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

PARODONTAX DAILY FLUORIDE TOOTHPASTE (IB2108)

Registration number

IB2108 * SODIUM FLUORIDE, FORMULATED PRODUCT **Synonyms**

04-November-2021 Issue date

Version number

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

Identified uses Oral Care

> This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant

to medicinal use of the product. In this instance patients should consult prescribing

information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate

safety data sheet for each ingredient.

Brentford, Middlesex TW8 9GS UK

No other uses are advised. Uses advised against

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK Company name 980 Great West Road Address:

Telephone: +44-20-8047-5000 (General Inquiries)

Email: msds@gsk.com Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 3F GLOBAL INCIDENT RESPONSE

+(44) 20 35147487 or 0 800 680 0425 (In country) Telephone:

+(1) 760 476 3961 (International)

24/7; multi-language response

334878 **Contract Number:**

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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

Health hazards

Serious eye damage/eye irritation H319 - Causes serious eye Category 2

irritation.

Skin sensitisation Category 1 H317 - May cause an allergic skin

reaction.

Causes serious eye irritation. May cause an allergic skin reaction. Dangerous for the environment **Hazard summary**

if discharged into watercourses.

Occupational exposure to the substance or mixture may cause adverse health effects. See

section 11 of the SDS for additional information on health hazards.

2.2. Label elements

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

COCAMIDOPROPYL BETAINE, DODECYL SODIUM SULFATE, GLYCERIN, HARLEQUIN EC. Contains:

SODIUM BICARBONATE, Sodium fluoride

Material name: PARODONTAX DAILY FLUORIDE TOOTHPASTE (IB2108) SDS LIK 140540 Version #: 01 Issue date: 04-November-2021

Hazard pictograms



Signal word Warning

Hazard statements

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements

Prevention

P261 Avoid breathing mist/vapours.
P264 Wash thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear eye protection/face protection.

P280 Wear protective gloves.

Response

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage Not available.

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information 1.1 % of the mixture consists of component(s) of unknown acute oral toxicity. 71.494 % of the

mixture consists of component(s) of unknown acute dermal toxicity. 77.71 % of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 76.61 % of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

2.3. Other hazards Occupational Exposure Limits for constituents are listed in Section 8. See section 11 of the SDS

for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
SODIUM BICARBONATE	67.26	144-55-8 205-633-8	-	-	
Classificati	ion: -				
GLYCERIN	9.35	56-81-5 200-289-5	-	-	
Classificati	ion: -				
DODECYL SODIUM SULFATE	2	151-21-3 205-788-1	-	-	
Classificati	4;H332;(A		4;H302;(ATE: 1288 mg/kg), rit. 2;H315, Eye Dam. 1;H31 2		
COCAMIDOPROPYL BETAINE	1.134	61789-40-0 263-058-8	-	-	
Classificati	i on: Skin Irrit. 2 Chronic 2;		319, Aquatic Acute 1;H400,	Aquatic	
HARLEQUIN EC	1.1	Unassigned	-	-	
Classificati	ion: Skin Irrit. 2 Chronic 3;		319, Skin Sens. 1;H317, Aqı	uatic	
Sodium fluoride	0.2049	7681-49-4 231-667-8	-	009-004-00-7	#

Material name: PARODONTAX DAILY FLUORIDE TOOTHPASTE (IB2108)

140540 Version #: 01 Issue date: 04-November-2021

List of abbreviations and symbols that may be used above

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

M: M-factor

PBT: persistent, bioaccumulative and toxic substance. vPvB: very persistent and very bioaccumulative substance.

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements 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). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. The need for pre-placement and periodic health surveillance

must be determined by risk assessment.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if

symptoms develop or persist. Under normal conditions of intended use, this material is not

expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse.

Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large Ingestion

amount does occur, call a poison control centre immediately. Do not induce vomiting without

advice from poison control center.

4.2. Most important symptoms and effects, both acute and delayed

Severe eye irritation. May cause allergic skin reaction.

4.3. Indication of any immediate medical attention and special treatment needed

No specific antidotes are recommended. 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 Assume that this product is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing

media

Water. Foam. 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

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.

