75% Bis-stearoy dimethysilane

REPORT

Study Completion Date:
January 04, 1996

RCC
Copy of GLP Certificate

GLP-Bescheinigung

Hiermit wird bestätigt, daß die Prüfleistung(en)
CCR Cytotec Cell Research GmbH & Co. KG
in 64295 Dudenhofen, in den Leppsteinwiesen 19
(Ort, Anschrift)
der RCC/CCR Holding Verwaltungs GmbH
(Firma)
am 05./06./07. April 1995
(Datum)
von der für die Überwachung zuständigen Behörden über
die Einhaltung der Grundzüge der Guten Laborpraxis
inspeziert worden ist (sind).
Es wird hiermit bestätigt, daß folgende Prüfungen in
dieser Prüfleistung nach den Grundzügen der Guten
Laborpraxis durchgeführt werden.

Prüfkategorien nach § 19 d Abs. 3 Chemikalien-Gesetzes in der Fassung vom 29. Juli 1994 (BGBl. I S. 1703),
zuletzt geändert am 27. September 1994 (BGBl. I S. 2705) in Verbindung mit der Allgemeinen
Verwaltungswegordnung vom Verfahren der behördlichen Überwachung der Einhaltung der Grundzüge der Guten

Toxikologische Eigenschaften

Toxicological Properties

Prüfkategorien gemäß OECD Panel on Good Laboratory Practice (January 1992)

Toxicity Studies

Prüfungen auf toxikologische Eigenschaften
Prüfungen auf mutagene Eigenschaften (in vitro, in vivo)

Toxicity Studies

Mutagenity Studies

Im Auftrag

[Signature]

[Name]

Wiesbaden, den [ ] August 1995
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Project Staff Signatures

Study Director
Dr. Hans-Eric Wollny

Date: January 04, 1996

Management
Markus Arenz

Date: January 04, 1996

Quality Assurance

The study was performed in compliance with:


Guidelines

This study followed the procedures indicated by the following internationally accepted guidelines and recommendations:

First Addendum to OECD Guidelines for Testing of Chemicals,
Section 4, No. 471, "Salmonella typhimurium, Reverse Mutation Assay", adopted May 26, 1983 and

Archiving

C C R, D-64380 Roßdorf/F.R.G. will archive the following data for 30 years:

Raw data, protocol and copy of report.

The following sample will be archived for at least 2 years following the date on which the report is audited by the Quality Assurance Unit:

sample of the test article

No raw data or material relating to the study will be discarded without the sponsor's prior consent.
STATEMENT OF COMPLIANCE

Project Number: 522000
Test Material: WACKER BELSIL SDM 6022
Study Director: Dr. Hans-Eric Wollny
Title: Salmonella Typhimurium Reverse Mutation Assay with WACKER BELSIL SDM 6022

This study performed in the testing facility of CCR was conducted in compliance with Good Laboratory Practice Regulations.


There were no circumstances that may have affected the quality or integrity of the study.

Study Director

CCR
Dr. Hans-Eric Wollny

Date: January 04, 1996
SUMMARY OF RESULTS

This study was performed to investigate the potential of WACKER BELSIL SDM 6022 to induce gene mutations according to the plate incorporation test (experiment I) and the pre-incubation test (experiment II) using the Salmonella typhimurium strains TA 1535, TA 1537, TA 98 and TA 100.

The assay was performed in two independent experiments both with and without liver microsomal activation. Each concentration, including the controls, was tested in triplicate. The test article was tested at the following concentrations:

Exp. I: 33.3; 100.0; 333.3; 1000.0; 2500.0; 5000.0 μg/plate
Exp. II: 33.3; 100.0; 333.3; 1000.0; 2500.0; 5000.0 μg/plate

No toxic effects, evident as a reduction in the number of revertants, occurred in all strains up to the highest investigated dose with and without metabolic activation in both experiments.

The plates incubated with the test article showed normal background growth up to the highest investigated dose with and without S9 mix in all strains used.

No substantial increases in revertant colony numbers of any of the four tester strains were observed following treatment with WACKER BELSIL SDM 6022 at any dose level, either in the presence or absence of metabolic activation (S9 mix). There was also no tendency of higher mutation rates with increasing concentrations in the range below the generally acknowledged border of biological relevance.

