

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

### 1.1. Product identifier

**Trade name or designation of the mixture** SENSODYNE TOOTHPASTE (WITH TITANIUM DIOXIDE)

**Registration number** -

**Synonyms** IB0853 SENSODYNE LOW ABRASION \* IB1674 GENTLE WHITENING \* IB1850 SENSODYNE WITH VITAMINS \* IB2079 TARTAR CONTROL PLUS WHITENING \* MFC00858 PRONAMEL \* MFC01788 PRONAMEL (SE ASIA & AUSTRALIA) \* MFC01942 PRONAMEL FOR CHILDREN (EU) \* MFC02284 PRONAMEL GENTLE WHITENING (EU) \* MFC02141 EXTRA WHITENING (REPLACEMENT MINT FLAVOR) \* MFC02559 FRESHMINT (INDIA) \* MFC03145 SENSODYNE COMPLEX \* SENSODYNE MULTI-CARE (WHITE 1450PPM FLUORIDE) \* MFC03673 PRONAMEL EXTRA FRESHNESS (EU) \* MFC03673 PRONAMEL 1426 PPM FLUORIDE \* MFC03795 PRONAMEL ENAMEL CARE & GENTLE WHITENING \* MFC03941 SENSODYNE PROTECT AND REPAIR (USA) \* SENSODYNE REPAIR PROTECT US \* MFC03925 PRONAMEL MULTI-ACTION \* MFC04006 PRONAMEL (MISSISSIPPI FLAVOUR), 1450 PPM FLUORIDE \* MFC04008 PRONAMEL (OPTAMINT 134601 FLAVOUR), 1450 PPM FLUORIDE \* MFC04010 PRONAMEL GENTLE WHITENING TOOTHPASTE \* MFC04143 TRUE WHITE EXTRA FRESH (1100 PPM FLUORIDE) \* MFC04155 TRUE WHITE MINT (1100 PPM FLUORIDE) \* MFC04156 TRUE WHITE MINT \* MFC04254 PRONAMEL GENTLE WHITENING TOOTHPASTE 1000 PPM FLUORIDE \* MFC04276 TRUE WHITE EXTRA FRESH TOOTHPASTE \* MFC04281 PRONAMEL (SE ASIA & AUSTRALIA) WITH 1000 PPM FLUORIDE \* MFC20026 MULTICARE TOOTHPASTE \* MFC00556 GENTLE WHITENING (UK) \* MFC50156 FRESH IMPACT \* SODIUM FLUORIDE AND/OR POTASSIUM NITRATE, FORMULATED PRODUCT

**Issue date** 11-November-2014

**Version number** 11

**Revision date** 11-November-2014

**Supersedes date** 31-October-2014

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

**Identified uses** Cosmetic Product

**Uses advised against** No other uses are advised.

### 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

TRANSPORT EMERGENCIES::  
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

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
---------------	---	------------------	------------------------	-----------	-------

NOVAMINT 507306T	0 - <= 1.2	Unassigned	-	-	
------------------	------------	------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> Xi;R38, R43, N;R51/53
	<b>CLP:</b> Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411

FLAVOUR SLEEPY ED FS 2019	0 - < 1.0	Unassigned	-	-	
---------------------------	-----------	------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> Xi;R38, R43, N;R51/53
	<b>CLP:</b> Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411

SENSIDREAM FLAVOR 508915T	< 1	Unassigned	-	-	
---------------------------	-----	------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> Xi;R38, R43, R52/53
	<b>CLP:</b> Skin Irrit. 2;H315, Skin Sens. 1B;H317, Aquatic Chronic 3;H412

TIN (II) FLUORIDE	0 - < 0.5	7783-47-3 231-999-3	-	-	
-------------------	-----------	------------------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> Xn;R22, Xi;R38-41
	<b>CLP:</b> Acute Tox. 4;H302, Skin Irrit. 2;H315, Eye Dam. 1;H318, Aquatic Chronic 3;H412

Eucalyptol	< 0.2	470-82-6 207-431-5	-	-	
------------	-------	-----------------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> R10, R43
	<b>CLP:</b> Flam. Liq. 3;H226, Skin Sens. 1;H317

BUTYLATED HYDROXYANISOLE	0 <= 0.01	25013-16-5 246-563-8	-	-	
--------------------------	-----------	-------------------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> Carc. Cat. 3;R40, Xn;R22
	<b>CLP:</b> Acute Tox. 4;H302, Carc. 2;H351

Calcium carbonate	0 <= 10.0	471-34-1 207-439-9	-	-	
-------------------	-----------	-----------------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> -
	<b>CLP:</b> -

