SAFETY DATA SHEET

1. Identification

Product identifier **DENTURE ADHESIVE CREAM**

Other means of identification

Synonyms SUPER POLIGRIP / COREGA EXTRA CARE DENTURE ADHESIVE CREAM * DENTURE FIXATIVE * POLIDENT DENTURE ADHESIVE * SUPER POLI-GRIP * SUPER POLYGRIP ORIGINAL DENTURE ADHESIVE CREAM * SUPER POLIGRIP / COREGA EXTRA CARE DENTURE ADHESIVE CREAM * SUPER POLIGRIP FREE DENTURE ADHESIVE CREAM * SUPER POLIGRIP ORIGINAL DENTURE ADHESIVE CREAM * POLIGRIP / COREGA DENTURE ADHESIVE CREAM * SUPER POLIGRIP ULTRA FRESH DENTURE ADHESIVE CREAM * SUPER POLIGRIP DENTURE ADHESIVE CREAM * POLIGRIP / COREGA DENTURE ADHESIVE CREAM * POLIGRIP ULTRA FRESH DENTURE ADHESIVE CREAM * SUPER POLIGRIP / COREGA EXTRA CARE DENTURE ADHESIVE CREAM * POLIGRIP PARTIALS SEAL AND PROTECT ADHESIVE * PROJECT LOW COST ADHESIVE * SUPER POLIGRIP LOW GANTREZ DENTURE ADHESIVE CREAM * ULTRA POLIGRIP REGULAR (CANADA) * ULTRA POLIGRIP, DENTURE ADHESIVE CREAM * ULTRA POLIGRIP DENTURE FIXATIVE * POLIGRIP/COREGA ULTRA FRESH, DENTURE ADHESIVE CREAM * POLIGRIP ULTRA FRESH, DENTURE ADHESIVE CREAM FIXATIVE * POLIGRIP TOTAL CARE (UK) * DENTURE ADHESIVE CREAM FIXATIVE * COREGA FREE, DENTURE ADHESIVE CREAM * COREGA FRESH, DENTURE ADHESIVE CREAM * COREGA FRESH DENTURE FIXATIVE * COREGA CREAM, DENTURE ADHESIVE CREAM * COREGA CREAM DENTURE FIXATIVE * COREGA TOTAL ACTION FIXATIVE * POLIGRIP ULTRA FRESH, DENTURE ADHESIVE CREAM * POLIGRIP ULTRA FRESH DENTURE FIXATIVE * DENTURE ADHESIVE CREAM DENTURE FIXATIVE * POLIGRIP FRESH GEL, DENTURE ADHESIVE CREAM * POLIGRIP FRESH GEL DENTURE FIXATIVE * POLIGRIP GUM CARE * POLIDENT TOTAL FIX * MFC50883 * MFC50819 * MFC50814 * MFC50937 * MFC50930 * MFC50887 * MFC50886 * MFC50884 * MFC50882 * MFC50881 * MFC50880 * MFC50885 * B50814 * B50930 * IB1689 * IB1967 * IB1742 * IB1690 * IB1688 * IB1649 * IB1544 * IB1380 * IB2115 * IB1183 * IB0754 * PROJECT DOUBLE * DENTURE ADHESIVE FIXATIVE, FORMULATED PRODUCT

Recommended use Medical Device

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	%
SODIUM CARBOXYMETHYL CELLULOSE	CELLULOSE, CARBOXYMETHYL ETHER, SODIUM SALT CELLULOSE SODIUM GLYCOLATE SODIUM CELLULOSE GLYCOLATE SODIUM GLYCOLATE CELLULOSE CARBOXYMETHYLCELLULOSE SODIUM CARBOXYMETHYLCELLULOSE SODIUM SALT ALMELOSE CMC-NA CMC CARBOXYMETHYL CELLULOSE SODIUM CARBOXYMETHYLCELLULOSE AQUALON(R) CELLULOSE GUM AQUACIDE II OHS80080 RTECS FJ5950000 CELLULOSE CARBOXY METHYL ETHER, SODIUM SALT	9004-32-4	24 - 34
PHARMACEUTICAL GRADE PETROLATUM	PETROLEUM JELLY VASELINE WHITE PETROLEUM JELLY WHITE PETROLEUM USP PETROLATO (PETROLIO) PETROLATUM PRETOLATO PÉTROLATUM VASELIN	8009-03-8	26 - < 30
GANTREZ	SODIUM, CALCIUM METHYL VINYL ETHER MALEIC ACID MIXED SALT FORMULA NO: M801886 METHYL VINYL ETHER-MALEIC ACID COPOLYMER CALCIUM SODIUM SALT MALEIC ACID, METHYL VINYL ETHER POLYMER, CALCIUM SODIUM SALT	62386-95-2	15 - 30
LIGHT MINERAL OIL	OHS12791 RTECS PY8047000	8042-47-5	15 - < 18
L-MENTHOL	CYCLOHEXANOL, 5-METHYL-2-(1-METHYLETHYL)-, (1R-(1ALPHA,2BETA, 5ALPHA))- (1R-(1ALPHA,2BETA,5ALPHA))-5-METHYL-2-(1-METHYLETHYL)-CYCLOHEXANOL LEVOMENTHOL L-MENTHOL (L)-MENTHOL	2216-51-5	0 - < 0.5
PROPYL PARABEN	PROPYL P-HYDROXYBENZOATE PROTABEN 4-HYDROXYBENZOIC ACID, PROPYL ESTER P-HYDROXYBENZOIC ACID, PROPYL ESTER PASEPTOL PARASEPT PROPYL ASEPTOFORM PROPYL P-OXYBENZOATE	94-13-3	0 - < 0.1
Other components below reportable levels			<5