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency

personnel

Wear appropriate personal protective equipment.

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 Use water spray to reduce vapours or divert vapour cloud drift.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. 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. Put material in suitable, covered, labeled

containers.

6.4. Reference to other

For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

sections

SECTION 7: Handling and storage

7.1. Precautions for safe

handling

Avoid contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Store in 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	Туре	Value	Form
COCAMIDOPROPYL BETAINE (CAS 61789-40-0)	OHC	1	>1000 - ≤5000 mcg/m3
	PDE	3000 mcg/day	Parenteral, Inhalation
		10000 mcg/day	Oral, Dermal
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	1	>1000 - ≤5000 mcg/m3
SODIUM BICARBONATE (CAS 144-55-8)	OHC	1	>1000 - =5000 mcg/m3</td
UK. EH40 Workplace Exposure Li	mits (WELs)		
Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m3	
EU. Indicative Exposure Limit Val	ues in Directives 91/322/EEC,	2000/39/EC, 2006/15/EC, 2009/1	61/EU, 2017/164/EU
Components	Туре	Value	
Sodium fluoride (CAS	TWA	2.5 mg/m3	

Biological limit values

7681-49-4)

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)

Exposure guidelines

8.2. Exposure controls

Appropriate engineering controls

Not available.

General ventilation normally adequate. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the

outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

Personal protection equipment should be chosen according to the CEN standards and in **General information**

discussion with the supplier of the personal protective equipment. Follow all local regulations if

personal protective equipment (PPE) is used in the workplace.

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

EN 166).

Skin protection

- Hand protection Not normally needed. Select suitable chemical resistant protective gloves (EN 374) with a

protective index 6 (>480min permeation time).

Not normally needed. Wear suitable protective clothing as protection against splashing or - Other

contamination. (EN 14605 for splashes, EN ISO 13982 for dust).

No personal respiratory protective equipment normally required. When workers are facing Respiratory protection

concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic,

inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical stateLiquid.FormPaste.

Pump/tube.

ColourNot available.OdourNot available.Melting point/freezing pointNot available.Boiling point or initial boilingNot available.

point and boiling range

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Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Flash point Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

pH Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Vapour pressureNot available.Vapour densityNot available.Relative densityNot available.Particle characteristicsNot available.

Other safety characteristics

Explosive properties Not explosive.

Oxidising properties Not established.

Percent volatile 17.7 % estimated

SECTION 10: Stability and reactivity

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

10.2. Chemical stabilityMaterial is stable under normal conditions.

10.3. Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoidContact with incompatible materials.

10.5. Incompatible materials Strong oxidising agents.

10.6. Hazardous None known. Irritating and/or toxic fumes and gases may be emitted upon the product's

decomposition products decomposition.

SECTION 11: Toxicological information

General information 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 Health injuries are not known or expected under normal use. Direct contact with eyes may cause

temporary irritation.

Ingestion Health injuries are not known or expected under normal use. May be harmful if swallowed.

However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms Severe eye irritation. May cause an allergic skin reaction.

11.1. Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components Species Test Results

COCAMIDOPROPYL BETAINE (CAS 61789-40-0)

Acute Oral

LD50 Mouse > 2000 mg/kg

DODECYL SODIUM SULFATE (CAS 151-21-3)

Acute

Oral

LD50 Rat 1288 mg/kg

GLYCERIN (CAS 56-81-5)

Acute Oral

LD50 Rat > 2000 mg/kg

SODIUM BICARBONATE (CAS 144-55-8)

<u>Acute</u>

Oral

LD50 Rat >= 7300 mg/kg

4220 - 8290 mg/kg

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

Serious eye damage/eye

irritation

Health injuries are not known or expected under normal use. Direct contact with eyes may cause

temporary irritation.

Respiratory sensitisation No studies have been conducted.

Skin sensitisation The product contains a small amount of sensitising substance which may provoke an allergic

reaction among sensitive individuals in contact with skin.

Germ cell mutagenicityNo data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Carcinogenicity Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result

of occupational exposure.

IARC Monographs. Overall Evaluation of Carcinogenicity

Sodium fluoride (CAS 7681-49-4) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity -

single exposure

Not assigned.