COCOAMIDOPROPYL BETAINE	0 <= 2.1	61789-40-0 263-058-8	-	-	
-------------------------	----------	-------------------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> N;R50/53
	<b>CLP:</b> Aquatic Acute 1;H400, Aquatic Chronic 1;H410

D-PANTHENOL	0 <= 0.1	81-13-0 201-327-3	-	-	
-------------	----------	----------------------	---	---	--

<b>Classification:</b>	<b>DSD:</b> -
	<b>CLP:</b> -

DEVELOPMINT TP12995A	0 <= 0.7		-	-	
----------------------	----------	--	---	---	--

<b>Classification:</b>	<b>DSD:</b> Xn;R22-65, R43, N;R51/53
	<b>CLP:</b> Acute Tox. 4;H302, Asp. Tox. 1;H304, Skin Sens. 1;H317, Aquatic Chronic 2;H411

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
FLAVOUR CONFIDENT WHITE 509321	0 <= 1.4	Unassigned -	-	-	
<b>Classification:</b>	<b>DSD:</b> R10, Xi;R36/38, R43, N;R51/53				
	<b>CLP:</b> Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Aquatic Chronic 2;H411				
OPTAMINT FLAVOUR	0 <= 1.2	Unassigned -	-	-	
<b>Classification:</b>	<b>DSD:</b> R10, R43, N;R51/53				
	<b>CLP:</b> Flam. Liq. 3;H226, Skin Sens. 1;H317, Aquatic Chronic 2;H411				
PEPPERMINT OIL	0 <= 1.0	8006-90-4 -	-	-	
<b>Classification:</b>	<b>DSD:</b> Xi;R38, R43, N;R51/53				
	<b>CLP:</b> Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411				
POLYETHYLENE GLYCOL STEARATE	0 <= 3.0	9004-99-3 -	-	-	
<b>Classification:</b>	<b>DSD:</b> Xi;R36/37/38				
	<b>CLP:</b> Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335				
Potassium chloride	0 <= 3.75	7447-40-7 231-211-8	-	-	
<b>Classification:</b>	<b>DSD:</b> R52/53				
	<b>CLP:</b> Aquatic Chronic 3;H412				
Potassium nitrate	0 <= 5.0	7757-79-1 231-818-8	-	-	
<b>Classification:</b>	<b>DSD:</b> O;R8				
	<b>CLP:</b> Ox. Sol. 3;H272				
POTASSIUM PYROPHOSPHATE, ANHYDROUS	0 <= 5.1	7320-34-5 230-785-7	-	-	
<b>Classification:</b>	<b>DSD:</b> Xi;R36				
	<b>CLP:</b> Eye Irrit. 2;H319				
Silicon dioxide	0 <= 10.5	7631-86-9 231-545-4	-	-	
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				
Sodium fluoride	0 <= 0.3152	7681-49-4 231-667-8	-	009-004-00-7	#
<b>Classification:</b>	<b>DSD:</b> T;R25, Xi;R36/38, R32				
	<b>CLP:</b> Acute Tox. 3;H301, Skin Irrit. 2;H315, Eye Irrit. 2;H319				
SODIUM TRIPOLYPHOSPHATE	0 <= 5.0	7758-29-4 231-838-7	-	-	
<b>Classification:</b>	<b>DSD:</b> Xi;R36/38, R52/53				
	<b>CLP:</b> Skin Irrit. 2;H315, Eye Irrit. 2;H319, Aquatic Chronic 3;H412				

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Titanium dioxide	0.10 <= 1.00	13463-67-7 236-675-5	-	-	
<b>Classification:</b>	<b>DSD:</b> - <b>CLP:</b> -				
TOCOPHERYL ACETATE	0 <= 0.2	7695-91-2 231-710-0	-	-	
<b>Classification:</b>	<b>DSD:</b> - <b>CLP:</b> -				
TP 16430 JIAOLONG EC	0 <= 1.0	Unassigned	-	-	
<b>Classification:</b>	<b>DSD:</b> R10, Xn;R22-65, Xi;R36/38, R43, N;R50/53 <b>CLP:</b> Flam. Liq. 3;H226, Acute Tox. 4;H302, Asp. Tox. 1;H304, Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Aquatic Acute 1;H400, Aquatic Chronic 3;H412				
TP13980J ASWAN (JAP) FLAVOUR	0 <= 1.1		-	-	
<b>Classification:</b>	<b>DSD:</b> Xi;R38, R43, N;R51/53 <b>CLP:</b> Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411				
ZINC CITRATE	0 <= 1.0	546-46-3 208-901-2	-	-	
<b>Classification:</b>	<b>DSD:</b> N;R50-53 <b>CLP:</b> Aquatic Acute 1;H400				

Other components below reportable levels >78.0

#### 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** If you feel unwell, seek medical advice (show the label where possible).