Appropriate reference mutagens were used as positive controls and showed a distinct increase of induced revertant colonies.

Conclusion

In conclusion, it can be stated that during the described mutagenicity test and under the experimental conditions reported, the test article did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used.

Therefore, WACKER BELSIL SDM 6022 is considered to be non-mutagenic in this Salmonella typhimurium reverse mutation assay.
Distributed for Comment Only -- Do Not Cite or Quote

RESEARCH TOXICOLOGY CENTRE S.p.A.

BELSIL SDH 6022 - contain N 75%

DELAYED DERMAL SENSITISATION STUDY Bis—Stearoyl dimethylsilane

IN THE GUINEA PIG

FINAL REPORT

RTC Study Number: 4978
RTC Report Number: 4978/T/001/96

Seen and approved by:

A. Nunciata
Responsible for Toxicological Experimentation as authorized by the Italian Ministry of Health

A. Marzoli
President

Sede: Via Ico Sport, 12 - 00140 ROMA (Roma) - ITALIA Telephone: + 39.0.310991 - Fax +39.0.310957 - C.P. 13301 - 00142 Roma For Lauretana
RTC Report Number: 4978/T/001/96

COMPLIANCE STATEMENT

We, the undersigned, hereby declare that this report is a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of this study conducted by Research Toxicology Centre S.p.A. were performed in accordance with:


(C. Longobardi, Biol.D.)
Study Director: 08-07-96

(J. Brightwell, Ph.D.)
Scientific Director: 8.07.96
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1. **SUMMARY**

The potential of the test substance, Belsil SDM 6022, to induce and elicit delayed dermal sensitisation was assessed by a guinea pig model using the maximisation test of Magnusson and Kligman.

The concentrations of the test substance used in the main study were determined by the results of preliminary screening tests.

The main sensitisation test was undertaken using a test group of twenty animals and a control group of ten animals. In an attempt to induce sensitisation, test animals were intradermally injected with an emulsion of Freund's complete adjuvant and the test substance at 10% concentration in both the selected vehicle and an emulsion of Freund's complete adjuvant. One week later this was boosted by topical application of the test substance at 75% concentration in the vehicle over the injection sites. Control group animals were treated in the same manner but the selected vehicle (Alembicol D) was used in place of the test substance. Two weeks after the second induction stage, all animals were challenged by topical application of both the vehicle and the test substance at a concentration of 50%.

At challenge, response to both the test substance and vehicle was observed in two animals of the test group twenty four hours after dosing. Response to the vehicle alone was also observed in another two animals of the test group in the same period. Recovery had occurred within forty eight hours.

Changes in body weight during the period of the study were generally similar in animals from both test and control groups.

These results indicate that the test substance does not elicit a sensitisation response in the guinea pig, the observed reaction being attributed to irritation. Classification based on these results would indicate the following:-

Classification: Not required
Symbol: None indicated
R phrase: None indicated
Memorandum

TO: Lillian Gill, D.P.A.
Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Beth A. Lange, Ph.D.
Industry Liaison to the CIR Expert Panel

DATE: February 1, 2016

SUBJECT: Comments on the Scientific Literature Review: Safety Assessment of Alkoxy Alkyl Silanes as Used in Cosmetics (SLR posted on the CIR website January 19, 2016)

Impurities - Octamethyltetrasiloxane and Cyclotetrasiloxane (INCI name) are two names for the same compound. Therefore, just one of these names should be used in the first paragraph of the Impurities section.

Acute, Inhalation - The pulmonary installation studies should not be included under inhalation exposure, as installation directly into the lungs results in different distribution than following inhalation. Did the study authors compare the results of coated particles with uncoated particles?

“titanium oxide” needs to be corrected to “titanium dioxide”

Genotoxicity - When describing exposure as amount/plate, please be consistent in calling this a dose or a concentration. Units of µg/ml should be called concentration.

Table 2 - The footnotes do not appear to be correctly placed as footnote “a” mentions water solubility and log Kow values but it is also placed with estimates of Density/Specific Gravity, Vapor pressure and Boiling point.