Safety Assessment of Perfluorohexylethyl Triethoxysilane as Used in Cosmetics

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*All interested persons are provided 60 days from the above release date (i.e., **October 19, 2026**) to comment on this safety assessment, and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available for review by any interested party, and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Executive Director, Dr. Bart Heldreth.*

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ABBREVIATIONS

BALF	bronchoalveolar lavage fluid
CFR	Code of Federal Regulations
CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
CRDE	calculated relative daily exposure
DAF	dermal absorption factor
Dictionary	*International Cosmetic Ingredient Dictionary*
DNEL	derived no effect level
EC	European Commission
ECHA	European Chemicals Agency
EPA	US Environmental Protection Agency
FDA	US Food and Drug Administration
log K_{ow}	octanol-water partition coefficient
LD_{50}	median lethal dose
l.o.	leave-on
MoCRA	Modernization of Cosmetics Regulation Act of 2022
MOE	margin of exposure
NOAEL	no-observed-adverse-effect level
NR	not reported
OECD	Organisation for Economic Co-operation and Development
Panel	Expert Panel for Cosmetic Ingredient Safety
PFAS	per- and polyfluoroalkyl substances
PFHxA	undecafluorohexaonic acid (aka perfluorohexanoic acid)
PND	post-natal day
POD	point of departure
PTFE	polytetrafluoroethylene
QPPR	quantitative property-property relationship
QSAR	quantitative structure-activity relationship
QSPR	quantitative structure-property relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RLD	Registration and Listing Data
r.o.	rinse-off
SCCS	Scientific Committee on Consumer Safety
SED	systemic exposure dose
TG	test guideline
US	United States

INTRODUCTION

This assessment reviews the safety of Perfluorohexylethyl Triethoxysilane as used in cosmetic formulations. According to the *International Cosmetic Ingredient Dictionary (Dictionary)*, Perfluorohexylethyl Triethoxysilane is reported to function as a binder and a skin conditioning agent.[1]

The Expert Panel for Cosmetic Ingredient Safety (Panel) reviewed the safety of polyfluorinated polymers in a safety assessment that was published in 2023. In that assessment, the Panel concluded that PTFE and hexafluoropropylene/ tetrafluoroethylene copolymer (both are fluoropolymers) are safe in the present practices of use and concentration, as described in that safety assessment.[2] The Panel concluded that the data were insufficient to determine the safety of the 10 remaining ingredients named in that report, all of which were not reported as in use in cosmetic products; 4 of those ingredients were fluorinated-side-chain polymers (acrylates/perfluorohexylethyl methacrylate copolymer, behenyl methacrylate/perfluorooctylethyl methacrylate copolymer, C6-14 perfluoroalkylethyl acrylate/HEMA copolymer, and stearyl methacrylate/perfluorooctylethyl methacrylate copolymer) and 6 were fluorinated polyethers (acrylates/methoxy PEG-23 methacrylate/perfluorooctyl ethyl acrylate copolymer, PEG-10 acrylate/perfluorohexylethyl acrylate copolymer, polyperfluoroethoxymethoxy difluoroethyl PEG diisostearate, polyperfluoroethoxymethoxy difluoroethyl PEG ether, polyperfluoroethoxymethoxy difluorohydroxyethyl ether, and polyperfluoroethoxymethoxy difluoromethyl ether).

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an extensive search of the world's literature; a search was last conducted August 2026. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the Cosmetic Ingredient Review (CIR) website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

Section 3506 of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) states the Secretary of Health and Human Services "shall assess the use of perfluoroalkyl and polyfluoroalkyl substances in cosmetic products and the scientific evidence regarding the safety of such use in cosmetic products, including any risks associated with such use;" this report was to be published on the US Food and Drug Administration (FDA) website.[3] Accordingly, the safety assessment was prepared by the FDA, and the report was published in December 2025; it should be noted that relevant information on Perfluorohexyl-ethyl Triethoxysilane was incorporated into this safety assessment.[4]

Much of the data included in this safety assessment was found on the European Chemicals Agency (ECHA) website.[5] Please note that the ECHA website provides summaries of information generated by industry, and it is those summary data that are reported in this safety assessment when ECHA is cited.