### 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** Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.  
**Eye contact** Rinse with water. Get medical attention if irritation develops and persists.  
**Ingestion** 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** Provide general supportive measures and treat symptomatically.

## SECTION 5: Firefighting measures

**General fire hazards** This product is non-flammable.

### 5.1. Extinguishing media

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

<b>Unsuitable extinguishing media</b>	None known.
<b>5.2. Special hazards arising from the substance or mixture</b>	During fire, gases hazardous to health may be formed.
<b>5.3. Advice for firefighters</b>	
<b>Special protective equipment for firefighters</b>	Wear suitable protective equipment.
<b>Special fire fighting procedures</b>	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

<b>For non-emergency personnel</b>	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.
<b>For emergency responders</b>	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** Stop the flow of material, if this is without risk. Following product recovery, flush area with water.

**6.4. Reference to other sections** For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

## 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. Observe good industrial hygiene practices.

**7.2. Conditions for safe storage, including any incompatibilities** Room temperature - normal conditions. Store in original tightly closed container.

**7.3. Specific end use(s)** Cosmetic Product

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

GSK			
Components	Type	Value	Note
BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)	OHC	2	
COCOAMIDOPROPYL BETAINE (CAS 61789-40-0)	OHC	1	PROVISIONAL
D-PANTHENOL (CAS 81-13-0)	OHC	2	PROVISIONAL
Potassium chloride (CAS 7447-40-7)	8 HR TWA	5000 mcg/m3	
SODIUM TRIPOLYPHOSPHATE (CAS 7758-29-4)	OHC	1	
	OHC	1	
ZINC CITRATE (CAS 546-46-3)	OHC	1	
UK. EH40 Workplace Exposure Limits (WELs)			
Components	Type	Value	Form
Calcium carbonate (CAS 471-34-1)	TWA	4 mg/m3	Respirable.
		4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable
		10 mg/m3	Inhalable dust.
Silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
Sodium fluoride (CAS 7681-49-4)	TWA	2.4 mg/m3	Respirable dust.
		2.5 mg/m3	

**UK. EH40 Workplace Exposure Limits (WELs)**

Components	Type	Value	Form
TIN (II) FLUORIDE (CAS 7783-47-3)	STEL	4 mg/m3	
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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

Components	Type	Value
Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m3

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Recommended monitoring procedures</b>	Follow standard monitoring procedures.
<b>Derived no-effect level (DNEL)</b>	Not available.
<b>Predicted no effect concentrations (PNECs)</b>	Not available.
<b>8.2. Exposure controls</b>	
<b>Appropriate engineering controls</b>	No special ventilation requirements.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>General information</b>	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
<b>Eye/face protection</b>	Do not get in eyes. Wear safety glasses with side shields (or goggles). (eg. EN 166) Eye wash fountain is recommended.
<b>Skin protection</b>	
- Hand protection	Not normally needed.
- Other	No special protective equipment required.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.
<b>Thermal hazards</b>	Not available.
<b>Hygiene measures</b>	Wash hands before breaks and immediately after handling the product.
<b>Environmental exposure controls</b>	
<b>Hazard guidance and control recommendations</b>	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**

<b>Physical state</b>	Liquid.
<b>Form</b>	Paste.Pump/tube.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	9 - 10
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Expected to be non-flammable based on components present.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.

Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	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.
Oxidizing 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	None under normal conditions.
10.5. Incompatible materials	Not available.
10.6. Hazardous decomposition products	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.
---------------------	---

### Information on likely routes of exposure

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.
Ingestion	Expected to be a low ingestion hazard. Health injuries are not known or expected under normal use.

Symptoms	None known. 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
BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)		
Acute		
Oral		
LD50	Rat	2 g/kg
Calcium carbonate (CAS 471-34-1)		
Acute		
Oral		
LD50	Rat	6450 mg/kg
COCOAMIDOPROPYL BETAINE (CAS 61789-40-0)		
Acute		
Oral		
LD50	Mouse	> 2000 mg/kg
D-PANTHENOL (CAS 81-13-0)		
Acute		
Oral		
LD50	Mouse	15 g/kg
Eucalyptol (CAS 470-82-6)		
Acute		
Oral		
LD50	Rat	2480 mg/kg

Components	Species	Test results
PEPPERMINT OIL (CAS 8006-90-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	2426 mg/kg
Potassium chloride (CAS 7447-40-7)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	2600 mg/kg
POTASSIUM PYROPHOSPHATE, ANHYDROUS (CAS 7320-34-5)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 4640 mg/kg
<i>Oral</i>		
LD50	Rat	4640 mg/kg
SODIUM TRIPOLYPHOSPHATE (CAS 7758-29-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	3120 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

