

## 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

## 1. Identification

<b>Product identifier</b>	<b>SHUMITECT KIDS</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	SENSODYNE PRONAMEL FOR CHILDREN (JAPAN) * PROJECT LITTLE BRIDGE * MFC 02151 * SODIUM FLUORIDE, FORMULATED PRODUCT
<b>Recommended use</b>	Cosmetic Product
<b>Recommended restrictions</b>	No other uses are advised.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	
GlaxoSmithKline US 5 Moore Drive Research Triangle Park, NC 27709 USA US General Information (normal business hours): +1-888-825-5249 Email Address: msds@gsk.com Website: www.gsk.com EMERGENCY PHONE NUMBERS - TRANSPORT EMERGENCIES:: US / International toll call +1 703 527 3887 available 24 hrs/7 days; multi-language response	

## 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
COCOAMIDOPROPYL BETAINE	COCOAMIDO BETAINE * N-(COCO ALKYL) AMIDO PROPYL DIMETHYL BETAINE * COCONUT OIL AMIDOPROPYL BETAINE	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 * SODIUM HYDRATE	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
COCOAMIDOPROPYL BETAINE (CAS 61789-40-0)	OHC	1	PROVISIONAL
D-SORBITOL (CAS 50-70-4)	OHC	1	
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 15 mg/m3	Respirable fraction. Total dust.
SODIUM FLUORIDE (CAS 7681-49-4)	PEL	2.5 mg/m3	
SODIUM HYDROXIDE (CAS 1310-73-2)	PEL	2 mg/m3	

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

Components	Type	Value	Form
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. 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**

<b>Eye/face protection</b>	Do not get in eyes. Wear safety glasses with side shields (or goggles). Eye wash fountain is recommended.
<b>Hand protection</b>	Not normally needed.
<b>Other</b>	No special protective equipment required.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.
<b>Thermal hazards</b>	Not available.

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

**9. Physical and chemical properties****Appearance**

<b>Physical state</b>	Liquid.
<b>Form</b>	Paste.
<b>Color</b>	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**

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	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**

**Ingestion** Health injuries are not known or expected under normal use.

**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.

**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.

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
COCOAMIDOPROPYL BETAINE (CAS 61789-40-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	> 2000 mg/kg
D-SORBITOL (CAS 50-70-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	15.9 g/kg
GLYCERIN (CAS 56-81-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
SODIUM HYDROXIDE (CAS 1310-73-2)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	1350 mg/kg
<i>Oral</i>		
LD50	Rat	104 - 340 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
<b>Chronic</b>		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
<b>Subacute</b>		
<i>Inhalation</i>		
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.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
<b>Subchronic</b>		
<i>Inhalation</i>		
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.

**Irritation Corrosion - Skin**

TITANIUM DIOXIDE

Acute dermal irritation; OECD 404, Literature data

Result: Non-irritant

Species: Rabbit

Literature data

Result: Non-irritant

Species: Guinea pig

Literature data

Result: Non-irritant

Species: Human

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

**Eye**

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  
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  
Result: Negative  
Species: Mouse  
25000 - 50000 ppm, Dietary study - Literature data.  
Result: Negative  
Species: Rat  
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 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
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
Chronic			
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)			
Acute			
	IC50	Activated sludge	2930 mg/L, 3 hours
Aquatic			
Acute			
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			
Acute			
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			
Acute			
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

#### 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<sub>oc</sub>**

D-SORBITOL	0.3 Estimated
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**Mobility in general****Volatility****Henry's law**

D-SORBITOL	0 atm m <sup>3</sup> /mol Estimated
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<b>Other adverse effects</b>	Not available.
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**13. Disposal considerations**

<b>Disposal instructions</b>	Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.
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<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
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<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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<b>Waste from residues / unused products</b>	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).
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<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.
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**14. Transport information****DOT**

Not regulated as a dangerous good.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	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.
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**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.
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SODIUM HYDROXIDE (CAS 1310-73-2)	Listed.
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**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

<b>Hazard categories</b>	Immediate Hazard - Yes
	Delayed Hazard - Yes
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

<b>SARA 311/312 Hazardous chemical</b>	No
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**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.**US state regulations****US. Massachusetts RTK - Substance List**

GLYCERIN (CAS 56-81-5)

SODIUM FLUORIDE (CAS 7681-49-4)

SODIUM HYDROXIDE (CAS 1310-73-2)

TITANIUM DIOXIDE (CAS 13463-67-7)

**US. New Jersey Worker and Community Right-to-Know Act**

GLYCERIN (CAS 56-81-5)

SODIUM FLUORIDE (CAS 7681-49-4)

SODIUM HYDROXIDE (CAS 1310-73-2)

TITANIUM DIOXIDE (CAS 13463-67-7)

**US. Pennsylvania Worker and Community Right-to-Know Law**

GLYCERIN (CAS 56-81-5)

SODIUM FLUORIDE (CAS 7681-49-4)

SODIUM HYDROXIDE (CAS 1310-73-2)

TITANIUM DIOXIDE (CAS 13463-67-7)

**US. Rhode Island RTK**

SODIUM FLUORIDE (CAS 7681-49-4)

SODIUM HYDROXIDE (CAS 1310-73-2)

**US. California Proposition 65**

WARNING: This product contains a chemical known to the State of California to cause cancer.

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

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

**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** 09-17-2014**Revision date** 09-17-2014**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: Product and Company Identification  
Composition / Information on Ingredients: Undisclosed Ingredient Statement  
Physical & Chemical Properties: Multiple Properties  
Regulatory Information: United States