SAFETY DATA SHEET



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

1.1. Product identifier

Trade name or designation

POLIDENT DENTU-CREME

Registration number

of the mixture

Synonyms POLIDENT DENTU-CREME (US) * POLIDENT DENTURE CLEANSER PASTE (CANADA) *

POLIDENT EN PATE NETTOYEUR POUR DENTIERS * MMI NO 0529 * FORMULA NO.

B1033/IB1033, FORMULATED PRODUCT

Issue date 27-August-2014

Version number

Revision date 27-August-2014

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

Identified uses Medical Device

> 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.

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

Classification Xi:R36/38

The full text for all R-phrases is displayed in section 16.

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

Health hazards

Skin corrosion/irritation H315 - Causes skin irritation. Category 2 Serious eye damage/eye irritation Category 2 H319 - Causes serious eye

irritation.

Hazard summary

Physical hazards Not classified for physical hazards.

Health hazards Irritating to eyes and skin. Occupational exposure to the substance or mixture may cause adverse

health effects.

Environmental hazards Not classified for hazards to the environment.

Specific hazards None known

Material name: POLIDENT DENTU-CREME

Main symptoms Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred

vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction.

2.2. Label elements

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

ALUMINUM SILICATE, BRILLIANT BLUE FCF, CALCIUM PHOSPHATE, DIBASIC, Calcium Contains:

carbonate, DODECYL SODIUM SULFATE, GLYCERIN, L-MENTHOL, OIL OF SPEARMINT,

PEPPERMINT OIL, PROPYL PARABEN, Propylene glycol

Hazard pictograms



Signal word Warning

Hazard statements

Causes skin irritation. H315

Causes serious eye irritation. H319

Precautionary statements

Prevention

Wash thoroughly after handling. P264

Wear protective gloves. P280 Wear eye/face protection. P280

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.

Specific treatment (see on this label). P321

If skin irritation occurs: Get medical advice/attention. P332 + P313 If eye irritation persists: Get medical advice/attention. P337 + P313

Not available. Storage Not available. Disposal

EUH208 - Contains OIL OF SPEARMINT, PEPPERMINT OIL. May produce an allergic reaction. Supplemental label information

2.3. Other hazards Assume that this product is capable of sustaining combustion. 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
CALCIUM PHOSPHATE	, DIBAS	SIC	20	7757-93-9 231-826-1	-	-	
Classification:	DSD:	Xi;R36	/38				
	CLP:	Skin Irr	it. 2;H3	15, Eye Irrit. 2;H319			
Propylene glycol			20	57-55-6 200-338-0	-	-	
Classification:	DSD:	-					
	CLP:	-					
ALUMINUM SILICATE			12	14504-95-1 238-509-7	-	-	

Classification: DSD: -

CLP: -

Calcium carbonate 12 471-34-1 207-439-9

Classification: DSD: -

CLP: -

SDS IRELAND 126809 Version No.: 07 Revision date: 27-August-2014 Issue date: 27-August-2014

CAS-No. / EC No. REACH Registration No. INDEX No. Chemical name **Notes**

DODECYL SODIUM SULFATE 151-21-3 3 205-788-1

Classification: **DSD:** F;R11, Xn;R22, Xi;R36/38

> CLP: Flam. Sol. 1;H228, Acute Tox. 4;H302, Skin Irrit. 2;H315, Eye Irrit. 2;H319,

STOT SE 3:H335

GLYCERIN 1.0 - 2.0 56-81-5

200-289-5

Classification: DSD: -

CLP: -

OIL OF SPEARMINT 0.1 - 1.08008-79-5

Classification: **DSD:** R10, Xn;R22-65, Xi;R36/38, R43, N;R51/53

> Flam. Liq. 3;H226, Acute Tox. 4;H302, Asp. Tox. 1;H304, Skin Irrit. 2;H315, CLP:

Skin Sens. 1;H317, Eye Irrit. 2;H319, Aquatic Chronic 2;H411

L-MENTHOL 0.1 - 0.52216-51-5

218-690-9

Classification: **DSD:** Xi;R38, R52/53

CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319

PEPPERMINT OIL 0.1 - 0.38006-90-4

Classification: **DSD:** Xi;R38, R43, N;R51/53

CLP: Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411

PROPYL PARABEN 0.1 94-13-3

202-307-7

Classification: DSD: -

CLP: -

BRILLIANT BLUE FCF 0 - 0.013844-45-9

223-339-8

Classification: **DSD:** Xi;R36/38

CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319

Other components below reportable levels 30.0 -31.0

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).

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

SECTION 4: First aid measures

General information 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. Under normal conditions of intended use, this material is not expected to be an

inhalation hazard. Call a physician if symptoms develop or persist.