CHEMISTRY

Definition and Structure

According to the *Dictionary*, Perfluorohexylethyl Triethoxysilane (CAS No. 51851-37-7) is an organic compound that conforms to the following chemical structure as shown in Figure 1.[CIR Staff]

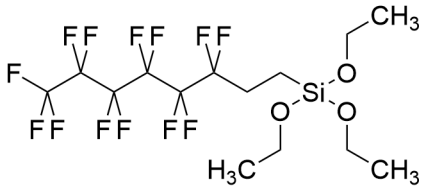


Figure 1. Perfluorohexylethyl Triethoxysilane

Per- and polyfluoroalkyl substances (PFAS) are a complex group of synthetic chemicals which each comprise, in part, a carbon chain with multiple fluorine atoms as substituents.[6] Perfluorohexylethyl Triethoxysilane is one example of a perfluoroalkyl substance. Since the fluorine-carbon covalent bond is extremely strong, PFAS rates of decomposition are very slow.

Chemical Properties

Perfluorohexylethyl Triethoxysilane is reported to be a colorless liquid.[5] Perfluorohexylethyl Triethoxysilane has a molecular weight of 510.36 g/mol. The melting point and water solubility for Perfluorohexylethyl Triethoxysilane are < -100ºC and < 2 mg/l at 20ºC and a pH of 6.29, respectively, and the octanol-water partition coefficient (log K_{ow}) is estimated as 7.2 at 20ºC. Other chemical properties can be found in Table 1.

Method of Manufacture

Method of manufacture data were not found in the published literature, and unpublished data were not submitted.

Impurities

Impurities data were not found in the published literature, and unpublished data were not submitted.

USE

Cosmetic

The safety of the cosmetic ingredient addressed in this assessment is evaluated based on data received from the FDA and the cosmetics industry on the expected use of Perfluorohexylethyl Triethoxysilane in cosmetics. Registration and Listing Data (RLD) obtained from the FDA report frequency of use, and responses to a survey conducted by the Personal Care Products Council (Council) indicate maximum reported concentrations of use; it is these values that define the present practices of use and concentration that are assessed by the Panel. Since 2024, as a result of the MoCRA, manufacturers and processors are required to register facilities and list their products (and ingredients therein) with the FDA (i.e., RLD). An exception is made for small businesses (average gross annual sales in the US of cosmetic products for the previous 3-yr period is less than $1,000,000, adjusted for inflation), which are exempt from MoCRA reporting for most cosmetic product categories. Eye area products, injected products, internal use products, or products that alter appearance for more than 24 h, and the facilities that manufacture these products, are not included in this exemption.[7] Another change resulting from MoCRA is the addition of tattoo preparations (permanent tattoo inks, temporary tattoo inks, and other tattoo products) to the product categories for which companies need to list their products with FDA. However, evaluating the safety of ingredients as used in tattoo preparations is not within the purview of the Panel; accordingly, such use is not included as part of the present practices of use that are assessed by the Panel.

According to RLD obtained from the FDA in 2025, Perfluorohexylethyl Triethoxysilane is reported to be used in 161 formulations (Table 2).[8,9] In 2025, the concentration of use survey conducted by the Council reported no uses of Perfluorohexylethyl Triethoxysilane.[10]

Perfluorohexylethyl Triethoxysilane is used in products that are applied near the eye (e.g., eye shadow, concentration of use not reported), that can be incidentally ingested (e.g., lipsticks and lip glosses), and in products that result in mucous membrane exposure (e.g., bath soaps and body washes). Additionally, Perfluorohexylethyl Triethoxysilane is used in powders (e.g., face powders) and could therefore be incidentally inhaled. In practice, as stated in the Panel's respiratory exposure resource document https://www.cir-safety.org/cir-findings), most droplets/particles incidentally inhaled from cosmetics would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.

