SAFETY DATA SHEET

1. Identification

Product identifier **AQUAFRESH MILK TEETH (ACORN) 500PPM FLUORIDE WHITE PASTE**

Other means of identification

Synonyms AQUAFRESH MILK TEETH (ACORN) 500PPM FLUORIDE WHITE PASTE * AQUAFRESH PERLICKA PINK TOOTHPASTE 500PPM F * MFC03579 * MFC04619 * SODIUM FLUORIDE, FORMULATED PRODUCT

Recommended use Oral Care

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249

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

EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

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	%
GLYCEROL	GLYCERINE 1,2,3-PROPANETRIOL GLYCYL ALCOHOL TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE GLYCERIN, ANHYDROUS GLYCERIN 1,2,3-PROPANTRIOL	56-81-5	10 - < 20
ZEODENT 153			10 - < 20
ZEODENT 113		112926-00-8	5 - < 10
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	1 - < 3

Chemical name	Common name and synonyms	CAS number	%
XANTHAN GUM	ACTIGUM CX 9 BIOPOLYMER XB-23 XANTHAN GUM BIOZAN R ENORFLO X FLOCON 1035 GALAXY XB KELFLO KELTROL (GUM) KELZAN KENTROL POLYSACCHARIDE B 1459 RHODOPOL 23 XANFLOOD XANTHOMONAS GUM	11138-66-2	1.2
LUCYMINT FLAVOUR 508695		Unassigned	< 1
TEGO BETAIN CK D	COCOAMIDOPROPYL BETAINE (SOLID) FATTY ACID AMIDO ALKYL BETAINE	Unassigned	< 0.3
SODIUM FLUORIDE	SODIUM MONOFLUORIDE NATURAL VILLIAUMITE	7681-49-4	0.11
COSMETIC PINK RC	C.I. 73360 HELINDONE PINK CN BENZO[B]THIOPHEN-3(2H)-ONE,6-CHLORO-2-(6-CHLORO-4-METHYL-3-OXOBENZO[B] THIEN-2(3H)-YLIDENE)-4-METHYL-(9CI) [.DELTA.2,2(3H,3H)-BIBENZO[B] THIOPHENE]-3,3-DIONE,6,6-DICHLORO-4, 4 -DIMETHYL-(8CI) (DELTA,(SUP2,2(3H,3H)-BIBENZO(B) THIOPHENE-3,3-DIONE,6,6-DICHLORO-4 , 4-DIMETHYL-(8CI) AMCOVAT PINK FFD AMANTHRENE PINK FF CALCOLOID PINK FFC CALCOPHYL RED FF CALCOPHYL PINK 2FF C.I. PIGMENT RED 181 D&C RED 30 6-CHLORO-2-(6-CHLORO-4-METHYL-3-OXOBENZO(B)THIEN-2(3H)-YLIDENE)-4-METH YL-BENZO(B)THIOPHEN)3(2H)-ONE 6,6-DICHLORO-4,4-DIMETHYL-(DELTA(2,2((3,3H))-BIBENZO(B)THIOPHENE)-3 ,3-DIONE	2379-74-0	0.02
Other components below reportable levels			60 - < 70

*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 with plenty of soap and 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 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. Foam. Dry chemical powder. Carbon dioxide (CO2).

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	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
Specific methods	Not established.
General fire hazards	Assume that this product is capable of sustaining combustion.

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. 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.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Prevent product from entering drains. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. 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	Wear personal protective equipment. Observe good industrial hygiene practices. 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.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Room temperature - normal conditions.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
COSMETIC PINK RC (CAS 2379-74-0)	OHC	3	SKIN SENSITISER

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

Components	Type	Value	Form
GLYCEROL (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.

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

Components	Type	Value
ZEODENT 113 (CAS 112926-00-8)	TWA	0.8 mg/m3
		20 mppcf

US. ACGIH Threshold Limit Values

Components	Type	Value
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
SODIUM FLUORIDE (CAS 7681-49-4)	TWA	2.5 mg/m3
ZEODENT 113 (CAS 112926-00-8)	TWA	6 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	*

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

Exposure guidelines

Appropriate engineering controls No special ventilation requirements. General ventilation normally adequate.

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.

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. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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.

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

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None under normal conditions.
Incompatible materials	Not available.
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	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms 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
COSMETIC PINK RC (CAS 2379-74-0)		
Acute		
Oral		
LD50	Rat	> 2000 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	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months

Components	Species	Test Results
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.
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 mg/kg

* 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
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 This product is not expected to cause skin sensitization.

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
Micronucleus Assay in vitro, CHO cells, Literature data
Result: Negative

Mutagenicity

TITANIUM DIOXIDE	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 Health injuries are not known or expected under normal use. Risk of cancer cannot be excluded with prolonged exposure. 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.

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

IARC Monographs. Overall Evaluation of Carcinogenicity

SODIUM FLUORIDE (CAS 7681-49-4)	3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.
ZEODENT 113 (CAS 112926-00-8)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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 None known.

12. Ecological information

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

Components		Species	Test Results
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

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
TEGO BETAIN CK D			
Aquatic			
Acute			
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
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	3.6 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	0.9 mg/l, 21 days
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test
XANTHAN GUM (CAS 11138-66-2)			
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.

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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

TEGO BETAIN CK D	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)

TEGO BETAIN CK D	100 %, 20 Days Modified Sturm test., Activated sludge 84 %, 30 days Closed bottle test, Activated sludge

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

GLYCEROL	-1.76

Bioconcentration factor (BCF)

SODIUM FLUORIDE	2.3 Measured

Mobility in soil No data available.

Mobility in general Not available.

Other adverse effects None known.

13. Disposal considerations

Disposal instructions	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.
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). 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.

14. Transport information

DOT

Not regulated as a dangerous good.

Not available.

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	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.

15. Regulatory information

US federal regulations

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

SODIUM FLUORIDE (CAS 7681-49-4) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

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

COSMETIC PINK RC (CAS 2379-74-0)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Massachusetts RTK - Substance List

GLYCEROL (CAS 56-81-5)
SODIUM FLUORIDE (CAS 7681-49-4)
TITANIUM DIOXIDE (CAS 13463-67-7)
ZEODENT 113 (CAS 112926-00-8)

US. New Jersey Worker and Community Right-to-Know Act

GLYCEROL (CAS 56-81-5)
SODIUM FLUORIDE (CAS 7681-49-4)
TITANIUM DIOXIDE (CAS 13463-67-7)
ZEODENT 113 (CAS 112926-00-8)

US. Pennsylvania Worker and Community Right-to-Know Law

GLYCEROL (CAS 56-81-5)
SODIUM FLUORIDE (CAS 7681-49-4)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

SODIUM FLUORIDE (CAS 7681-49-4)

US. California Proposition 65

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

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

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

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
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
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	06-23-2015
Revision date	06-23-2015
Version #	02
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 1 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 Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Multiple Properties Toxicological Information: Toxicological Data Regulatory Information: United States