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

PARADONTAX COMPLETE PROTECTION EXTRA FRESH

Registration number

Synonyms SODIUM FLUORIDE, FORMULATED PRODUCT

22-June-2017 Issue date

Version number

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

Identified uses Oral Care

No other uses are advised. Uses advised against

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK 980 Great West Road

Brentford, Middlesex TW8 9GS UK

UK General Information (normal business hours): +44-20-8047-5000

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

1.4. Emergency telephone

number

CHEMTREC TRANSPORT EMERGENCIES:

Customer Number: CCN9484

UK In-country toll call: +(44)-870-8200418 International toll call: +1 703 527 3887

available 24 hrs/7 days; multi-language response

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 will support combustion at elevated temperatures.

See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
SODIUM BICARBONATE	60 - < 70	144-55-8 205-633-8	-	-	
Classification: -					
GLYCERIN	5 - < 10	56-81-5 200-289-5	-	-	

Classification:

SDS LIK 137502 Version #: 01 Issue date: 22-June-2017

Chemical name		%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
FREEZE MATCHA MIN ⁻ 510493 1T	ΓFLAVOUR	1 - < 3	Mixture -	-	-	
Classification:	Skin Irrit. 2;	H315, Skir	Sens. 1;H317, Eye	e Irrit. 2;H319, Aquatic Chronic	3;H412	
SODIUM LAURETH SUI	LFATE	2	9004-82-4	-	-	
Classification:	Acute Tox.	4;H302, Sk	kin Irrit. 2;H315, Eye	e Irrit. 2;H319, Aquatic Chronic	3;H412	
TIXOSIL		1 - < 3	Unassigned 231-545-4	-	-	
Classification:	-					
XANTHAN GUM		< 1	11138-66-2 234-394-2	-	-	
Classification:	-					
Sodium fluoride		0.31	7681-49-4 231-667-8	-	009-004-00-7	#
Classification:	Acute Tox. 3	3;H301, Sk	sin Irrit. 2;H315, Eye	e Irrit. 2;H319		
Titanium dioxide		0.2	13463-67-7 236-675-5	-	-	
Classification:	Carc. 2;H35	1				

Other components below reportable levels 10 - < 20

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.

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.

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

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

Direct contact with eyes may cause temporary irritation.

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 This product will support combustion at elevated temperatures.

5.1. Extinguishing media

Suitable extinguishing Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

media

None known. Unsuitable extinguishing

media

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 Wear suitable protective equipment.

Special fire fighting

procedures

Use standard firefighting procedures and consider the hazards of other involved materials.

Not established. Specific methods

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. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapour. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. 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. 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.

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

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.

7.2. Conditions for safe storage, including any

incompatibilities

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

7.3. Specific end use(s)

Oral Care

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

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Components	Туре	Value	
SODIUM BICARBONATE (CAS 144-55-8)	8 HR TWA	5000 mcg/m3	
	OHC	1	
UK. EH40 Workplace Expos	sure Limits (WELs)		
Components	Туре	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m3	
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
,		10 mg/m3	Inhalable
TIXOSIL 73	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.
EU. Indicative Exposure Li	mit Values in Directives 91/322/EEC, 20	000/39/EC, 2006/15/EC, 2009	9/161/EU
Components	Туре	Value	
Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m3	
ogical limit values	No biological exposure limits noted for	the ingredient(s).	

Follow standard monitoring procedures.

SDS UK

Recommended monitoring

procedures

Derived no effect levels

(DNELs)

Not available.

Predicted no effect

concentrations (PNECs)

Not available.

Exposure guidelines

8.2. Exposure controls

Appropriate engineering

controls

General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information 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.

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

EN 166).

Skin protection

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select - Hand protection

suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min

permeation time).

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

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

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

> 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.

Always observe good personal hygiene measures, such as washing after handling the material Hygiene measures

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. Paste. **Form**

Colour Not available. Odour Not available. **Odour threshold** Not available. Not available. Нα Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Flash point

Evaporation rate

Flammability (solid, gas)

Not available. Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

Not applicable.

(%)

Flammability limit - upper

Not available.

(%)

Vapour pressure Not available. Vapour density Not available. Relative density Not available.

Solubility(ies)

Not available. Solubility (water)

SDS LIK

Partition coefficient (n-octanol/water)

Not available.

Not available. **Auto-ignition temperature Decomposition temperature** Not available. Not available. **Viscosity** Not explosive. **Explosive properties** Not oxidising. Oxidising properties

9.2. Other information

Percent volatile 24.6 % estimated

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

10.4. Conditions to avoid

reactions

No dangerous reaction known under conditions of normal use.

Heat, flames and sparks. Contact 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. decomposition products

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 Causes mild skin irritation. May cause an allergic skin reaction.

Eye contact Direct contact with eyes may cause temporary irritation.