With the advent of MoCRA and the current product categories outlined therein, it is now mandatory that cosmetic products used in airbrush delivery systems be reported as such for some, but not all, product categories in the RLD. In other words, a reliable source of frequency of use data regarding the use of cosmetic ingredients in conjunction with airbrush delivery systems is now available in some instances. Additionally, the concentration of use surveys are conducted based on the same product categories as identified in the RLD. Based on RLD, some products containing Perfluorohexylethyl Triethoxysilane are marketed for use with airbrush delivery systems. However, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety. Without information regarding the consumer habits and practices data or product particle size data (or other relevant particle data, e.g., diameter) related to this use technology, the data profile is incomplete, and the Panel is not able to determine safety for use in airbrush formulations. Accordingly, the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

In the US, the use of PFAS is a quickly-evolving issue, with significant regulatory variance state-to-state. At least 11 states have banned or limited the use of PFAS in cosmetics and other products with effective dates between 2025 – 2028; at least 8 additional states have proposed similar legislation.[4] The European Union has included an amendment in Annex XVII to Regulation (EC) No 1907/2006 regarding undecafluorohexaonic acid (PFHxA; aka perfluorohexanoic acid), its salts and PFHxA-related substances.[11] Perfluorohexylethyl Triethoxysilane falls within the scope of this entry as it contains a linear perfluorohexyl group with the formula C_6F_{13}-. According to the Annex, cosmetic products as defined in Article 2(1), point (a), of Regulation (EC) No 1223/2009, should not contain a concentration equal to or greater than 25 ppb for the sum of PFHxA and its salts, or 1000 ppb for the sum of PFHxA-related substances.[12]

TOXICOKINETIC STUDIES

Dermal Absorption

Computational Analyses/ Predictions

Based on water solubility and log K_{ow}, dermal absorption of Perfluorohexylethyl Triethoxysilane was predicted to be unlikely.[5] Systemic absorption of its hydrolysis product was also expected to be minimal because of its low water solubility and the slow hydrolysis of the parent compound. However, these predictions may be uncertain because of the surface-active properties of the parent compound.

Absorption, Distribution, Metabolism, and Excretion

Computational Analyses/ Predictions

Oral

Based on physicochemical properties, gastrointestinal absorption of Perfluorohexylethyl Triethoxysilane is unlikely.[5] Micellar solubilization is needed due to its lipophilicity and low water solubility.

Inhalation

The absorption of Perfluorohexylethyl Triethoxysilane via inhalation was estimated using a quantitative structure-activity relationship (QSAR) model.[5] Using the dimensionless Henry coefficient and the vapor pressure of ~ 1.6×10^{-6}, 1 was predicted, indicating no uptake in systemic circulation, even if lung exposure occurred.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Dermal

Perfluorohexylethyl Triethoxysilane was applied undiluted at 2000 mg/kg/bw to the skin of male and female Wistar rats (5/sex) for 24 h.[5] Observations were made for 14 d for mortalities, dermal response, and body weight changes. The median lethal dose (LD_{50}) was concluded to be > 2000 mg/kg bw due to the absence of mortalities, dermal irritation, or other abnormal clinical signs observed in the rats.

Oral

Perfluorohexylethyl Triethoxysilane was administered undiluted via gavage to Wistar rats (3/sex) at 2000 mg/kg.[5] In the 14-d observation period following the single administration, clinical signs and body weights were taken on days 0, 7, and 14. There were no deaths or signs of systemic reaction to the treatment, resulting in an LD_{50} > 2000 mg/kg bw.

Inhalation

Male BALB/cA mice (n = 8) were exposed to 1.8 mg/m^3 Perfluorohexylethyl Triethoxysilane for 60 min (followed by 30 min recovery) in an acute inhalation study.[13] There was a significant increase in bronchoalveolar lavage fluid (BALF) lymphocytes, but not a significant loss in body weight or increase in BALF protein concentrations. The study concluded that Perfluorohexylethyl Triethoxysilane had little to no effect on pulmonary function.

