



SAFETY DATA SHEET

1. Identification

Product identifier RAXIBACUMAB INJECTION (1700 MG/34ML)

Other means of identification

Synonyms RAXIBACUMAB, 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	%
RAXIBACUMAB			5
GLYCINE	AMINOACETIC ACID 2-AMINOACETIC ACID AMINOETHANOIC ACID GLYCOCOLL GLYCOSTHENE	56-40-6	1.8

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	1
SODIUM CITRATE, ANHYDROUS	1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-, TRISODIUM SALT 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID TRISODIUM SALT CITREME CITRIC ACID, TRISODIUM SALT RTECS GE8300000	68-04-2	0.28
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID CITIRIC ACID	77-92-9	0.01
Other components below reportable levels			91.91

*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	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching), somnolence, pain.
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. Foam. 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	This product is non-flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
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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. Cover with plastic sheet to prevent spreading. 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. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions**7. Handling and storage****Precautions for safe handling**

Use care in handling/storage. Avoid prolonged exposure. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Do not allow material to freeze.

8. Exposure controls/personal protection**Occupational exposure limits****GSK****Components****Type****Value****Note**

CITRIC ACID ANHYDROUS (CAS 77-92-9)

8 HR TWA

5000 mcg/m3

GLYCINE (CAS 56-40-6)

OHC

1

8 HR TWA

5000 mcg/m3

RAXIBACUMAB SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)

OHC

1

OHC

2

8 HR TWA

5000 mcg/m3

Provisional

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

15 mg/m3

Respirable fraction. 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

10 mg/m3

Respirable. Total

Biological limit values

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

Exposure guidelines**Appropriate engineering controls**

General ventilation normally adequate.

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	Liquid.
Form	Liquid.
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 applicable.

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 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.

Ingestion	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	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching), somnolence, pain.	
Information on toxicological effects		
Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.	
Components	Species	Test Results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
<u>Acute</u>		
Oral		
LD50	Rat	3000 mg/kg
GLYCINE (CAS 56-40-6)		
<u>Acute</u>		
Oral		
LD50	Rat	7930 mg/kg
* 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.	
Irritation Corrosion - Skin: P.I.I. value		
CITRIC ACID ANHYDROUS	OECD 404	Result: Mild to moderate irritant. Species: Rabbit
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use.	
Eye		
CITRIC ACID ANHYDROUS	OECD 405	Acute ocular irritation; OECD 405 Result: Severe Irritant Species: Rabbit
Respiratory or skin sensitization		
Respiratory sensitization	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.	
Skin sensitization	Health injuries are not known or expected under normal use.	
Germ cell mutagenicity	Health injuries are not known or expected under normal use. No studies have been conducted.	
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. No studies have been conducted.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not available.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not available.		
Reproductive toxicity	Health injuries are not known or expected under normal use. No studies have been conducted.	
Reproductivity		
RAXIBACUMAB	Embryo-foetal development	Result: Negative Species: Rabbit
Specific target organ toxicity - single exposure	Not assigned.	
Specific target organ toxicity - repeated exposure	Not assigned.	
Aspiration hazard	Not an aspiration hazard.	
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
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Aquatic		
<i>Acute</i>		
Algae	NOEC	Green algae (Scenedesmus quadricauda) 425 mg/l, 8 days Static Test
Crustacea	EC50	Water flea (Daphnia magna) 120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) 1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus) 440 - 760 mg/l, 96 hours Static test
GLYCINE (CAS 56-40-6)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Fathead minnow (Adult Pimephales promelas) > 100 mg/l
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 161 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) 2031 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus) 590 - 1018 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.

Photolysis

Half-life (Photolysis-atmospheric)

GLYCINE 4.6 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CITRIC ACID ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge

SODIUM CITRATE, ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge

SUCROSE 69 % BOD5

Percent degradation (Aerobic biodegradation-ready)

GLYCINE 78.13 % BOD20

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

GLYCINE -3.21

SUCROSE -3

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

GLYCINE 0 Estimated

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS < 0 atm m³/mol Calculated, 25 °C

GLYCINE 0 atm m³/mol Estimated

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 established.

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
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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 Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)	Not listed.
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US. Massachusetts RTK - Substance List

SUCROSE (CAS 57-50-1)

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

Not listed.

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

SUCROSE (CAS 57-50-1)

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

*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	11-23-2015
Version #	01
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 0 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.