

1. Identification

Product identifier	POLIGRIP/POLIDENT/COREGA MAX HOLD AND COMFORT
Other means of identification	
Product code	MFC05612
Synonyms	MFC05612 * POLIDENT MAX HOLD & COMFORT DENTURE ADHESIVE CREAM * POLIGRIP MAX AND HOLD COMFORT - PROJECT QUANTUM * POLIGRIP CUSHION AND COMFORT DENTURE ADHESIVE * COREGA MAX HOLD & COMFORT * POLIDENT POWER MAX * COREGA MAX HOLD AND FRESH * COREGA COMFORT
Recommended use	Consumer Healthcare Product Medicinal Device Cosmetic Product 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	

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

Telephone:	3E GLOBAL INCIDENT RESPONSE +(1) 760 476 3971 (In country) +(1) 760 476 3962 or +(1) 866 519 4752 (International) 24/7; multi-language response
Contract Number:	335879

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.

Hazard(s) not otherwise classified (HNOC)**Supplemental information**

This product will support combustion at elevated temperatures.
See section 11 of the SDS for additional information on health hazards.

28% of the mixture consists of component(s) of unknown acute oral toxicity. 57% of the mixture consists of component(s) of unknown acute dermal toxicity. 57% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 57% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
MINERAL OIL U.S.P.	WHITE MINERAL OIL WHITE MINERAL OIL, (PETROLEUM) WHITE OIL (REFINED PETROLEUM OIL) LIQUID PARAFFIN BP MINERAL OIL, WHITE PARAFFIN OIL	8042-47-5	20 - < 30
PHARMACEUTICAL GRADE PETROLATUM	PETROLEUM JELLY VASELINE WHITE PETROLEUM JELLY WHITE PETROLEUM USP PETROLATO (PETROLIO) PETROLATUM PRETOLATO PÉTROLATUM VASELIN WHITE PETROLATUM USP YELLOW PETROLATUM SOFT PARAFFIN	8009-03-8	20 - < 30
POLISALT	METHYL VINYL ETHER-MALEIC ACID COPOLYMER CALCIUM SODIUM SALT CALCIUM/SODIUM PVM/MA COPOLYMER GANTREZ MS-955 (ISP) MALEIC ACID, METHYL VINYL ETHER POLYMER, CALCIUM SODIUM SALT Gantrez Double Salt OraRez MSL GANTREZ-77 (DOUBLE SALT) SODIUM, CALCIUM METHYL VINYL ETHER MALEIC ACID MIXED SALT	62386-95-2	10 - < 20
2-PROPENOIC ACID HOMOPOLYMER	CARBOPOL RESINS CARBOMER RESINS CARBOPOL 980 NF CARBOPOL 940 CARBOPOL 941 CARBOPOL 960 CARBOPOL 961 CARBOMER 934 CARBOMER(R) 934 CARBOMER 940 NF CARBOPOL 981 CARBOXYVINYL POLYMER CARBOPOL 971P NF CARBOPOL 974P NF	9003-01-4	5 - < 10
Other components below reportable levels			20 - < 30

4. First-aid measures**Inhalation**

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Wash off with 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

Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures**Suitable extinguishing media**

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

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

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

Cool containers exposed to heat with water spray and remove container, if no risk is involved.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

Will burn if involved in a fire.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. 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**

Avoid prolonged or repeated contact with skin. Avoid prolonged exposure.

Conditions for safe storage, including any incompatibilities

Keep away from heat and sources of ignition. Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK**Components****Type****Value****Form**

POLYACRYLIC ACID (CAS 9003-01-4)

OHC

3

>10 - ≤100 mcg/m³

POLISALT (CAS 62386-95-2)

OHC

1

1000 - 5000 mcg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value****Form**

MINERAL OIL U.S.P. (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**

MINERAL OIL U.S.P. (CAS 8042-47-5)

TWA

5 mg/m³

Inhalable fraction.

US. ACGIH Threshold Limit Values			
Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m3	Inhalable fraction.
US. NIOSH: Pocket Guide to Chemical Hazards			
Components	Type	Value	Form
MINERAL OIL U.S.P. (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	Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.		
Individual protection measures, such as personal protective equipment			
Eye/face protection	Wear safety glasses with side shields (or goggles).		
Skin protection			
Hand protection	Wear appropriate chemical resistant gloves.		
Other	Wear suitable protective clothing.		
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.		
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.		

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Paste.
Color	Beige.
Odor	Not available.
Odor threshold	Not available.
pH	7
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 applicable.
Upper/lower flammability or explosive limits	
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	Heat, flames and sparks. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful. 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	Not available.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort.

Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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Components	Species	Test Results
2-PROPENOIC ACID HOMOPOLYMER (CAS 9003-01-4)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2500 mg/kg
MINERAL OIL U.S.P. (CAS 8042-47-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg > 15 g/kg
<u>Chronic</u>		
Oral		
NOAEL	Rat	>= 3000 mg/kg, 2 years
POLISALT (CAS 62386-95-2)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg/day Read across from similar polymers

Skin corrosion/irritation	Health injuries are not known or expected under normal use.
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Irritation Corrosion - Skin POLISALT

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

Serious eye damage/eye irritation

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

Eye

POLISALT

0, Read across from similar polymers

Result: Minimal Irritant

Respiratory or skin sensitization**Respiratory sensitization**

No studies have been conducted.

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

POLISALT

0, Read across from similar polymers

Result: Not considered to be genotoxic

Carcinogenicity

Carcinogenic effects are not expected as a result of occupational exposure.

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

2-PROPENOIC ACID HOMOPOLYMER (CAS 9003-01-4) 3 Not classifiable as to carcinogenicity to humans.

MINERAL OIL U.S.P. (CAS 8042-47-5) 3 Not classifiable as to carcinogenicity to humans.

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8) 3 Not classifiable as to carcinogenicity 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

Contains no ingredient listed as toxic to reproduction.

Specific target organ toxicity - single exposure

Not assigned.

Specific target organ toxicity - repeated exposure

Not assigned.

Aspiration hazard

Not established.

Chronic effects

Prolonged inhalation may be harmful.

12. Ecological information**Ecotoxicity**

No data available for this product.

Components**Species****Test Results**

2-PROPENOIC ACID HOMOPOLYMER (CAS 9003-01-4)

Aquatic*Acute*

Crustacea

EC50

Water flea (Daphnia magna)

> 168 to < 280 mg/l, 96 hours Static test

Fish

EC50

Bluegill sunfish (Adult Lepomis macrochirus)

> 580 to < 2000 mg/l, 96 hours Static test

Persistence and degradability

Not available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations**Disposal instructions**

Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

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. 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.
Read safety instructions, SDS and emergency procedures before handling.

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 This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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)

Not 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 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. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

MINERAL OIL U.S.P. (CAS 8042-47-5)

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	Yes
Canada	Domestic Substances List (DSL)	Yes

Country(s) or region	Inventory name	On inventory (yes/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)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*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	01-19-2023
Revision date	01-19-2023
Version #	03
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: Disposal Hazard(s) identification: Prevention Hazard(s) identification: Response Hazard(s) identification: Storage Composition / Information on Ingredients: Disclosure Overrides Other information, including date of preparation or last revision: References Other information, including date of preparation or last revision: List of abbreviations