Short-Term Toxicity Studies

Oral

In a combined repeated-dose oral toxicity study with a reproduction/developmental toxicity screening test conducted in accordance with the Organisation for Economic Co-operation and Development (OECD) test guideline (TG) 422, Wistar rats (10/sex/group) were administered 0, 50, 100, or 150 mg/kg bw/d Perfluorohexylethyl Triethoxysilane in liquid paraffin via gavage for 28 d (males) or up to 54 d (females).[5] Additional recovery groups (6/sex/group) were included for the control and highest-dose groups and were observed without treatment for 14 d (males) or 16 d (females) following the last administration. Due to morbidity and mortality, surviving animals in the highest-dose group received a reduced dose of 125 mg/kg bw/d from premating day 14 onwards. Dose-dependent, treatment-related morbidity and mortality, decreased body weight, and progressive neuromuscular effects, including ataxia, primarily hind-limb paresis, and hypotonia, occurred in the 100 mg/kg bw/d and the higher dose groups. Histopathologic examination revealed progressive peripheral polyneuropathy indicative of a primary distal axonopathy; these lesions and associated clinical signs did not fully resolve during the recovery period. The no-observed-adverse-effect level (NOAEL) was determined to be 50 mg/kg bw/d for systemic toxicity.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

Oral

As part of the combined OECD TG 422 study described above, the main group animals (excluding the recovery groups) were also evaluated for reproductive and developmental toxicity. [5] Following 14 d of premating treatment, male and female Wistar rats were paired 1:1 for up to 14 d; with dosing continuing throughout the mating period; treatment continued for 28 d in males and through gestation and lactation for up to 54 d in females. The copulation index was reduced in the highest-dose group; however, this finding was considered secondary to generalized physical debilitation associated with polyneuropathy and was not considered an adverse reproductive effect. No treatment-related histopathologic findings were observed in the reproductive organs, and sperm staging revealed no abnormalities. No adverse effects on fertility were identified. No toxicologically relevant effects were observed on the developmental endpoints evaluated, including litter parameters, pup growth, viability, sex ratio, or gross external abnormalities. Interpretation of the highest-dose litter data was limited because only 3 pregnant females survived through the end of the study. The NOAEL was reported to be ≥ 125 mg/kg bw/d for reproductive toxicity.

GENOTOXICITY STUDIES

Details of the genotoxicity studies for Perfluorohexylethyl Triethoxysilane summarized below are described in Table 3.

In in vitro gene mutation assays, Perfluorohexylethyl Triethoxysilane was not mutagenic. Negative results were reported in two Ames assays *using Salmonella typhimurium* strains at concentrations up to 1000 or 5000 µg/plate and in an OECD TG 490 mouse lymphoma assay using L5178Y cells at concentrations up to 2 mg/ml, with and without metabolic activation.[5] In a chromosomal damage assay using OECD TG 473, Perfluorohexylethyl Triethoxysilane was tested in two experiments in Chinese hamster lung fibroblast (V79) cells. Experiment 1 utilized the test substance at up to 200 µg/ml with metabolic activation for 4 h and experiment 2 tested Perfluorohexylethyl Triethoxysilane at up to 500 µg/ml without metabolic activation for 21 h. Perfluorohexylethyl Triethoxysilane was negative for the induction of chromosome aberrations in both components of the study.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

Animal

Perfluorohexylethyl Triethoxysilane was tested for dermal irritation potential according to OECD TG 404 in small white Russian rabbits (n = 3).[5] The test substance was applied to 6 cm^2 of the skin for 4 h under a semi-occlusive bandage, and observations were made 30 – 60 min and, 2, 48, and 72 h after the application. One rabbit exhibited very slight erythema and edema, while another exhibited very slight edema only. No signs of skin irritation were observed in the remaining rabbit. Perfluorohexylethyl Triethoxysilane was not irritating to rabbit skin.

Sensitization

Animal

A Buehler test was performed according to OECD TG 406 in 20 female Dunkin-Hartley guinea pigs to test the skin sensitization potential of Perfluorohexylethyl Triethoxysilane.[5] The 6-h induction exposures occurred 3 times at weekly intervals (0, 7, and 14 d) with 100% of the test substance. The challenge exposure occurred once for 6 h with 50% of the test substance before observations were made 30 and 54 h after application. The test animals (n = 20) and negative controls (n = 10) did not show evidence of sensitization.

