

1. Identification

Product identifier	SENSODYNE PRONAMEL HIGH FLUORIDE
Other means of identification	
Synonyms	SENSODYNE PROSCHMELZ FLUORID GELÉE, OROMUCOSAL GEL * SODIUM FLUORIDE, FORMULATED PRODUCT
Recommended use	Oral Care
Recommended restrictions	No other uses are advised.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	<p>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</p>

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	%
SODIUM FLUORIDE	SODIUM MONOFLUORIDE * NATURAL VILLIAUMITE	7681-49-4	2.77
DODECYL SODIUM SULFATE	DODECYL SULFATE, SODIUM SALT * SODIUM LAURYL SULPHATE * LAURYL SULFATE SODIUM SALT	151-21-3	1.12
SODIUM HYDROXIDE	CAUSTIC SODA * SODIUM HYDRATE	1310-73-2	0.05
Other components below reportable levels			>95.0

*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	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation develops and persists.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Do not induce vomiting. 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

Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

General information

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media

Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO₂).

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

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

Move containers from fire area if you can do so without risk.

Specific methods

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

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. 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

Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Type

Value

DODECYL SODIUM SULFATE (CAS 151-21-3)

OHC

2

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

Components

Type

Value

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-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

US. ACGIH Threshold Limit Values

Components	Type	Value
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 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. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed.

Other Not normally needed.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not available.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties**Appearance**

Physical state Liquid.

Form Gel.

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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
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	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	Direct contact with eyes may cause temporary irritation.
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Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test Results
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Acute		
<i>Oral</i>		
LD50	Rat	1288 mg/kg
SODIUM HYDROXIDE (CAS 1310-73-2)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	1350 mg/kg
<i>Oral</i>		
LD50	Rat	104 - 340 mg/kg

* 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.
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Corrosivity	
SODIUM HYDROXIDE	Literature search Result: Causes severe burns.

Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
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Eye	
SODIUM HYDROXIDE	Literature search Result: Causes severe burns.

Respiratory or skin sensitization

Respiratory sensitization	Not available.
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Skin sensitization	Health injuries are not known or expected under normal use.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Health injuries are not known or expected under normal use.
IARC Monographs. Overall Evaluation of Carcinogenicity	
SODIUM FLUORIDE (CAS 7681-49-4) 3 Not classifiable as to carcinogenicity 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.
Further information	None known.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
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Components		Species	Test Results
DODECYL SODIUM SULFATE (CAS 151-21-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	4.6 mg/l, 96 hours Flow-through test
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-thought Test
Fish	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days Flow-through test
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 Oncorhynchus 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 Oncorhynchus mykiss)	45.4 mg/l, 96 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.
Bioaccumulative potential	No data available.

Partition coefficient n-octanol / water (log Kow)

DODECYL SODIUM SULFATE

1.6

Bioconcentration factor (BCF)

SODIUM FLUORIDE

2.3 Measured

Mobility in soil

Not available.

Mobility in general

Not available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. 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). Avoid discharge into water courses or onto the ground.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. 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 listed.

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

Immediate Hazard - No
Delayed Hazard - No
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.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

SODIUM FLUORIDE (CAS 7681-49-4)

SODIUM HYDROXIDE (CAS 1310-73-2)

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

SODIUM FLUORIDE (CAS 7681-49-4)

SODIUM HYDROXIDE (CAS 1310-73-2)

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

SODIUM FLUORIDE (CAS 7681-49-4)

SODIUM HYDROXIDE (CAS 1310-73-2)

US. Rhode Island RTK

SODIUM FLUORIDE (CAS 7681-49-4)

SODIUM HYDROXIDE (CAS 1310-73-2)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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	01-28-2015
Version #	01
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.