Specific target organ toxicity -

repeated exposure

Not assigned.

Assissing the second No.

Aspiration hazard

Not established.

Mixture versus substance

information

No information available.

11.2. Information on other hazards

Endocrine disrupting

Not available.

properties

Other information Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12: Ecological information

12.1. Toxicity

No data available for this product. Contains a substance which causes risk of hazardous effects to

the environment.

Acute

Algae EC50 Green algae (Selenastrum 272 mg/l, 96 hours

capricornutum)

Crustacea EC50 Water flea (Daphnia magna) 340 mg/l, 48 hours Static test

EC50 Fish Fathead minnow (Juvenile Pimephales 180 mg/l, 96 hours Static renewal test

promelas)

Mosquito fish (Adult Gambusia affinis) 418 mg/l, 96 hours Static test Rainbow trout (Juvenile Oncorhyncus 108 mg/l, 96 hours Static test

mykiss)

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

degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

COCAMIDOPROPYL BETAINE 97 %, 28 days Modified Zahn-Wellens, DOC removal.,

Activated sludge

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

COCAMIDOPROPYL BETAINE 99 %, 28 days Modified Zahn-Wellens, DOC removal.,

Activated sludge

Percent Degradation (Aerobic Biodegradation-Ready)

COCAMIDOPROPYL BETAINE 100 %, 20 Days Modified Sturm test., Activated sludge

84 %, 30 days Closed Bottle test, Activated sludge

DODECYL SODIUM SULFATE 95 % OECD 301 B

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient

n-octanol/water (log Kow)

DODECYL SODIUM SULFATE 1.6
GLYCERIN -1.76

Bioconcentration factor (BCF)

Sodium fluoride 2.3 Measured

12.4. Mobility in soilNo data available.Mobility in generalNot available.12.5. Results of PBT and vPvBNot available.

assessment

12.6. Endocrine disrupting

Not available.

properties

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

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

disposal.

EU waste codeThe 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 in accordance with all applicable

regulations.

Special precautionsDispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number Not available.14.2. UN proper shipping Not available.

name

14.3. Transport hazard class(es)

Class Not available.

Subsidiary risk -

14.4. Packing group Not available.

14.5. Environmental hazards No.

Special Provisions Not available

RID

14.1. UN number Not available. **14.2. UN proper shipping** Not available.

name

14.3. Transport hazard class(es)

Class Not available.

Subsidiary risk

14.4. Packing group Not available.

14.5. Environmental hazards No.

ADN

14.1. UN number Not available.14.2. UN proper shipping Not available.

name

14.3. Transport hazard class(es)

Class Not available.

Subsidiary risk

14.4. Packing group Not available.

14.5. Environmental hazards No.

IATA

14.1. UN number Not available.14.2. UN proper shipping Not available.

name

14.3. Transport hazard Not available.

class(es)

Subsidiary class(es)

14.4. Packing groupLabels required
Not available.
Not available.

14.5. Environmental hazards No.

IMDG

14.1. UN number Not available.14.2. UN proper shipping Not available.

name

14.3. Transport hazard class(es)

Class Not available.

Subsidiary risk -

14.4. Packing group Not available.

14.5. Environmental hazards Marine pollutantNo.

EmS Not available.

Not available.

14.7. Transport in bulk Not applicable.

according to Annex II of

MARPOL73/78 and the IBC Code

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 (EU) 2019/1021 On persistent organic pollutants (recast), 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 Sodium fluoride (CAS 7681-49-4)

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 Regulation (EC) 1272/2008 (CLP

Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation

(EC) No 1907/2006, as amended.

National regulations According to Directive 92/85/EEC as amended, pregnant women should not work with the product,

if there is the least risk of exposure.

Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended. Follow national regulation for work with chemical agents in accordance with Directive 98/24/EC, as amended.

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

H228 Flammable solid. H301 Toxic if swallowed. H302 Harmful if swallowed. H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation. H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.

Revision information None.

Training information Follow training instructions when handling this material.

DisclaimerThe 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.

Material name: PARODONTAX DAILY FLUORIDE TOOTHPASTE (IB2108)

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