OCULAR IRRITATION STUDIES

Animal

The ocular irritation potential lof Perfluorohexylethyl Triethoxysilane was tested according to OECD TG 405 in 3 small white male Russian rabbits treated for 24 h before observations were made 1, 24, 48, and 72 h afterwards.[5] After 1 h, there was distinct hyperemia of blood vessels for all test animals. One animal additionally exhibited erythema and slight edema, which persisted through the 24-h observation period. However, by 48 and 72 h, all 3 of the test animals appeared normal. Perfluorohexylethyl Triethoxysilane was very slightly and transiently irritating to the eyes of rabbits and not classified as an eye irritant.

RISK ASSESSMENT

Based on a quantitative structure-property relationship (QSPR) algorithm which utilizes the function of liquid and content of tissues with the K_{ow}, Perfluorohexylethyl Triethoxysilane is predicted to distribute in the adipose tissue should systemic exposure occur.[5] Regarding the metabolism of Perfluorohexylethyl Triethoxysilane, this substance will hydrolyze and form [2-(perfluorohexyl)ethyl]silanetriol and ethanol upon absorption into the body. (No other information was provided.) The fraction predicted to be soluble in blood may provide a qualitative indication of the potential for urinary excretion. Using a quantitative property-property relationship (QPPR) approach with K_{ow} as the input parameter, and assuming that human blood contains 0.7% lipids, the distribution of the substance in the blood can be estimated. Accumulation is likely if the parent substance, Perfluorohexylethyl Triethoxysilane, is absorbed. However, for the hydrolysis product, [2-(perfluorohexyl)ethyl]silanetriol, the model predicted a blood-soluble fraction of 18%, indicating a potential for elimination and it would be unlikely to accumulate.

ECHA reports long-term systemic derived no-effect levels (DNELs) for exposure via the inhalation, dermal, and oral routes for workers occupationally-exposed to Perfluorohexylethyl Triethoxysilane and for the general population; these values were determined based on a systemic toxicity NOAEL of 50 mg/kg bw/d from an oral repeated-dose study in Wistar rats.[5] The overall assessment factors accounted for animal-to-human allometric scaling, remaining interspecies differences, exposure-duration extrapolation, and intraspecies variability, resulting in overall factors of 300 for exposed workers and 600 for the general population. For workers exposed to Perfluorohexylethyl Triethoxysilane, the long-term systemic DNELs were 0.17 mg/kg bw/d for dermal exposure and 1.17 mg/m^3 for inhalation exposure. For the general population, the corresponding DNELs were 0.083 mg/kg bw/d for both oral and dermal exposure and 0.29 mg/m^3 for inhalation exposure.

An FDA report reviewing the use of PFAS in cosmetic products and their associated risks (that was prepared as directed by MoCRA) included an assessment of Perfluorohexylethyl Triethoxysilane.[4] In a conservative body-lotion exposure scenario, the FDA used a relative daily exposure of 123.2 mg/kg bw/d,[14] the upper end of the literature-reported recommended use range (0.82%),[15] and a dermal absorption rate of 50% (in the absence of experimental data), resulting in an SED of 0.505 mg/kg bw/d.[4] The systemic toxicity NOAEL of 50 mg/kg bw/d from an oral repeated-dose study in rats, based

on peripheral nervous system toxicity observed at higher doses, was adjusted using an assumed oral absorption rate of 50%, resulting in a systemic POD of 25 mg/kg bw/d. The calculated MOE was 50. Given that the POD was derived from a relatively short-term animal study of 28 - 54 d, FDA applied an additional uncertainty factor of 3 to the default target MOE of 100, resulting in a target MOE of ≥300.[4] The calculated MOE was below the target MOE, indicating a potential safety concern. The FDA noted that the reliability of the assessment was subject to uncertainty because the assumed use concentration of 0.82% may have overestimated actual exposure and the oral and dermal absorption rates were unknown. Please note that the Council's survey did not report a use concentration for Perfluorohexylethyl Triethoxysilane in any cosmetic product category; therefore, CIR staff could not conduct an MOE calculation based on current reported use practices.

