



SAFETY DATA SHEET

1. Identification

Product identifier**NUCALA****Other means of identification****Synonyms**

NUCALA (ANZ) * MEPOLIZUMAB FOR INJECTION, 100 MG/VIAL * MEPOLIZUMAB FOR INJECTION, 250 MG/VIAL * MEPOLIZUMAB DP FOR INJECTION * MEPOLIZUMAB DRUG PRODUCT FOR INJECTION * MEPOLIZUMAB, 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

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.comWebsite: www.gsk.com

CHEMTREC EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:

Customer Number: CCN9484

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	%
SUCROSE	SUGAR CANE SUGAR BEET SUGAR CONFECTIONER'S SUGAR ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL GRANULATED SUGAR SUCRALOX	57-50-1	57 - 63
MEPOLIZUMAB	SB-240563	196078-29-2	35 - 41

Chemical name	Common name and synonyms	CAS number	%
DISODIUM HYDROGEN PHOSPHATE	DISODIUM HYDROGEN ORTHOPHOSPHATE PHOSPHORIC ACID, DISODIUM SALT DIBASIC SODIUM PHOSPHATE DISODIUM MONOHYDROGEN PHOSPHATE DSP EXSICCATED SODIUM PHOSPHATE SODA PHOSPHATE DISODIUM PHOSPHORIC ACID SODIUM MONOHYDROGEN PHOSPHATE DISODIUM ACID ORTHOPHOSPHATE DISODIUM HYDROPHOSPHATE HYDROGEN DISODIUM PHOSPHATE DISODIUM HYDROGEN PHOSPHATE ANHYDROUS SODIUM PHOSPHATE DIBASIC DISODIUM PHOSPHATE TRISODIUM PHOSPHATE	7558-79-4	2 - 3

Other components below reportable levels

0.25

*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. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. dizziness symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing) Rash. Coughing. May cause allergic respiratory reaction. May cause an allergic skin reaction. Abdominal pain. decrease in blood pressure Headache.

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.

5. Fire-fighting measures

Suitable extinguishing media

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

Unsuitable extinguishing media

None known.

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. May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. 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.

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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/open flames/hot surfaces. - No smoking. Keep formation of airborne dusts to a minimum. Avoid prolonged exposure.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. 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**

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	Note
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)	8 HR TWA	5000 mcg/m3	
MEPOLIZUMAB (CAS 196078-29-2)	OHC	1	>100 - <=1000 mcg/m3
	OHC	2	

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

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values

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

Exposure guidelines**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.

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	Solid.
Form	Lyophilised powder.Vial.
Color	Not available.

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 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.

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 Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Dust may irritate respiratory system. 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

Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. dizziness symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing) Rash. Coughing. May cause allergic respiratory reaction. May cause an allergic skin reaction. Abdominal pain. decrease in blood pressure Headache.

Information on toxicological effects**Acute toxicity**

May be harmful if swallowed. Health injuries are not known or expected under normal use.

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

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)

Acute**Oral**

LD50

Rat

17 g/kg

MEPOLIZUMAB (CAS 196078-29-2)

Acute**Other**

NOAEL

Monkey

> 300 mg/kg intravenous dosing

Chronic**Other**

NOAEL

Monkey

> 100 mg/kg, 6 months weekly intravenous dosing, 7 doses total

> 10 mg/kg, 6 months weekly subcutaneous dosing, 7 doses total

* 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.

Serious eye damage/eye irritation

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

Respiratory or skin sensitization**Respiratory sensitization**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization

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. Due to partial or complete lack of data the classification is not possible.

Mutagenicity

MEPOLIZUMAB

SAR / QSAR

Result: No structural alerts identified.

Carcinogenicity

MEPOLIZUMAB

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

SAR / QSAR

Result: No structural alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Due to partial or complete lack of data the classification is not possible.

Reproductivity

MEPOLIZUMAB

Fertility/foetal development, study conducted with SB-264091 (rat anti-human IL5 monoclonal antibody)

Result: NOAEL (male & female fertility & in utero development) = 50 mg/kg intravenous weekly doses (maximum dose)

Species: Mouse

Pre- and Post-natal development

Result: NOAEL (maternal and foetal) = 100 mg/kg/ intravenous weekly doses (maximum dose)

Species: Monkey

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.
Chronic effects	Prolonged inhalation may be harmful.
Further information	Caution - Pharmaceutical agent. 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
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50 Water flea (Daphnia magna)	252 mg/l

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

Persistence and degradability Not available.

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

SUCROSE 69 % BOD5

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SUCROSE -3

Mobility in soil Not available.

Mobility in general Not available.

Volatility

Henry's law

SUCROSE < 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. Do not discharge into drains, water courses or onto the ground. 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). Avoid discharge into water courses or onto the ground.

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.

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

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) 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 - Yes Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No
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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.
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US state regulations	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.
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16. Other information, including date of preparation or last revision

Issue date	07-15-2014
Revision date	08-17-2017
Version #	07
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 ACA.
HMIS® ratings	Health: 1 Flammability: 2 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 2 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	Physical & Chemical Properties: Multiple Properties