Remove contaminated clothing. Immediately flush skin with plenty of water. If skin irritation occurs: Skin contact

Get medical advice/attention. Take off contaminated clothing and wash before reuse.

Material name: POLIDENT DENTU-CREME

3 / 11 126809 Version No.: 07 Revision date: 27-August-2014 Issue date: 27-August-2014

SDS IRELAND

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Rinse thoroughly with plenty of

water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy

to do. Continue rinsing. Get medical attention if irritation develops and persists.

Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

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

Ingestion

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

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

SECTION 5: Firefighting measures

General fire hazards Assume that this product is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing

media

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 methodsUse 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. Wear appropriate protective equipment and clothing during clean-up. 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.

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. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Use water spray to reduce vapours or divert vapour cloud drift. 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.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

7.2. Conditions for safe Store in original tightly closed container. Store away from incompatible materials (see Section 10

of the SDS).

storage, including any incompatibilities

Medical Device

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

7.3. Specific end use(s)

Material name: POLIDENT DENTU-CREME SDS IRELAND

Occupational exposure limits

GSK				
Components	Туре	Value	Note	
BRILLIANT BLUE FCF (CAS 3844-45-9)	OHC	3		
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)	OHC	1		
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	2		
L-MENTHOL (CAS 2216-51-5)	OHC	1	SKIN SENSITISER	
PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3		
	OHC	1		
Ireland. Occupational Expo	sure Limits			
Components	Туре	Value	Form	
ALUMINUM SILICATE (CAS 14504-95-1)	TWA	2 mg/m3		
Calcium carbonate (CAS 471-34-1)	TWA	4 mg/m3	Respirable dust.	
,		10 mg/m3	Total inhalable dust.	
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.	
Propylene glycol (CAS 57-55-6)	TWA	470 mg/m3	Total vapour and particulates.	
		10 mg/m3	Particulate.	
		150 ppm	Total vapour and particulates.	
logical limit values	lo biological exposure limits noted for the ingredient(s).			
commended monitoring occurres	Follow standard monitoring procedures.			
rived no-effect level (DNEL)	Not available.			
dicted no effect	Not available.			

8.2. Exposure controls

concentrations (PNECs)

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) 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. Eye wash facilities and emergency shower must be available when handling this product. 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

General information

Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection

Wear safety glasses with side shields (or goggles). (eg. EN 166)

Skin protection

- Hand protection

Wear appropriate chemical resistant gloves. The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other

Wear appropriate chemical resistant clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection

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). In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protective equipment (RPE) is not required for normal handling of this product.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures

For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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.

Material name: POLIDENT DENTU-CREME

SDS IRELAND

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

range

Not available. Flash point **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. Not available. Vapour density Not available. Relative density

Solubility(ies)

Not available. Solubility (water) Solubility (other) Not available. Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available. **Decomposition temperature** Not available. Not available. **Viscosity** Not available. **Explosive properties** Not available. Oxidizing properties

No relevant additional information available. 9.2. Other information

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 Acids. Fluorine.

10.6. Hazardous Irritating and/or toxic fumes and gases may be emitted upon the products 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

Ingestion May be harmful if swallowed.

Prolonged inhalation may be harmful. Under normal conditions of intended use, this material is Inhalation

not expected to be an inhalation hazard. May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Skin contact Causes skin irritation. May cause an allergic skin reaction.

Material name: POLIDENT DENTU-CREME SDS IRELAND **Eye contact** Causes serious eye irritation.

Symptoms Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred

vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction.

11.1. Information on toxicological effects

Acute toxicity May irritate eyes and skin.

	, , , , , , , , , , , , , , , , , , , ,	
Components	Species	Test results
BRILLIANT BLUE FCF (CA	AS 3844-45-9)	
Acute		
Oral		
LD50	Rat	11.3 g/kg
Calcium carbonate (CAS 4	1 71-34-1)	
Acute		
Oral		
LD50	Rat	6450 mg/kg
CALCIUM PHOSPHATE, I	DIBASIC (CAS 7757-93-9)	
Acute		
Dermal		
LD50	Rabbit	> 7940 mg/kg
Oral		
LD50	Rat	> 10 g/kg
DODECYL SODIUM SULF	FATE (CAS 151-21-3)	
Acute		
Oral		
LD50	Rat	1288 mg/kg
GLYCERIN (CAS 56-81-5))	
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
L-MENTHOL (CAS 2216-5	51-5)	
Acute		
Oral		
LD50	Rat	3300 mg/kg
OIL OF SPEARMINT (CAS	S 8008-79-5)	
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
PEPPERMINT OIL (CAS 8	3006-90-4)	
Acute		
Oral	_	
LD50	Rat	2426 mg/kg
PROPYL PARABEN (CAS	3 94-13-3)	
Acute		
Oral		
LD50	Rat	> 2000 mg/kg

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

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye

Material name: POLIDENT DENTU-CREME

Causes serious eye irritation.

irritation

Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.

