SAFETY DATA SHEET

1. Identification

Product identifier **TRACRIUM INJECTION**

Other means of identification Not available.

Synonym(s) TRACRIUM INJECTION 10 MG/ML * TRACRIUM 2.5 ML INJEKTIONSLOSUNG * TRACRIUM 5 ML INJEKTIONSLOSUNG * ATRACURIUM BESYLATE, 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

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
ATRACURIUM BESYLATE	ATRACURIUM BESILATE ATRACURIUM DIBESYLATE 2,2'-(1,5-PENTANEDIYLBIS(OXY(3-OXO-3,1 ((3,4-DIMETHOXYPHENYL)METHYL)-1,2,3, METHYLISOQUINOLINIUM) DIBENZENESULFONATE 2-(2-CARBOXYETHYL)-1,2,3,4-TETRAHYDF VERATRYLISOQUINOLINIUM BENZENESULFONATE PENTAMETHYLENE ESTER N,N'-DIMETHYL-N,N'-(4,10-DIOXA-3,11-DIO TETRAHYDROPAPAVERINIUM DIBESYLATE 2,2'-(3,11-DIOXO-4,10-DIOXATRIDECAMET DIMETHOXY-2-METHYL-1-VERATRYLISOC GR 31146B 33A74 BW-33A ATRACURIUM BESYLATE	64228-81-5	1

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
BENZENESULFONIC ACID	PHENYLSULFONIC ACID BESYLIC ACID OHS02640 RTECS DB4200000	98-11-3	< 0.2
Other components below reportable levels			>98.0

*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 Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Get medical advice/attention if you feel unwell.

Most important symptoms/effects, acute and delayed The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); changes in heart rate or pulse; changes in blood pressure.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

General information 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

Suitable extinguishing media Water fog. 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 Water runoff can cause environmental damage.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.

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. Prevent product from entering drains. 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 in original containers for re-use. For waste disposal, see section 13 of the MSDS.

Environmental precautions Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value
ATRACURIUM BESYLATE (CAS 64228-81-5)	15 MIN STEL	100 mcg/m3
	OHC	3

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

Appropriate engineering controls No special ventilation requirements.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection For prolonged or repeated skin contact use suitable protective gloves. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided.

Other Wear suitable protective clothing.

Respiratory protection No personal respiratory protective equipment normally required.

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 Solution.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH 3.2 - 3.7

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) 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 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 None known.

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 May be harmful if swallowed.

Inhalation Based on available data, the classification criteria are not met.

Skin contact None known.

Eye contact None known. Avoid contact with eyes.

Symptoms related to the physical, chemical and toxicological characteristics The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); changes in heart rate or pulse; changes in blood pressure.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test Results
ATRACURIUM BESYLATE (CAS 64228-81-5)		
Acute		
Inhalation		
LC50	Rat	> 15.4 mg/l
Oral		
Evident Toxicity	Rat	> 50 mg/kg
Subacute		
Other		
LOEL	Monkey	>= 0.5 mg/kg/day, 28 Day, subcutaneous injection, 0.25 mg twice/day
	Rat	>= 2.5 mg/kg/day, 14 Day, subcutaneous injection

* 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.

Corrosivity

ATRACURIUM BESYLATE
OECD 404
Result: Negative; not considered a significant irritant
Species: Rabbit

Irritation Corrosion - Skin

BENZENESULFONIC ACID
Acute dermal irritation; OECD 404
Result: Severely irritating.
Species: Rabbit

Serious eye damage/eye irritation Avoid contact with eyes.

Eye

BENZENESULFONIC ACID
OECD 405, Score 10 on a 1-10 scale.
Result: Severely irritant
Species: Rabbit

Respiratory sensitization Not available.

Skin sensitization Not established.

Sensitization

BENZENESULFONIC ACID
SAR / QSAR, DEREK, Lhasa, UK
Result: Negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

ATRACURIUM BESYLATE	Ames Result: Negative
BENZENESULFONIC ACID	Ames Result: Negative
ATRACURIUM BESYLATE	Cytogenetic Analysis In Vivo, bone marrow Result: Negative Species: Rat L5178Y mouse lymphoma thymidine kinase locus assay Result: Positive at cytotoxic concentrations
BENZENESULFONIC ACID	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Knowledge about carcinogenicity is incomplete.

BENZENESULFONIC ACID	SAR, DEREK, Lhasa, UK Result: Negative

Reproductive toxicity Due to lack of data the classification is not possible.

ATRACURIUM BESYLATE	>= 0.15 mg/kg/day Embryofetal Development, sub-cutaneous administration Result: Negative Species: Rabbit Embryofetal Development, sub-cutaneous administration Result: Negative Species: Rat

Specific target organ toxicity - single exposure Nervous system. Circulatory system.

Specific target organ toxicity - repeated exposure Not available.

Aspiration hazard Not available.

Further information None known.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
ATRACURIUM BESYLATE (CAS 64228-81-5)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	4000 mg/l, 3 hours, Nominal, OECD 209
	NOEC	Residential sludge	320 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	14 mg/l, 48 hours, Nominal, OECD 202
	NOEC	Water flea (Daphnia magna)	5.6 mg/l, 48 hours

* 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-aqueous)

ATRACURIUM BESYLATE	2.5 Days, pH 5 Buffer Solution Estimated

Hydrolysis

Half-life (Hydrolysis-neutral)

ATRACURIUM BESYLATE	6 Hours (based on similar material), pH 7 Buffer Solution

Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)

ATRACURIUM BESYLATE	-0.96 (calculated)

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international 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 a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

IMDG

Not regulated as a dangerous good.

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 This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

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	No
SARA 311/312 Hazardous chemical	No
NFPA ratings	Health: 2 Flammability: 1 Instability: 0
HMIS® ratings	Health: 2* Flammability: 1 Physical hazard: 0

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.
Food and Drug Administration (FDA)	Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

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)	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)	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 11-29-2013

Revision date 11-29-2013

Version # 08

Further information HMIS® is a registered trade and service mark of the NPCA.

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: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Ecological Information: GSK Environmental Hazard Assessment Concentration
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: United States