



# SAFETY DATA SHEET

## 1. Identification

Product identifier

**ULTRA COREGA ADHESIVE POWDER**

Other means of identification

Synonyms

WERNETS ULTRA (UK) \* ULTRA COREGA POWDER \* SUPER POLI-GRIP POWDER \* SPG POWDER \* POLIDENT DENTU-GRIP \* IB0872 \* GANTREZ-77, FORMULATED PRODUCT

Recommended use

Medical Device

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	%
GANTREZ-77 (DOUBLE SALT)	SODIUM, CALCIUM METHYL VINYL ETHER MALEIC ACID MIXED SALT * FORMULA NO: M801886	62386-95-2	50
CARBOXYMETHYLCELLULOSE	CARBOXYMETHYLATED CELLULOSE PULP * CARBOXYMETHYL CELLULOSE ETHER * CELLULOSE CARBOXYMETHYLATE * CELLULOSEGLYCOLIC ACID * GLYCOLIC ACID CELLULOSE ETHER * CELLULOSE, CARBOXYMETHYL ETHER * CELLULOSE CARBOXYMETHYLATE ETHER * CMC * CARBOSE * CM-CELLULOSE * COLLORESINE * THYLOSE * CARBOXYMETHYL CELLULOSE * OHS84039 * RTECS FJ5700000	9000-11-7	49.6

Other components below reportable levels

0.4

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

Material name: ULTRA COREGA ADHESIVE POWDER

127545 Version #: 06 Revision date: 08-07-2014 Issue date: 08-07-2014

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## 4. First-aid measures

<b>Inhalation</b>	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	None known. Dusts may irritate the respiratory tract, skin and eyes.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder.
<b>Unsuitable extinguishing media</b>	Carbon dioxide (CO2).
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Assume that this product is capable of sustaining combustion.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Avoid inhalation of dust from the spilled material. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimize dust generation and accumulation. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Provide appropriate exhaust ventilation at places where dust is formed. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes. Avoid prolonged exposure. Practice good housekeeping.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### GSK

#### Components

	Type	Value	Note
CARBOXYMETHYLCELLULOSE (CAS 9000-11-7)	OHC	1	
GANTREZ-77 (DOUBLE SALT) (CAS 62386-95-2)	OHC	1	1000-5000 mcg/m3

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	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. Good general ventilation (typically 10 air changes per hour) 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. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
<b>Hand protection</b>	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
<b>Skin protection</b>	
<b>Other</b>	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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

<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.

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

## 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** Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
**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

**Ingestion** Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard.  
**Inhalation** Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.  
**Skin contact** Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.  
**Eye contact** Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

**Symptoms related to the physical, chemical and toxicological characteristics** None known. Dusts may irritate the respiratory tract, skin and eyes.

### Information on toxicological effects

**Acute toxicity** Health injuries are not known or expected under normal use.

Components	Species	Test Results
CARBOXYMETHYLCELLULOSE (CAS 9000-11-7)		
<b>Acute</b>		
<i>Oral</i>		
LD	Rat	> 5 g/kg
GANTREZ-77 (DOUBLE SALT) (CAS 62386-95-2)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg/day Read across from similar polymers

\* 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. Prolonged skin contact may cause temporary irritation.

#### Irritation Corrosion - Skin

GANTREZ-77 (DOUBLE SALT) Read across from similar polymers  
Result: Non-irritant

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

#### Eye

GANTREZ-77 (DOUBLE SALT) Read across from similar polymers  
Result: Minimal Irritant

### Respiratory or skin sensitization

**Respiratory sensitization** Health injuries are not known or expected under normal use.

**Skin sensitization** Health injuries are not known or expected under normal use.

#### Maximisation assay (Magnusson and Kligman)

CARBOXYMETHYLCELLULOSE Result:

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Health injuries are not known or expected under normal use.

**Mutagenicity**

GANTREZ-77 (DOUBLE SALT)

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. Health injuries are not known or expected under normal use.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity** Health injuries are not known or expected under normal use. 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.

**Chronic effects** Prolonged inhalation may be harmful.

**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
CARBOXYMETHYLCELLULOSE (CAS 9000-11-7)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
<b>Aquatic</b>			
<i>Acute</i>			
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 Oncorhynchus mykiss)	> 20000 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)**

CARBOXYMETHYLCELLULOSE 7 %, 28 days Zahn-Wellens, Activated sludge

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Other adverse effects** Not available.

**13. Disposal considerations**

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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).

**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** One or more components are not listed on 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 1910.1001-1050)

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. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

#### 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

Country(s) or region	Inventory name	On inventory (yes/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

<b>Issue date</b>	08-07-2014
<b>Revision date</b>	08-07-2014
<b>Version #</b>	06
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1 Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 1 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Transport Information: Agency Name, Packaging Type, and Transport Mode Selection Regulatory Information: Risk Phrases - Class.