

1. Identification

Product identifier	CICATRIN POWDER
Other means of identification	Not available.
Synonym(s)	CICATRIN POWDER 15G * CICATRIN POWDER 50G * CICATRIN PO CUTANEO * CICTRIN POLVO * ZINC BACITRACIN AND NEOMYCIN SULFATE, FORMULATED PRODUCT
Recommended use	Medicinal 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

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	%
STARCH	ARROWROOT STARCH CORN STARCH POTATO STARCH RICE STARCH	9005-25-8	98.7
GLYCINE	AMINOACETIC ACID 2-AMINOACETIC ACID AMINOETHANOIC ACID GLYCOCOLL GLYCOSTHENE	56-40-6	1
NEOMYCIN SULFATE	NEOMYCIN, SULFATE (SALT) NEOMYCIN SULPHATE MYCIFRADIN SULFATE MYCERIN SULPHATE 242 (GW ACN) MYCIGUENT NEOMIX OTOBiotic OHS84263 RTECS QP4375000 NEOMYCIN SULFATE USP POWDER 50/50	1405-10-3	<1

Chemical name	Common name and synonyms	CAS number	%
ZINC BACITRACIN	BACITRACIN ZINC BACIFERM ZINC-BACITRACIN BACITRACIN, ZINC SALT 93Z59 GR 31385A	1405-89-6	<1
L-CYSTEINE	CYS L-(+)-CYSTEINE 2-AMINO-3-MERCAPTOPROPIONIC ACID BETA-MERCAPTOALANINE ALPHA-AMINO-BETA-THIOLPROPIONIC ACID AMINO-THIO LACTIC ACID 2-AMINO-3-MERCAPTOPROPANOIC ACID 1-BETA-MERCAPTO ALANINE HALF CYSTINE THIOSERINE CYSTEINE CYSTEIN L-BETA-MERCAPTOALANINE L-2-AMINO-3-MERCAPTOPROPANOIC ACI D (R)-(+)-CYSTEINE CYSTEINE, L-	52-90-4	0.2
L-(-)-THREONINE	2-AMINO-3-HYDROXYBUTANOIC ACID THREONIN THREONINE (S)-THREONINE L-THREONINE THREONINE, L- ALPHA-AMINO-BETA-HYDROXYBUTYRIC ACID C4H9NO3 OHS60737 RTECS XO8590000 PROTEINOGENE AMINOSÄUREN UND STEREOISOMERE D-FORMEN UND IHRE SALZE MIT GEGENIONEN DER WGK 1	72-19-5	0.1

*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. 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. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).
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	Water fog. Foam. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide (CO2).
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	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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 entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. 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 exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
GLYCINE (CAS 56-40-6)	8 HR TWA	5000 mcg/m3	
	OHC	1	
L-(-)-THREONINE (CAS 72-19-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	
L-CYSTEINE (CAS 52-90-4)	OHC	2	PROVISIONAL
NEOMYCIN SULFATE (CAS 1405-10-3)	8 HR TWA	2000 mcg/m3	
	OHC	1	SKIN SENSITISER
		1	REPRODUCTIVE HAZARD
ZINC BACITRACIN (CAS 1405-89-6)	8 HR TWA	1500 mcg/m3	
	OHC	1	

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

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
STARCH (CAS 9005-25-8)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values

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

Appropriate engineering controls

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.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields (or goggles).

Hand protection

Wear protective gloves.

Other

Wear appropriate chemical resistant clothing.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment. 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.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder.Bottle.
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	Heat, flames and sparks. Contact with incompatible materials. Minimize dust generation and accumulation. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Incompatible materials	Acids.
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	Expected to be a low ingestion hazard. Health injuries are not known or expected under normal use.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	May cause skin irritation.
Eye contact	May be irritating to eyes.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. The possible symptoms of overexposure include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).

Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test Results
GLYCINE (CAS 56-40-6)		
Acute		
<i>Oral</i>		
LD50	Rat	7930 mg/kg
L-CYSTEINE (CAS 52-90-4)		
Acute		
<i>Oral</i>		
LD50	Rat	1890 mg/kg
NEOMYCIN SULFATE (CAS 1405-10-3)		
Acute		
<i>Oral</i>		
LD50	Mouse	> 8000 mg/kg

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

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation. May be irritating to the skin.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation. May be irritating to eyes.
Respiratory or skin sensitization	
Respiratory sensitization	Health injuries are not known or expected under normal use.
Skin sensitization	Contains a potential skin sensitizer. May cause an allergic skin reaction.
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.
Carcinogenicity	Health injuries are not known or expected under normal use.
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	Health injuries are not known or expected under normal use.
Specific target organ toxicity - single exposure	None known.
Specific target organ toxicity - repeated exposure	None known.
Aspiration hazard	Not likely, due to the form of the product.
Further information	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity	No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.
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Components	Species	Test Results
GLYCINE (CAS 56-40-6)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Fathead minnow (Adult Pimephales promelas) > 100 mg/l
ZINC BACITRACIN (CAS 1405-89-6)		
Aquatic		
<i>Acute</i>		
Algae	NOEC	> 10 mg/l
Crustacea	EC50	Water flea (Daphnia magna) 34 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss) 74 mg/l, 96 hours

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

Persistence and degradability

Photolysis	
Half-life (Photolysis-atmospheric)	
GLYCINE	4.6 Hours Estimated

Biodegradability**Percent degradation (Aerobic biodegradation-soil)**

ZINC BACITRACIN > 50 %, 20 Days

Bioaccumulative potential**Partition coefficient n-octanol / water (log Kow)**

GLYCINE -3.21

L-CYSTEINE -2.49

Mobility in soil**Adsorption****Soil/sediment sorption - log Koc**

GLYCINE 0 Estimated

Mobility in general**Volatility****Henry's law**GLYCINE 0 atm m³/mol Estimated**Other adverse effects** Not available.**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** 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)

ZINC BACITRACIN (CAS 1405-89-6) Listed.

SARA 304 Emergency release notification

Not regulated.

US. 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 - Yes

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**

STARCH (CAS 9005-25-8)

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

ZINC BACITRACIN (CAS 1405-89-6) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

STARCH (CAS 9005-25-8)

US. Rhode Island RTK

ZINC BACITRACIN (CAS 1405-89-6)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

NEOMYCIN SULFATE (CAS 1405-10-3) Listed: October 1, 1992

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
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
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	04-24-2014
Revision date	04-24-2014
Version #	05
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. 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: Business Units

Composition / Information on Ingredients: Ingredients

Physical & Chemical Properties:

Transport Information: Agency Name, Packaging Type, and Transport Mode Selection

Regulatory Information: United States