SAFETY DATA SHEETS

This SDS packet was issued with item:

071227941

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071501345

SAFETY DATA SHEET

1. Identification

Product identifier **SENSODYNE SENSITIVITY & GUM RELIEF (WITH STANNOUS FLUORIDE AND SODIUM FLUORIDE)**

Other means of identification

Synonyms MFC04850 SENSODYNE SENSITIVITY & GUM RELIEF 1450PPM FLUORIDE, HONEYSUCKLE * MFC04852 SENSODYNE SENSITIVITY & GUM RELIEF 1450PPM FLUORIDE, CHRYSANTHEMUM * MFC04992 SENSODYNE SENSITIVITY & GUM RELIEF 1450PPM FLUORIDE, MINT CONDITION * MFC04993 SENSODYNE SENSITIVITY & GUM RELIEF 1450PPM FLUORIDE, FREEZE EXTRA G CARE * MFC05079 SENSODYNE SENSITIVITY & GUM RELIEF 1450PPM FLUORIDE, REGULAR * MFC05080 SENSODYNE SENSITIVITY & GUM RELIEF 1450PPM FLUORIDE, WHITENING * MFC05221 SENSODYNE SENSITIVITY & GUM RELIEF 1450PPM FLUORIDE, EXTRA FRESH * PROJECT 55 - CHINA * PROJECT 55 GLOBAL * PROJECT 55 GLOBAL- LOW ABRASION * SODIUM FLUORIDE AND STANNOUS FLUORIDE, FORMULATED PRODUCT

Recommended use Oral Care

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE OSMOGLYN	56-81-5	54.8 - < 57
MACROGOL 400 BPC		107-21-1	20
SILICON DIOXIDE	SILICA SILICA GEL AMORPHOUS SILICA DIATOMACEOUS EARTH INFUSORIAL EARTH CAB-O-SIL M-5	7631-86-9	8 - < 12
SODIUM TRIPOLYPHOSPHATE	TRIPHOSPHORIC ACID, PENTASODIUM SALT PENTASODIUM TRIPHOSPHATE PENTASODIUM TRIPOLYPHOSPHATE SODIUM TRIPHOSPHATE SODIUM POLYPHOSPHATE SODIUM PHOSPHATE	7758-29-4	5
SODIUM LAURYL SULPHATE	DODECYL SULFATE, SODIUM SALT SODIUM LAURYL SULPHATE LAURYL SULFATE SODIUM SALT	151-21-3	1.1
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	1
MINT HERBAL BLAST FLAVOR	050004 56T	Mixture	0 - 1.3
FREEZE EXTRA G CARE 510681 1T		Mixture	0 - 1.28
CRYSTAL HERB FLAVOUR W_1622414	W_1622414	Mixture	0 - 1.2
GUMMY CARE FLAVOR 510639 1T		Unassigned	0 - 1.2
STANNOUS FLUORIDE	STANNOUS FLUORIDE TIN BIFLUORIDE	7783-47-3	0.454
COCAMIDOPROPYL BETAINE	COCOAMIDO BETAINE N-(COCO ALKYL) AMIDO PROPYL DIMETHYL BETAINE COCONUT OIL AMIDOPROPYL BETAIN E 1-PROPANAMINIUM, 3-AMINO-N-(CARBOXYMETHYL)-N,N-DI M 1-PROPANAMINIUM, 3-AMINO-N-(CARBOXYMETHYL)-N,N-DI METHYL-, N-COCO ACYL DERIVATIVES, HYDROXIDES, INNER SALTS 1-PROPANAMINIUM,3-AMINO-N-(CARB OXYMETHYL)-N,N-DIMETHYL-,N-COCO ACYL DERIVS.,HYDROXIDES,INNER SALTS	61789-40-0	0.36
SODIUM FLUORIDE	SODIUM MONOFLUORIDE NATURAL VILLIAUMITE	7681-49-4	0.07
Other components below reportable levels			1.66

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. 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 Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion Call a POISON CENTER or doctor/physician if you feel unwell.

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

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

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

5. Fire-fighting measures

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

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

Fire fighting equipment/instructions 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.

General fire hazards This product will support combustion at elevated temperatures.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures 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 vapor. Do not touch or walk through spilled material. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up Large Spills: Stop the flow of material, if this is without risk. Use water spray to reduce vapors or divert vapor cloud drift. 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. Prevent product from entering drains. 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. For waste disposal, see section 13 of the SDS.

Never return spills to original containers for re-use.