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

4. First-aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Water.
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	In the event of fire, cool tanks with water spray. Cool containers exposed to heat with water spray and remove container, if no risk is involved.
Specific methods	Move containers from fire area if you can do so without risk.
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. Keep out of low areas. Wear appropriate personal protective equipment. 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. Dike far ahead of spill for later disposal. Use water spray to reduce vapors or divert vapor cloud drift. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Never return spills in original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Keep away from heat, sparks and open flame. Avoid prolonged or repeated contact with skin. Avoid prolonged exposure. Use only in well-ventilated areas.
Conditions for safe storage, including any incompatibilities	Keep away from heat and sources of ignition. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
GANTREZ (CAS 62386-95-2)	OHC	1	1000-5000 mcg/m3
L-MENTHOL (CAS 2216-51-5)	OHC	1	SKIN SENSITISER
PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3	
	OHC	1	

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

Components	Type	Value	Form
LIGHT MINERAL OIL (CAS 8042-47-5)	PEL	5 mg/m3	Mist.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
LIGHT MINERAL OIL (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
LIGHT MINERAL OIL (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls General ventilation normally adequate. 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

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. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

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 Cream.

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 > 233.6 °F (> 112 °C) Closed Cup (Estimation based on components).

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	Keep away from heat, sparks and open flame. Contact with incompatible materials.
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	Prolonged inhalation may be harmful.
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.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
GANTREZ (CAS 62386-95-2)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg/day Read across from similar polymers
LIGHT MINERAL OIL (CAS 8042-47-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
L-MENTHOL (CAS 2216-51-5)		
Acute		
Oral		
LD50	Rat	3300 mg/kg

Components	Species	Test Results
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
Oral		
LD50	Rat	> 15 g/kg
Chronic		
Oral		
NOAEL	Rat	>= 3000 mg/kg, 2 years
PROPYL PARABEN (CAS 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 Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

GANTREZ — 0, Read across from similar polymers
Result: Non-irritant

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

GANTREZ — 0, Read across from similar polymers
Result: Minimal Irritant

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

GANTREZ — 0, Read across from similar polymers
Result: Not considered to be genotoxic

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

PHARMACEUTICAL GRADE PETROLATUM — >= 3000 mg/kg/day 2 year bioassay, oral administration
Result: NOAEL
Species: Rat
Dermal application
Result: Negative
Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

LIGHT MINERAL OIL (CAS 8042-47-5) — 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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 Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not likely, due to the form of the product.

Chronic effects Prolonged inhalation may be harmful.

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

12. Ecological information

Ecotoxicity 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
L-MENTHOL (CAS 2216-51-5)			
Aquatic			
Acute			
Algae	EC50	Green algae (Desmodesmus subspicatus)	21.4 mg/l, 72 hours OECD 201
Crustacea	EC50	Water flea (Daphnia magna)	37.7 mg/l, 24 hours OECD 202
Fish	LC50	Zebra danio (Danio rerio)	15.6 mg/l, 96 hours EU Method C.1
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	9.65 mg/l, 72 hours OECD 201
SODIUM CARBOXYMETHYL CELLULOSE (CAS 9004-32-4)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	100 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 20000 mg/l, 96 hours Static test

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

Persistence and degradability Not available.

Photolysis

Half-life (Photolysis-atmospheric)

L-MENTHOL	16 Hours Estimated
LIGHT MINERAL OIL	< 1 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

SODIUM CARBOXYMETHYL CELLULOSE	7 %, 28 days Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

L-MENTHOL	0 %, 28 days
LIGHT MINERAL OIL	24 %, 28 days Modified Sturm test., Activated sludge

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

L-MENTHOL	3.3
PROPYL PARABEN	3.04

Bioconcentration factor (BCF)

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

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

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN	3.04

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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	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.

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	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)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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))

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)
PROPYL PARABEN (CAS 94-13-3)

US. Massachusetts RTK - Substance List

LIGHT MINERAL OIL (CAS 8042-47-5)
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

Not listed.

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

LIGHT MINERAL OIL (CAS 8042-47-5)
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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	02-13-2014
Revision date	02-11-2016
Version #	12
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 0 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