0, Literature data  
Result: Non-irritant  
Species: Guinea pig  
0, Literature data  
Result: Non-irritant  
Species: Human



<b>Irritation Corrosion - Skin</b>		Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
TITANIUM DIOXIDE		
<b>Serious eye damage/eye irritation</b>		
<b>Eye</b>		OECD 405, Literature data Result: Mild irritant Species: Rabbit
TITANIUM DIOXIDE		
<b>Respiratory sensitisation</b>		
<b>Skin sensitisation</b>		Health injuries are not known or expected under normal use.
<b>Sensitisation</b>		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
TITANIUM DIOXIDE		
<b>Germ cell mutagenicity</b>		
<b>Mutagenicity</b>		No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
TITANIUM DIOXIDE		
<b>Carcinogenicity</b>		
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
<b>Carcinogenicity</b>		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
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)		2B Possibly carcinogenic to humans.
Silicon dioxide (CAS 7631-86-9)		3 Not classifiable as to carcinogenicity to humans.
Sodium fluoride (CAS 7681-49-4)		3 Not classifiable as to carcinogenicity to humans.
TIN (II) FLUORIDE (CAS 7783-47-3)		3 Not classifiable as to carcinogenicity to humans.
Titanium dioxide (CAS 13463-67-7)		2B Possibly carcinogenic to humans.
<b>Reproductive toxicity</b>	Not available.	
<b>Specific target organ toxicity - single exposure</b>	None known.	

<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not available.
<b>Mixture versus substance information</b>	No information available.
<b>Other information</b>	Not available.

## SECTION 12: Ecological information

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

Components		Species	Test results
BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	2.5 - 5.3 mg/l, 48 hours Static test
Calcium carbonate (CAS 471-34-1)			
<b>Aquatic</b>			
Fish	LC50	Western mosquitofish (Gambusia affinis)	> 56000 mg/l, 24 hours
COCOAMIDOPROPYL BETAINE (CAS 61789-40-0)			
<b>Aquatic</b>			
<i>Acute</i>			
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
<i>Chronic</i>			
Crustacea	LOEC	Water flea (Daphnia magna)	3.6 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	0.9 mg/l, 21 days
Eucalyptol (CAS 470-82-6)			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	102 mg/l, 96 hours Flow-through test
Potassium chloride (CAS 7447-40-7)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	NOEC	Green algae (Chlorella vulgaris)	600 mg/l, 4 months
Crustacea	EC50	Water flea (Daphnia magna)	83 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	951 mg/l, 96 hours Static test
		Channel catfish (Adult Ictalurus punctatus)	720 mg/l, 48 hours Static test
		Fathead minnow (Adult Pimephales promelas)	880 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	435 mg/l, 96 hours Static test
Potassium nitrate (CAS 7757-79-1)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	490 mg/l, 48 hours Static test

Components		Species	Test results
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> )	420 mg/l, 96 hours Static test
		Guppy (Juvenile <i>Poecilia reticulata</i> )	180 mg/l, 96 hours Static test
		Mosquito fish (Adult <i>Gambusia affinis</i> )	22.5 mg/l, 96 hours Static test
Silicon dioxide (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	440 mg/l, 72 hours
	NOEC	Green algae ( <i>Selenastrum capricornutum</i> )	60 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile <i>Cyprinus carpio</i> )	> 10000 mg/l, 72 hours
		Zebra fish (Adult <i>Brachydanio rerio</i> )	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes
Sodium fluoride (CAS 7681-49-4)			
Acute			
	IC50	Activated sludge	2930 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	272 mg/l, 96 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	340 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile <i>Pimephales promelas</i> )	180 mg/l, 96 hours Static renewal test
		Mosquito fish (Adult <i>Gambusia affinis</i> )	418 mg/l, 96 hours Static test
		Rainbow trout (Juvenile <i>Oncorhyncus mykiss</i> )	108 mg/l, 96 hours Static test
SODIUM TRIPOLYPHOSPHATE (CAS 7758-29-4)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Algae	60 - 120 mg/l
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	1089 mg/l, 50 hours
Fish	EC50	Golden ide/orfe (Adult <i>Leuciscus idus</i> )	1650 mg/l, 48 hours
		Orange-red killfish (Adult <i>Oryzias latipes</i> )	590 mg/l, 48 hours Static test
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 1000 mg/l, 48 hours Static test
TOCOPHERYL ACETATE (CAS 7695-91-2)			
Aquatic			
Acute			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	> 25.5 mg/l, 72 hours
	NOEC	Green algae ( <i>Selenastrum capricornutum</i> )	25.5 mg/l, 72 hours
Fish	EC50	Rainbow trout (Adult <i>Oncorhyncus mykiss</i> )	> 91.1 mg/l, 96 hours
	NOEC	Rainbow trout (Adult <i>Oncorhyncus mykiss</i> )	91.1 mg/l, 96 hours