Environmental precautions Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

7. Handling and storage

Precautions for safe handling No special control measures required for the normal handling of this product. Avoid contact with eyes, skin, and clothing. Provide adequate ventilation. Use personal protective equipment as required. Wash contaminated clothing before reuse. Avoid breathing mist or vapor.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Keep away from heat, sparks and open flame.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
COCAMIDOPROPYL BETAINE (CAS 61789-40-0)	OHC	1	PROVISIONAL
SODIUM LAURYL SULPHATE (CAS 151-21-3)	OHC	2	

GSK

Components	Type	Value	Note
SODIUM TRIPOLYPHOSPHATE (CAS 7758-29-4)	OHC	1	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
SODIUM FLUORIDE (CAS 7681-49-4)	PEL	2.5 mg/m3	
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value	Form
SODIUM FLUORIDE (CAS 7681-49-4)	TWA	2.5 mg/m3	Dust.
STANNOUS FLUORIDE (CAS 7783-47-3)	TWA	2.5 mg/m3	Dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3	
		20 mppcf	
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
MACROGOL 400 BPC (CAS 107-21-1)	STEL	10 mg/m3	Aerosol, inhalable.
		50 ppm	Vapor fraction
	TWA	25 ppm	Vapor fraction
SODIUM FLUORIDE (CAS 7681-49-4)	TWA	2.5 mg/m3	
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3
SODIUM FLUORIDE (CAS 7681-49-4)	TWA	2.5 mg/m3

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
SODIUM FLUORIDE (CAS 7681-49-4)	3 mg/l	Fluoride	Urine	*
	2 mg/l	Fluoride	Urine	*

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
STANNOUS FLUORIDE (CAS 7783-47-3)	3 mg/l	Fluoride	Urine	*
	2 mg/l	Fluoride	Urine	*

* - For sampling details, please see the source document.

Appropriate engineering controls No special ventilation requirements.

Individual protection measures, such as personal protective equipment

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

Skin protection

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

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

Respiratory protection No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards Not available.

General hygiene considerations 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.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Paste.Pump/tube.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Other information

Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

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	May cause an allergic skin reaction. May cause skin irritation.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	May be harmful if swallowed. Health injuries are not known or expected under normal use.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

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

Components	Species	Test Results
COCAMIDOPROPYL BETAINE (CAS 61789-40-0)		
Acute		
Oral		
LD50	Mouse	> 2000 mg/kg
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
SODIUM LAURYL SULPHATE (CAS 151-21-3)		
Acute		
Oral		
LD50	Rat	1288 mg/kg
SODIUM TRIPOLYPHOSPHATE (CAS 7758-29-4)		
Acute		
Oral		
LD50	Rat	3120 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg

Components	Species	Test Results
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	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
Subacute		
Inhalation		
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.
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.

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

Skin corrosion/irritation May cause 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 or skin sensitization

Respiratory sensitization Not available.

Skin sensitization Health injuries are not known or expected under normal use. May cause an allergic skin reaction.

Sensitization

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 mutagenicity No 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

Mutagenicity

TITANIUM DIOXIDE	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

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

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 - 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

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.
STANNOUS FLUORIDE (CAS 7783-47-3)	3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

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

12. Ecological information

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

Components		Species	Test Results
COCAMIDOPROPYL BETAINE (CAS 61789-40-0)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	0.55 mg/l, 96 hours

Components		Species	Test Results
	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
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	3.6 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	0.9 mg/l, 21 days
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	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 (Selenastrum capricornutum)	272 mg/L, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	340 mg/L, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	180 mg/L, 96 hours Static renewal test
		Mosquito fish (Adult Gambusia affinis)	418 mg/L, 96 hours Static test
		Rainbow trout (Juvenile Oncorhyncus mykiss)	108 mg/L, 96 hours Static test
SODIUM LAURYL SULPHATE (CAS 151-21-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.6 mg/l, 96 hours Flow-through test
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-though Test
Fish	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days Flow-through test
SODIUM TRIPOLYPHOSPHATE (CAS 7758-29-4)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours

Components		Species	Test Results
Aquatic			
Acute			
Algae	EC50	Algae	60 - 120 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	1089 mg/l, 50 hours
Fish	EC50	Golden ide/orfe (Adult Leuciscus idus)	1650 mg/l, 48 hours
		Orange-red killfish (Adult Oryzias latipes)	590 mg/l, 48 hours Static test
TITANIUM DIOXIDE (CAS 13463-67-7)			
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

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

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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

COCAMIDOPROPYL BETAINE	97 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge 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
SODIUM LAURYL SULPHATE	95 % OECD 301 B

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

GLYCERIN	-1.76
MACROGOL 400 BPC	-1.36
SODIUM LAURYL SULPHATE	1.6

Bioconcentration factor (BCF)

SODIUM FLUORIDE	2.3 Measured

Mobility in soil No data available.

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products 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.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

MACROGOL 400 BPC (CAS 107-21-1) Listed.
SODIUM FLUORIDE (CAS 7681-49-4) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Serious eye damage or eye irritation
Respiratory or skin sensitization
Carcinogenicity

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
MACROGOL 400 BPC	107-21-1	20

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

MACROGOL 400 BPC (CAS 107-21-1)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

GLYCERIN (CAS 56-81-5) Other Flavoring Substances with OSHA PEL's

US state regulations

California Proposition 65

WARNING: WARNING: This product contains a chemical known to the State of California to cause cancer.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

California Proposition 65 - CRT: Listed date/Developmental toxin

MACROGOL 400 BPC (CAS 107-21-1) Listed: June 19, 2015

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

MACROGOL 400 BPC (CAS 107-21-1)
TITANIUM DIOXIDE (CAS 13463-67-7)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 05-04-2018

Revision date 09-26-2019

Version # 04

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 2*
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 2
Flammability: 1
Instability: 0

References GSK Hazard Determination

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.

Revision information
Product and Company Identification: Synonyms
Hazard(s) identification: Response
Composition / Information on Ingredients: Ingredients