

SAFETY DATA SHEETS

This SDS packet was issued with item:

071068683

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071068691 071068782



SAFETY DATA SHEET

1. Identification

Product identifier SHUMITECT KIDS

Other means of identification

Synonyms SENSODYNE PRONAMEL FOR CHILDREN (JAPAN) * PROJECT LITTLE BRIDGE * MFC 02151
* SODIUM FLUORIDE, FORMULATED PRODUCT

Recommended use Cosmetic Product

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

Telephone: CHEMTREC EMERGENCY NUMBERS
+(1) 703 527 3887 (International)
24/7; multi-language response

Contract Number: CCN9484

Telephone: VERISK 3E GLOBAL INCIDENT RESPONSE
+(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
D-SORBITOL	SORBITOL L-GULITOL 1,2,3,4,5,6-HEXANEHEXOL D-SORBOL	50-70-4	< 25
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHIDROXYPROPANE 1,2,3-TRIHIDROXYPROPANE OSMOGLYN	56-81-5	< 10

Chemical name	Common name and synonyms	CAS number	%
COCOAMIDOPROPYL BETAINE	COCOAMIDO BETAINE N-(COCO ALKYL) AMIDO PROPYL DIMETHYL BETAINE COCONUT OIL AMIDOPROPYL BETAIN E 1-PROPANAMINIUM, 3-AMINO-N-(CARBOXYMETHYL)-N,N-DI M 1-PROPANAMINIUM, 3-AMINO-N-(CARBOXYMETHYL)-N,N-DI METHYL-, N-COCO ACYL DERIVATIVES, HYDROXIDES, INNER SALTS 1-PROPANAMINIUM,3-AMINO-N-(CARB OXYMETHYL)-N,N-DIMETHYL-,N-COCO ACYL DERIVS.,HYDROXIDES,INNER SALTS	61789-40-0	< 1.5
SODIUM FLUORIDE	SODIUM MONOFLUORIDE NATURAL VILLIAUMITE	7681-49-4	< 0.25
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	< 0.15
SODIUM HYDROXIDE	CAUSTIC SODA LYE SODIUM HYDRATE HIDROXIDO SODICO HIDRÓXIDO DE SÓDIO CAUSTIC SODA SOLUTION Caustic soda (as NaOH) Soda lye Soda, caustic	1310-73-2	< 0.01
Other components below reportable levels			< 70

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Wash off with soap and plenty of water.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Call a POISON CENTER or doctor/physician if you feel unwell.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	If you feel unwell, seek medical advice (show the label where possible).

5. Fire-fighting measures

Suitable extinguishing media	Water. Carbon dioxide (CO2). Dry chemical powder. Foam.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	This product is non-flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Local authorities should be advised if significant spillages cannot be contained. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. Following product recovery, flush area with water. Collect spillage. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. Observe good industrial hygiene practices. Provide adequate ventilation.

Conditions for safe storage, including any incompatibilities

Room temperature - normal conditions. Store in original tightly closed container.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Type

Value

Note

COCAMIDOPROPYL
BETAINE (CAS
61789-40-0)

OHC

1

PROVISIONAL

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components

Type

Value

Form

GLYCERIN (CAS 56-81-5)

PEL

5 mg/m3

Respirable fraction.
Total dust.

15 mg/m3

2.5 mg/m3

SODIUM FLUORIDE (CAS
7681-49-4)

PEL

2 mg/m3

SODIUM HYDROXIDE
(CAS 1310-73-2)

PEL

2 mg/m3

TITANIUM DIOXIDE (CAS
13463-67-7)

PEL

15 mg/m3

Total dust.

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components

Type

Value

Form

SODIUM FLUORIDE (CAS
7681-49-4)

TWA

2.5 mg/m3

Dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components

Type

Value

Form

TITANIUM DIOXIDE (CAS
13463-67-7)

TWA

5 mg/m3

Respirable fraction.

15 mg/m3

50 mppcf

15 mppcf

Total dust.

Total dust.

Respirable fraction.

US. ACGIH Threshold Limit Values

Components

Type

Value

SODIUM FLUORIDE (CAS
7681-49-4)

TWA

2.5 mg/m3

SODIUM HYDROXIDE
(CAS 1310-73-2)

Ceiling

2 mg/m3

TITANIUM DIOXIDE (CAS
13463-67-7)

TWA

10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components

Type

Value

SODIUM FLUORIDE (CAS
7681-49-4)

TWA

2.5 mg/m3

SODIUM HYDROXIDE
(CAS 1310-73-2)

Ceiling

2 mg/m3

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
SODIUM FLUORIDE (CAS 7681-49-4)	3 mg/l	Fluoride	Urine	*
	2 mg/l	Fluoride	Urine	*

* - For sampling details, please see the source document.

Appropriate engineering controls No special ventilation requirements.

Individual protection measures, such as personal protective equipment

Eye/face protection Do not get in eyes. Wear safety glasses with side shields (or goggles). Eye wash fountain is recommended.

Skin protection

Hand protection Not normally needed.

Other No special protective equipment required.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not available.

General hygiene considerations Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Paste.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Not available.
Conditions to avoid	None under normal conditions.
Incompatible materials	Not available.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	None known. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use.
Symptoms related to the physical, chemical and toxicological characteristics	None known. Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test Results
COCOAMIDOPROPYL BETAINE (CAS 61789-40-0)		
<u>Acute</u>		
Oral		
LD50	Mouse	> 2000 mg/kg
D-SORBITOL (CAS 50-70-4)		
<u>Acute</u>		
Oral		
LD50	Rat	15.9 g/kg
GLYCERIN (CAS 56-81-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
SODIUM HYDROXIDE (CAS 1310-73-2)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	1350 mg/kg
Oral		
LD50	Rat	104 - 340 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
<u>Acute</u>		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
<u>Chronic</u>		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.