Components		Species	Test results
ZINC CITRATE (CAS 546-46-3)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	0.13 mg/l, 24 hours Static test
Crustacea	EC50	Water flea (Daphnia magna)	0.59 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	30.73 mg/l, 96 hours Static test
		Fathead minnow (Adult Pimephales promelas)	2.09 mg/l, 96 hours Static renewal test
		Mosquito fish (Adult Gambusia affinis)	439 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	2.1 mg/l, 96 hours Flow-through 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.

### Photolysis

#### Half-life (Photolysis-atmospheric)

BUTYLATED HYDROXYANISOLE	10.7 Hours Estimated
Eucalyptol	1.4 Days Estimated

### 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
TOCOPHERYL ACETATE	84 %, 28 days Modified MITI (II) Test.

#### Percent degradation (Aerobic biodegradation-ready)

COCOAMIDOPROPYL BETAINE	100 %, 20 Days Modified Sturm test., Activated sludge
	84 %, 30 days Closed Bottle test, Activated sludge
TOCOPHERYL ACETATE	17 %, 28 days Manometric Respirometry Test

## 12.3. Bioaccumulative potential

### Partition coefficient

#### n-octanol/water (log Kow)

Eucalyptol	2.74
TOCOPHERYL ACETATE	12.2 (Calculated).

### Bioconcentration factor (BCF)

Sodium fluoride	2.3 Measured
ZINC CITRATE	> 1000 Measured

## 12.4. Mobility in soil

### Adsorption

#### Soil/sediment sorption - log Koc

BUTYLATED HYDROXYANISOLE	3.14 Calculated
--------------------------	-----------------

### Mobility in general

#### Volatility

##### Henry's law

BUTYLATED HYDROXYANISOLE	0.000001 atm m <sup>3</sup> /mol Calculated
Eucalyptol	0.00011 atm m <sup>3</sup> /mol, 25 C Estimated

## 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).

#### Contaminated packaging

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

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

## SECTION 14: Transport information

### ADR

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

## 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**

Not listed.

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**

Not listed.

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

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**

Not listed.

**Regulation (EC) No. 689/2008 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**

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**

Not listed.

**Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding**

Not listed.

#### Other EU regulations

**Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**

Not listed.

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Sodium fluoride (CAS 7681-49-4)

**Directive 94/33/EC on the protection of young people at work**

Sodium fluoride (CAS 7681-49-4)

#### 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 statements or R-phrases and H-statements under Sections 2 to 15	<p>R10 Flammable.</p> <p>R22 Harmful if swallowed.</p> <p>R25 Toxic if swallowed.</p> <p>R32 Contact with acids liberates very toxic gas.</p> <p>R36 Irritating to eyes.</p> <p>R36/37/38 Irritating to eyes, respiratory system and skin.</p> <p>R36/38 Irritating to eyes and skin.</p> <p>R38 Irritating to skin.</p> <p>R40 Limited evidence of a carcinogenic effect.</p> <p>R41 Risk of serious damage to eyes.</p> <p>R43 May cause sensitization by skin contact.</p> <p>R50 Very toxic to aquatic organisms.</p> <p>R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>R53 May cause long term adverse effects in the aquatic environment.</p> <p>R65 Harmful: may cause lung damage if swallowed.</p> <p>R8 Contact with combustible material may cause fire.</p> <p>H226 Flammable liquid and vapour.</p> <p>H272 May intensify fire; oxidiser.</p> <p>H301 Toxic if swallowed.</p> <p>H302 Harmful if swallowed.</p> <p>H304 May be fatal if swallowed and enters airways.</p> <p>H315 Causes skin irritation.</p> <p>H317 May cause an allergic skin reaction.</p> <p>H318 Causes serious eye damage.</p> <p>H319 Causes serious eye irritation.</p> <p>H335 May cause respiratory irritation.</p> <p>H351 Suspected of causing cancer.</p> <p>H400 Very toxic to aquatic life.</p> <p>H410 Very toxic to aquatic life with long lasting effects.</p> <p>H411 Toxic to aquatic life with long lasting effects.</p> <p>H412 Harmful to aquatic life with long lasting effects.</p>
Revision information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients
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.