



SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture SENSODYNE PRONAMEL HIGH FLUORIDE
Registration number -
Synonyms SENSODYNE PROSCHMELZ FLUORID GELÉE, OROMUCOSAL GEL * SODIUM FLUORIDE, FORMULATED PRODUCT
Issue date 23-April-2018
Version number 01

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Oral Care
Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

Company name GlaxoSmithKline UK
Address: 980 Great West Road
Brentford, Middlesex TW8 9GS UK
Telephone: +44-20-8047-5000 (General Inquiries)
Email: msds@gsk.com
Website: www.gsk.com

EMERGENCY CONTACTS

Telephone: CHEMTREC EMERGENCY NUMBERS
+(44)-870-8200418 (In country)
+(1) 703 527 3887 (International)
24/7; multi-language response
Contract Number: CCN9484
Telephone: VERISK 3E GLOBAL INCIDENT RESPONSE
+(44) 20 35147487 or 0 800 680 0425 (In country)
+(1) 760 476 3961 (International)
24/7; multi-language response
Contract Number: 334878

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

2.3. Other hazards

This product is non-flammable.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
DODECYL SODIUM SULFATE	1 - < 3	151-21-3 205-788-1	-	-	

Classification: -

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sodium fluoride	1 - < 3	7681-49-4 231-667-8	-	009-004-00-7	#
Classification:	Acute Tox. 3;H301, Skin Irrit. 2;H315, Eye Irrit. 2;H319				
SODIUM HYDROXIDE	< 0.1	1310-73-2 215-185-5	-	011-002-00-6	
Classification:	Met. Corr. 1;H290, Skin Corr. 1A;H314, Eye Dam. 1;H318				

Other components below reportable levels >95.0

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.

4.1. Description of 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 CENTRE or doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation.

4.3. Indication of any 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.

SECTION 5: Firefighting measures

General fire hazards This product is non-flammable.

5.1. Extinguishing media

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

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

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

Special fire fighting procedures 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel 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.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

- 6.2. Environmental precautions** Avoid discharge into drains, water courses or onto the ground.
- 6.3. Methods and material 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.
- 6.4. Reference to other sections** For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

- 7.1. Precautions for safe handling** Avoid prolonged exposure. Observe good industrial hygiene practices.
- 7.2. Conditions for safe storage, including any incompatibilities** Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
- 7.3. Specific end use(s)** Oral Care

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value
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DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	2
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UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
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Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m ³
SODIUM HYDROXIDE (CAS 1310-73-2)	STEL	2 mg/m ³

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
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Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m ³
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Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no effect levels (DNELs) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls No special ventilation requirements. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information Not normally needed. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- Hand protection Not normally needed.

- Other Not normally needed.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not available.

Hygiene measures

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.

Environmental exposure controls

Hazard guidance and control recommendations Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Liquid.
Form Gel.
Colour Not available.

Odour Not available.

Odour 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.

Vapour pressure Not available.

Vapour 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.

Explosive properties Not available.

Oxidising properties Not available.

9.2. Other information No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability Material is stable under normal conditions.

10.3. Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid Contact with incompatible materials.

10.5. Incompatible materials Strong oxidising agents.

10.6. Hazardous decomposition products None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Health injuries are not known or expected under normal use. Occupational exposure to the substance or mixture may cause adverse effects.

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 Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test results
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Acute		
Oral		
LD50	Rat	1288 mg/kg
SODIUM HYDROXIDE (CAS 1310-73-2)		
Acute		
Dermal		
LD50	Rabbit	1350 mg/kg
Oral		
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.

Corrosivity

SODIUM HYDROXIDE

Literature search

Result: Causes severe burns.

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

Eye

SODIUM HYDROXIDE

Literature search

Result: Causes severe burns.

Respiratory sensitisation Not available.

Skin sensitisation 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.

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.

Mixture versus substance information No information available.

Other information None known.

SECTION 12: Ecological information

12.1. Toxicity 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.

Components	Species	Test results
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Aquatic		
<i>Acute</i>		
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
<i>Chronic</i>		
Algae	NOEC	Green algae (Desmodesmus subspicatus) 30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia 0.88 mg/l, 7 days Flow-through Test
Fish	NOEC	Fathead minnow (Pimephales promelas) 3.8 mg/l, 28 days Flow-through test

Components	Species	Test results
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

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

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

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

DODECYL SODIUM SULFATE 95 % OECD 301 B

12.3. 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

12.4. Mobility in soil Not available.

Mobility in general Not available.

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	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.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

Not available.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not established.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

H290 May be corrosive to metals.
H301 Toxic if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.

Revision information

None.

Training information

Follow training instructions when handling this material.

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.