Components	Species	Test Results
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
<u>Subacute</u> Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
<u>Subchronic</u> Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

SODIUM HYDROXIDE

Literature search
Result: Causes severe burns.

Irritation Corrosion - Skin

TITANIUM DIOXIDE

0, Literature data
Result: Non-irritant
Species: Guinea pig
0, Literature data
Result: Non-irritant
Species: Human
Acute dermal irritation; OECD 404, Literature data
Result: Non-irritant
Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

SODIUM HYDROXIDE

Literature search
Result: Causes severe burns.

TITANIUM DIOXIDE

OECD 405, Literature data
Result: Mild irritant
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization Health injuries are not known or expected under normal use.

Sensitization

TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum
Result: Negative
Species: Guinea pig
Test Duration: 48 hour exposure
Patch test, Literature data
Result: Negative
Species: Human

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

TITANIUM DIOXIDE

Ames, Literature data
Result: Negative
Micronucleus Assay in vitro, CHO cells, Literature data
Result: Negative

Mutagenicity
TITANIUM DIOXIDE

Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data
Result: Positive
Syrian Hamster Embryo (SHE) cell transformation assay
Result: Negative
WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data
Result: Positive

Carcinogenicity

Health injuries are not known or expected under normal use. Titanium Dioxide produced carcinogenic effects in a lifetime study in mice. High concentrations or doses administered over an extended period of time were required to produce adverse effects. Risk of cancer cannot be excluded with prolonged exposure.

TITANIUM DIOXIDE

0.5 mg/m3, Literature data
Result: Negative
Species: Rat
Test Duration: 24 months
0.72 - 14.8 mg/m3, Literature data
Result: Negative
Species: Mouse
10 - 250 mg/m3, Dietary study - Literature data.
Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration.
Species: Rat
Test Duration: 24 months
25000 - 50000 ppm, Dietary study - Literature data.
Result: Negative
Species: Rat
25000 - 50000 ppm, Dietary study
Result: Negative
Species: Mouse
7.2 - 14.8 mg/m3, Literature data
Result: Lung tumour
Species: Rat
Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

SODIUM FLUORIDE (CAS 7681-49-4)

3 Not classifiable as to carcinogenicity to humans.

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure

None known.

Specific target organ toxicity - repeated exposure

None known.

Aspiration hazard

Not available.

12. Ecological information

Ecotoxicity

Contains a substance which causes risk of hazardous effects to the environment.

Components	Species		Test Results
COCOAMIDOPROPYL BETAINE (CAS 61789-40-0)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	0.55 mg/l, 96 hours
	NOEC	Green algae (Scenedesmus subspicatus)	0.09 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	6.5 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	1.6 mg/l, 48 hours

Components		Species	Test Results
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	2 mg/l, 96 hours semi-static test conditions
	NOEC	Zebra fish (Adult Brachydanio rerio)	1.7 mg/l, 96 hours semi-static test conditions
Microtox	MIC	Pseudomonas	> 3000 mg/l, 16 hours
<i>Chronic</i> Crustacea	LOEC	Water flea (Daphnia magna)	3.6 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	0.9 mg/l, 21 days
SODIUM FLUORIDE (CAS 7681-49-4)			
<i>Acute</i>	IC50	Activated sludge	2930 mg/L, 3 hours
	Aquatic		
<i>Acute</i> Algae	EC50	Green algae (Selenastrum capricornutum)	272 mg/L, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	340 mg/L, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	180 mg/L, 96 hours Static renewal test
		Mosquito fish (Adult Gambusia affinis)	418 mg/L, 96 hours Static test
		Rainbow trout (Juvenile Oncorhyncus mykiss)	108 mg/L, 96 hours Static test
SODIUM HYDROXIDE (CAS 1310-73-2)			
Aquatic			
<i>Acute</i> Fish	EC50	Mosquito fish (Adult Gambusia affinis)	125 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	45.4 mg/l, 96 hours Static test
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Fish	LC50	Mummichog (Fundulus heteroclitus)	> 1000 mg/l, 96 hours
<i>Acute</i> Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

COCOAMIDOPROPYL BETAINE 97 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
99 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

COCOAMIDOPROPYL BETAINE 100 %, 20 Days Modified Sturm test., Activated sludge
84 %, 30 days Closed bottle test, Activated sludge

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

D-SORBITOL -2.2
GLYCERIN -1.76

Bioconcentration factor (BCF)

D-SORBITOL 1 Estimated
SODIUM FLUORIDE 2.3 Measured

Mobility in soil

Adsorption

Soil/sediment sorption - log K_{oc}

D-SORBITOL

0.3 Estimated

Mobility in general

Volatility

Henry's law

D-SORBITOL

0 atm m³/mol Estimated

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

SODIUM FLUORIDE (CAS 7681-49-4)

Listed.

SODIUM HYDROXIDE (CAS 1310-73-2)

Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes

Delayed Hazard - Yes

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

GLYCERIN (CAS 56-81-5)

Other Flavoring Substances with OSHA PEL's

US state regulations

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

SODIUM HYDROXIDE (CAS 1310-73-2)

TITANIUM DIOXIDE (CAS 13463-67-7)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	05-09-2018
Revision date	05-09-2018
Version #	02
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 0 Instability: 0
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Revision information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Multiple Properties Regulatory Information: United States