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

Direct contact with eyes may cause temporary irritation. **Symptoms**

11.1. Information on toxicological effects

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

Components **Test results Species**

GLYCERIN (CAS 56-81-5)

Acute

Oral

LD50 Rat > 2000 mg/kg

SODIUM BICARBONATE (CAS 144-55-8)

Acute

Oral

LD50 Rat >= 7300 mg/kg

SODIUM LAURETH SULFATE (CAS 9004-82-4)

Acute

Oral

LD50 Rat 1288 mg/kg

Titanium dioxide (CAS 13463-67-7)

Acute

Inhalation

LC50 Rat 6820 mcg/m3

Oral

LD50 Rat > 24 g/kg

Chronic

Inhalation

LOEC Rat 8.6 mg/m3, 1 years TiO2 accumulated in

interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.

NOAEC 250 mg/m3, 2 years Highest dose Rat

Components Species Test results

Subacute

Inhalation

LOEL Rat 0.1 - 35 mg/m3, 4 weeks Mild macrophage

hyperplasia, no change in

5 mg/m3, 24 months

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.

Subchronic

Inhalation

LOEC Rat 3.2 - 20 mg/m3. 8 min Accumulation of

TiO2 in macrophages and evidence of

pulmonary inflammation.

XANTHAN GUM (CAS 11138-66-2)

Acute

Inhalation

LC50 Rat > 21 mg/l, 1 hour exposure

Oral

LD50 Rat > 5000 mg/kg

Skin corrosion/irritation Causes mild skin irritation.

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

Titanium dioxide

OECD 405, Literature data

Result: Mild irritant Species: Rabbit

Respiratory sensitisation

ation Not available.

Skin sensitisation May cause an allergic skin reaction.

Sensitisation

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 mutagenicityNo 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

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

Mutagenicity Titanium dioxide

WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell

lymphoblastoid, Literature data

Result: Positive

Carcinogenicity

Titanium dioxide

Carcinogenic effects are not expected as a result of occupational exposure. Contains a material (Titanium dioxide) classified as a carcinogen by external agencies. These effects are linked only

Titalium dioxide) classified as a carcinogen by external agencies. These effects are im-

to high doses of this substance; lower doses did not cause this adverse effect.

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) Titanium dioxide (CAS 13463-67-7) TIXOSIL (CAS Unassigned) 3 Not classifiable as to carcinogenicity to humans.

2B Possibly carcinogenic to humans.

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.

Not available.

Aspiration hazard

Mixture versus substance

information

No information available.

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

SECTION 12: Ecological information

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

Components **Species Test results** SODIUM BICARBONATE (CAS 144-55-8) Aquatic Acute Algae EC50 Algae (Nitscheria linearis) 650 mg/l, 5 days EC50 Crustacea Water flea (Daphnia magna) 2350 mg/l, 48 hours Static test Bluegill sunfish (Adult Lepomis Fish EC50 8250 - 9000 mg/l, 96 hours Static test macrochirus) Mosquito fish (Adult Gambusia affinis) 7550 mg/l, 96 hours Static test Sodium fluoride (CAS 7681-49-4) Acute IC50 Activated sludge 2930 mg/l, 3 hours Aquatic 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

Material name: PARADONTAX COMPLETE PROTECTION EXTRA FRESH

137502 Version #: 01 Issue date: 22-June-2017 7 / ...

Components		Species	Test results
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 LAURETH SUL	FATE (CAS 9004-82-4)		
Aquatic			
Acute			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	3.12 mg/l, 48 hours
Titanium dioxide (CAS 13	3463-67-7)		
Aquatic			
Fish	LC50	Mummichog (Fundulus heteroclitus)	> 1000 mg/l, 96 hours
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test
XANTHAN GUM (CAS 1	1138-66-2)		
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

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

12.2. Persistence and

degradability

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

SODIUM LAURETH SULFATE 100 % River die away, River water

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

GLYCERIN -1.76

SODIUM LAURETH SULFATE 1.99 (calculated)

Bioconcentration factor (BCF)

Sodium fluoride 2.3 Measured

12.4. Mobility in soilNo data available.Mobility in generalNot available.12.5. Results of PBTNot available.

and vPvB assessment

12.6. Other adverse effects None known.

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 precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

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

RID

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

ADN

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.

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 (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

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 Regulation (EC) 1272/2008 (CLP

Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended. Additional information is given in the Safety Data Sheet.

National regulations Follow national regulation for work with chemical agents. 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.

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

Not available.

Material name: PARADONTAX COMPLETE PROTECTION EXTRA FRESH

137502 Version #: 01 Issue date: 22-June-2017 9 /

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

H301 Toxic if swallowed.
H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H351 Suspected of causing cancer.

H412 Harmful to aquatic life with long lasting effects.

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.

the canading of the material of product of any particular purposes.

137502 Version #: 01 Issue date: 22-June-2017 10 / 10

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