SUMMARY

The safety of Perfluorohexylethyl Triethoxysilane as used in cosmetics is reviewed in this safety assessment. Perfluorohexylethyl Triethoxysilane is reported to function in cosmetics as a binder and a skin conditioning agent.

According to RLD obtained from the FDA in 2025, Perfluorohexylethyl Triethoxysilane is reported to be used in 161 formulations. The concentration of use survey conducted in 2025 by the Council reported no concentration of uses.

The water solubility and log K_{ow} values indicate that dermal absorption of Perfluorohexylethyl Triethoxysilane would be unfavorable due to low water solubility and slow hydrolysis of the parent compound. The predictions could be uncertain due to the surface-active properties of the parent compound. Based on physicochemical properties, Perfluorohexylethyl Triethoxysilane is unlikely to be absorbed from the gastrointestinal tract in the absence of micellar solubilization.

The absorption of Perfluorohexylethyl Triethoxysilane via inhalation was estimated using a QSAR model. Using the dimensionless Henry coefficient and vapor pressure, the predicted value of 1 indicated no uptake in systemic circulation following lung exposure.

In acute dermal and oral toxicity studies, the LD_{50}s was concluded to be > 2000 mg/kg bw for Perfluorohexylethyl Triethoxysilane in Wistar rats. Additionally, in an acute inhalation study, BALB/cA mice were exposed to 1.8 mg/m^3 Perfluorohexylethyl Triethoxysilane and there was little to no effect on pulmonary function.

A combined repeated-dose toxicity study with reproduction/developmental toxicity screening was performed on male and female Wistar rats (10/sex/group) according to OECD TG 422. The rats received 0, 50, 100, or 150 mg/kg bw Perfluorohexylethyl Triethoxysilane via gavage; the high dose was reduced to 125 mg/kg bw on premating day 14 due to morbidity and mortality. There was evidence of decreased body weight, peripheral polyneuropathy, neuromuscular effects, and mortality at all the doses except for the low dose. For systemic toxicity, the NOAEL was determined to be 50 mg/kg bw/d. The same male and female Wistar rats used for the repeated-dose toxicity assessment were also evaluated for reproductive and developmental toxicity. After the 14 d of premating treatment, the rats were mated 1:1 for up to 14 d and continued dosing for up to 28 d (males) or 54 d (females). There were no findings in the reproductive organs histologically and sperm staging did not reveal abnormalities. The copulation index was reduced in the high-dose group compared to control while the fertility index and delivery index were comparable. For reproductive toxicity, the NOAEL was reported to be ≥ 125 mg/kg bw/d.

In in vitro gene mutation assays, Perfluorohexylethyl Triethoxysilane was not mutagenic. Negative results were reported in two Ames assays using *S. typhimurium* strains at concentrations up to 1000 or 5000 µg/plate and in an OECD TG 490 mouse lymphoma assay using L5178Y cells at concentrations up to 2 mg/ml, with and without metabolic activation. In a chromosomal damage assay using OECD TG 473, Perfluorohexylethyl Triethoxysilane was tested in two experiments in Chinese hamster lung fibroblast (V79) cells. Experiment 1 utilized the test substance at up to 200 µg/ml with metabolic activation for 4 h and experiment 2 tested up to 500 µg/ml without metabolic activation for 21 h. Perfluorohexylethyl Triethoxysilane was negative for the induction of chromosome aberrations in both components of the study.

Perfluorohexylethyl Triethoxysilane was applied to 6 cm^2 of the skin for 4 h under a semi-occlusive bandage in 3 small white Russian rabbits to test for dermal irritation according to OECD TG 404. Perfluorohexylethyl Triethoxysilane was considered not irritating to the skin despite some erythema and edema observed. A Buehler test was performed according to OECD TG 406 in 20 female Dunkin-Hartley guinea pigs to test the skin sensitization of Perfluorohexylethyl Triethoxysilane. The 20 test animals and 10 negative controls did not show evidence of sensitization.

The ocular irritation of Perfluorohexylethyl Triethoxysilane was tested in 3 small white male Russian rabbits in accord with OECD TG 405. There was evidence of distinct hyperemia of blood vessels, some erythema and slight edema. By 48 and 72 h, all of test animals appeared normal. Perfluorohexylethyl Triethoxysilane was very slightly irritating to the eyes and not classified as an eye irritant.

