# 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, IB0754 \* SUPER POLYGRIP ORIGINAL DENTURE ADHESIVE CREAM, IB1183 \* SUPER POLIGRIP / COREGA EXTRA CARE DENTURE ADHESIVE CREAM, MFC 50814 \* SUPER POLIGRIP FREE DENTURE ADHESIVE CREAM, MFC 50819 \* SUPER POLIGRIP ORIGINAL DENTURE ADHESIVE CREAM, MFC 50880 & 50885 \* POLIGRIP / COREGA DENTURE ADHESIVE CREAM, MFC 50881 \* SUPER POLIGRIP ULTRA FRESH DENTURE ADHESIVE CREAM. MFC 50882 \* SUPER POLIGRIP DENTURE ADHESIVE CREAM, MFC 50884 \* POLIGRIP / COREGA DENTURE ADHESIVE CREAM, MFC 50886 \* POLIGRIP ULTRA FRESH DENTURE ADHESIVE CREAM, MFC 50887 \* SUPER POLIGRIP / COREGA EXTRA CARE DENTURE ADHESIVE CREAM, MFC 50930 \* SUPER POLIGRIP LOW GANTREZ DENTURE ADHESIVE CREAM, MFC 50937 \*

DENTURE ADHESIVE FIXATIVE, FORMULATED PRODUCT

Recommended use Cosmetic Product

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** 

Material name: DENTURE ADHESIVE CREAM

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 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

# 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.

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

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 Unsuitable extinguishing

Foam. Dry chemical powder. Carbon dioxide (CO2).

Water.

media Specific hazards arising from

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

Specific methods

the chemical

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.

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.

**Environmental precautions** 

Never return spills in original containers for re-use. For waste disposal, see section 13 of the SDS. 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	
Com	pone

Components	Туре	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	

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Components	Туре	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.
<b>US. ACGIH Threshold Limit</b>	Values		
Components	Туре	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	Туре	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.
ogical limit values	No higherical exposure limits noted for the inc	radiant(s)	

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
Form
Color
Not available.

Odor threshold
PH
Not available.

Melting point/freezing point
Initial boiling point and boiling
Not available.
Not available.
Not available.
Not available.

range

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

Evaporation rate Not available.
Flammability (solid, gas) Not available.

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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. Not available. Vapor density Relative density Not available.

Solubility(ies)

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

(n-octanol/water) **Auto-ignition temperature** 

**Decomposition temperature** 

Not available. Not available. Not available.

10. Stability and reactivity

Reactivity Not available.

**Chemical stability** Material is stable under normal conditions.

Possibility of hazardous

reactions

**Viscosity** 

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

Prolonged inhalation may be harmful. Inhalation

Health injuries are not known or expected under normal use. Skin contact Eye contact Direct contact with eyes may cause temporary irritation.

Expected to be a low ingestion hazard. Ingestion

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

Rat LD50 > 2000 mg/kg

L-MENTHOL (CAS 2216-51-5)

Acute

Oral

LD50 Rat 3300 mg/kg

Material name: DENTURE ADHESIVE CREAM

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Components Species Test Results

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

<u>Acute</u>

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 eve damage/eve

Eve

irritation

Direct contact with eyes may cause temporary irritation.

0, Read across from similar polymers

Result: Minimal Irritant

Respiratory or skin sensitization

**GANTREZ** 

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

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 listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

**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 EC50 Green algae (Desmodesmus Algae 21.4 mg/l, 72 hours OECD 201 subspicatus) 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 9.65 mg/l, 72 hours OECD 201 subspicatus) 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 > 20000 mg/l, 96 hours Static test mykiss) \* Estimates for product may be based on additional component data not shown. Not available. **Photolysis** 

#### Persistence and degradability

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)** 

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

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

3.18 Estimated L-MENTHOL

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 listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

No

chemical

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

Not regulated.

(SDWA)

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#### **US** state regulations

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

#### 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

# 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

<sup>\*</sup>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

02-13-2014 Issue date **Revision date** 10-19-2015

Version # 10

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

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

Health: 2 NFPA ratings

Flammability: 1 Instability: 0

References **GSK Hazard Determination** 

The information and recommendations in this safety data sheet are, to the best of our knowledge, Disclaimer

> 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.

Material name: DENTURE ADHESIVE CREAM

SDS US

#### **Revision information**

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Ecological information: Persistence and degradability
Ecological information: Bioaccumulative potential
Ecological information: Mobility in soil
Regulatory Information: United States

Material name: DENTURE ADHESIVE CREAM

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