Skin sensitisation May cause an allergic skin reaction.

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

mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

BRILLIANT BLUE FCF (CAS 3844-45-9) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity -

single exposure

Based on available data, the classification criteria are not met.

Specific target organ toxicity -

repeated exposure **Aspiration hazard**

Based on available data, the classification criteria are not met.

Not likely, due to the form of the product. Due to partial or complete lack of data the classification

is not possible.

Mixture versus substance

information

No information available.

Other information None known. May cause allergic respiratory and skin reactions.

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
BRILLIANT BLUE	FCF (CAS 3844-	45-9)		
Aquatic				
Acute				
Crustace	a E	EC50	Water flea (Daphnia magna)	> 97 mg/l, 48 hours Static test
Fish	E	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 96 mg/l, 96 hours Static test
			Rainbow trout (Adult Oncorhyncus mykiss)	> 96 mg/l, 96 hours Static test
Calcium carbonate	e (CAS 471-34-1)			
Aquatic				
Fish	L	.C50	Western mosquitofish (Gambusia affinis)	> 56000 mg/l, 24 hours
DODECYL SODIU	JM SULFATE (CA	AS 151-21-3)		
Aquatic				
Acute				
Crustace	a E	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	E	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.6 mg/l, 96 hours Flow-through test
Chronic				
Algae	N	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustace	a N	OEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-though Test
Fish	N	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days Flow-through test
L-MENTHOL (CAS	S 2216-51-5)			
Aquatic				
Acute				
Algae	E	EC50	Green algae (Desmodesmus subspicatus)	21.4 mg/l, 72 hours OECD 201
Crustace	a E	C50	Water flea (Daphnia magna)	37.7 mg/l, 24 hours OECD 202
Fish	L	.C50	Zebra danio (Danio rerio)	15.6 mg/l, 96 hours EU Method C.1
Chronic				
Algae	N	NOEC	Green algae (Desmodesmus subspicatus)	9.65 mg/l, 72 hours OECD 201
Propylene glycol (CAS 57-55-6)			
Acute	,			
	IC	C50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic				
Acute				
Algae	E	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	N	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustace	a E	EC50	Daphnia	43500 mg/l, 48 hours

Material name: POLIDENT DENTU-CREME

SDS IRELAND 126809 Version No.: 07 Revision date: 27-August-2014 Issue date: 27-August-2014

Components		Species	Test results
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes

12.2. Persistence and

degradability

Photolysis

Half-life (Photolysis-aqueous)

Propylene glycol 1.3 - 2.3 years Estimated

Half-life (Photolysis-atmospheric)

L-MENTHOL 16 Hours Estimated Propylene glycol 32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

Propylene glycol 62 %, 5 days BOD5, Activated sludge

79 %, 20 Days BOD20, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

DODECYL SODIUM SULFATE 95 % OECD 301 B L-MENTHOL 0 %, 28 days

Percent degradation (Anaerobic biodegradation)

Propylene glycol 100 %, 9 days

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

DODECYL SODIUM SULFATE

GLYCERIN

L-MENTHOL

PROPYL PARABEN

Propylene glycol

-0.92
-1.35

Bioconcentration factor (BCF)

L-MENTHOL 1 - 15 Measured, Cyprinus carpio, carp

Propylene glycol < 1 Estimated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

L-MENTHOL 3.18 Estimated

Mobility in general

Volatility

Henry's law

L-MENTHOL 0.000015 atm m^3/mol Estimated

Propylene glycol 0 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN 3.04

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).

Material name: POLIDENT DENTU-CREME

126809 Version No.: 07 Revision date: 27-August-2014 Issue date: 27-August-2014

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 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. 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

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

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.

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

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

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(1) 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

Not listed.

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

Not listed.

Material name: POLIDENT DENTU-CREME SDS IRELAND

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

15.2. Chemical safety

assessment

Follow national regulation for work with chemical agents.

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

R10 Flammable.

R11 Highly flammable. R22 Harmful if swallowed.

R36/38 Irritating to eyes and skin.

R38 Irritating to skin.

R43 May cause sensitization by skin contact.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic

environment.

R65 Harmful: may cause lung damage if swallowed.

H226 Flammable liquid and vapour.

H228 Flammable solid. H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory irritation.

H411 Toxic to aquatic life with long lasting effects.

Product and Company Identification: Product and Company Identification **Revision information**

Composition / Information on Ingredients: Undisclosed Ingredient Statement

Physical & Chemical Properties:

Transport Information: Material Transportation Information

Regulatory Information: Risk Phrases - Class.

GHS: Classification

Training information

Disclaimer

Follow training instructions when handling this material.

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.