Perfluorohexylethyl Triethoxysilane is predicted to distribute in the adipose tissue, should systemic exposure occur, based on the QSPR algorithm. Perfluorohexylethyl Triethoxysilane is expected to hydrolyze and form [2-(perfluorohexyl)-ethyl]silanetriol and ethanol upon absorption into the body. The soluble fraction in blood can be used to determine the extent of urinary excretion of an ingredient. Using a QPPR approach, accumulation is likely if the parent substance, Perfluorohexyl-

ethyl Triethoxysilane, is absorbed. However, for the hydrolysis product, [2-(perfluorohexyl)ethyl]silanetriol, the predicted fraction of absorbed dose is 18%, and it has less potential for accumulation due to a higher potential of elimination.

Based on a systemic toxicity NOAEL of 50 mg/kg bw/d from an oral repeated-dose study in Wistar rats, ECHA reports DNELs for inhalation, dermal, and oral exposure routes for workers occupationally-exposed to Perfluorohexylethyl Triethoxysilane and the general population. For exposed workers, the long-term systemic DNELs were 0.17 mg/kg bw/d for dermal exposure and 1.17 mg/m³ for inhalation exposure. For the general population, the corresponding DNELs were 0.083 mg/kg bw/d for both oral and dermal exposure and 0.29 mg/m³ for inhalation exposure.

The FDA calculated an estimated SED of 0.505 mg/kg bw/d for Perfluorohexylethyl Triethoxysilane in body lotion. Using the systemic toxicity NOAEL of 50 mg/kg bw/d from an oral repeated-dose study in rats, the systemic POD was calculated to be 25 mg/kg bw/d with the MOE being 50. The calculated MOE was below the target MOE, indicating a potential safety concern; however, the reliability of the assessment was uncertain because it relied on conservative assumptions regarding use concentration and absorption. An MOE calculation was not conducted by CIR staff due to a lack of concentration of use data for Perfluorohexylethyl Triethoxysilane.

INFORMATION SOUGHT

The following information on Perfluorohexylethyl Triethoxysilane is being sought for use in the resulting safety assessment:

- Chemistry (including UV absorption), impurities, and method of manufacture
- Concentration of use
- Toxicokinetics data, specifically dermal absorption and/or penetration
- Inhalation toxicity data

TABLES

Table 1. Chemical properties of Perfluorohexylethyl Triethoxysilane

Property	Value	Reference
Physical Form	Liquid	[5]
Color	Colorless	[5]
Odor	Faint	[5]
Molecular Weight (g/mol)	510.36	[5]
Density (g/ml @ 20ºC)	1.3417	[5]
Vapor pressure (Pa @ 25ºC)	9.8 (estimated)	[5]
Melting Point (ºC)	< -100	[5]
Boiling Point (ºC)	225	[5]
Water Solubility (mg/l @ 20ºC & pH 6.29)	< 2	[5]
log K_{ow} (@ 20ºC)	7.2 (estimated)	[5]

Table 2. Frequency and concentration of use according to likely duration and exposure and by product category

	# of Uses	Max Conc of Use
	RLD (2025)[8,9]	% (2025)[10]
Totals*	**161**	**NR**
summarized by likely duration and exposure**		
Duration of Use		
Leave-On	*166*	*NR*
Rinse-Off	*3*	*NR*
Diluted for (Bath) Use	NR	*NR*
Unknown	NR	*NR*
Exposure Type		
Baby Products	NR	NR
Children's Makeup	NR	NR
Eye Area	16	NR
Incidental Ingestion	6	NR
Mucous Membrane	7	NR
Incidental Inhalation-Spray	20[a]; 15[b]	NR
Incidental Inhalation-Airbrush	1	NR
Incidental Inhalation-Powder	63; 15[b]	NR
Dermal Contact	163	NR
Deodorant (underarm)	NR	NR
Hair - Non-Coloring	NR	NR
Hair-Coloring	NR	NR
Nail	NR	NR
Other Preparations (Unknown Exposure Type)	NR	NR
as reported by product category		
Eye Makeup Preparations (other than children's eye makeup preparations)		
Eyebrow Pencil	5	NR
Eyeliner	2	NR
Eye Shadow	6	NR
Other Eye Makeup Preparations	3	NR
Makeup Preparations (not eye; not children's)		
Blushers and Rouges (all types)	8	NR
Face Powders	63	NR
Foundations	13 (traditional application); 1 (airbrush)	NR
Lipsticks and Lip Glosses	6	NR
Makeup Bases	3 (traditional application)	NR
Makeup Fixatives	2	NR
Other Makeup Preparations	20 (traditional application)	NR
Personal Cleanliness		
Bath Soaps and Body Washes	1	NR
Skin Care Preparations (creams, lotions, powder, and sprays)		
Cleansing (cold creams, cleansing lotions, liquids, and pads)	1	NR
Face and Neck (excluding shaving preparations)	7 (l.o.)	NR
Body and Hand (excluding shaving preparations)	4 (l.o.); 1 (r.o.)	NR
Moisturizing	16	NR
Other Skin Care Preparations	4 (l.o.)	NR
Suntan Preparations		
Suntan Gels, Creams, and Liquids	3	NR

NR – not reported

l.o. – leave-on; r.o. – rinse-off

*The sum of the counts given for duration of use and by exposure type, and the sum of the frequency reported by product category, may not equal the sum of total uses because each ingredient may be used in cosmetic formulations that are reported under more than one product category.

**Likely duration and exposure are derived from survey data based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)

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

[b] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

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

Table 3. Genotoxicity studies

Test Article	Vehicle	Concentration/Dose	Test System	Protocol	Results	Reference
IN VITRO						
Gene Mutation						
Perfluorohexylethyl Triethoxysilane	ethylene glycol dimethylether	0, 10, 31.6, 100, 316, and 1000 µg/l	*S. typhimurium* TA1535, TA1537, TA98, TA100 and TA102	OECD TG 471 (bacterial reverse mutation assay); cells treated for 48 h Appropriate negative (vehicle) and positive controls were used.	Test substance was negative with and without metabolic activation for all strains of bacteria in this study. Positive and negative controls gave expected results.	[5]
Perfluorohexylethyl Triethoxysilane	ethanol	0, 50, 150, 500, 1600, and 5000 µg/l	*S. typhimurium* TA1535, TA1537, T 98 and TA100	OECD TG 471 (bacterial reverse mutation assay); cells treated for 48 h Appropriate negative (vehicle) and positive controls were used.	Test substance was negative with and without metabolic activation for all strains of bacteria in this study. Positive and negative controls gave expected results.	[5]
Perfluorohexylethyl Triethoxysilane	ethanol	0, 0.05, 0.10, 0.25, 1, 1.5, 1.75, and 2 mg/ml	mouse lymphoma L5178Y cells	OECD TG 490 (in vitro mammalian cell gene mutation test using the thymidine kinase gene); cells treated for 4 h Appropriate negative (untreated or vehicle) and positive controls were used	Test substance was negative with and without metabolic activation for mutagenicity to mammalian cells. Positive and negative controls gave expected results.	[5]
Chromosomal Damage						
Perfluorohexylethyl Triethoxysilane	ethanol	Experiment I (without metabolic activation): 0, 20, 50, 100, and 200 µg/ml Experiment I (with metabolic activation): 0, 50, 100, 200 and 500 µg/ml Experiment II (without metabolic activation): 0, 100, 200 and 500 µg/ml	Chinese hamster lung fibroblasts (V79)	OECD TG 473 (in vitro mammalian chromosome aberration test); in experiment 1 cells were treated for 4 h with and without metabolic activation) while in experiment 2, cells treated for 21 h without metabolic activation Appropriate negative (untreated) and positive controls were used	Test substance was negative with and without metabolic activation for induction of chromosome aberrations in Chinese hamster lung fibroblasts (V79). Positive and negative controls gave expected results.	[5]

OECD – Organisation for Economic Co-operation and Development; TG – test guideline

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