

SAFETY DATA SHEET

1. Identification

Product identifier	NIMBEX
Other means of identification	Not available.
Synonym(s)	NIMBEX FORTE * NIMBEX INJECTION 2 MG/ML * NIMBEX INJECTION 5 MG/ML * NIMBEX INJECTION 10 MG/ML * NIMBIUM INJECTION * CIS-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	%
CIS-ATRACURIUM BESYLATE	51W89 (1R,1'R,2R,-2'R)-2,2'-(3,11-DIOXO-4,10-DIO- BIS(1,2,3,4-TETRAHYDRO-6,7-DIMETHOXY VERATRYLISOQUINOLINIUM)DIBENZENES GW312012A 1627 (GW ACN) CIS-ATRACURIUM CISATRACURIUM BESYLATE		96946-42-8	0.2< 1.05

Other components below reportable levels

90 - 100

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

4. First-aid measures

Inhalation	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 thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Do not induce vomiting without advice from poison control center. Rinse mouth.

Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. 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	No specific antidotes are recommended. Provide general supportive measures and treat symptomatically. In case of shortness of breath, give oxygen. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
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. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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	Move containers from fire area if you can do so without risk.
Specific methods	Move container from fire area if it can be done without risk.

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	<p>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.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p>
Environmental precautions	<p>Never return spills in original containers for re-use. For waste disposal, see section 13 of the MSDS.</p> <p>Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.</p>

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. 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
CIS-ATRACURIUM BESYLATE (CAS 96946-42-8)	15 MIN STEL	100 mcg/m3
	OHC	2

Biological limit values

Appropriate engineering controls	No biological exposure limits noted for the ingredient(s).
	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. Provide eyewash station.

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.
Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	An occupational/industrial hygiene monitoring method has been developed for this material. 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

Physical state	Liquid.
Form	Liquid.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	3.3 - 3.8
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	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	May be harmful if swallowed.
Inhalation	Not established.
Skin contact	Not established. May be irritating to the skin.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. 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.
CIS-ATRACURIUM BESYLATE	

Read across, Data for atracurium besylate
Result: Harmful if swallowed

Components	Species	Test Results
CIS-ATRACURIUM BESYLATE (CAS 96946-42-8)		
Acute		
<i>Other</i>		
NOAEL	Rat	2 mg/kg, subcutaneous injection
Subacute		
<i>Other</i>		
LOEL	Rabbit	2.5 mg/kg/day, subcutaneous injection, d6-10 of pregnancy
NOAEL	Dog	2 mg/kg, 3 weeks, subcutaneous injection, twice/week
	Monkey	3.75 mg/kg, 3 weeks, subcutaneous injection, twice/week

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

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
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Corrosivity

CIS-ATRACURIUM BESYLATE	SAR / QSAR, Data for cis-atracurium besylate Result: Negative; not considered a significant irritant Species: Rabbit
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Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
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Eye

CIS-ATRACURIUM BESYLATE	Data from cis-atracurium besylate
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Respiratory sensitization	Not established.
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Skin sensitization	Not established.
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Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
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CIS-ATRACURIUM BESYLATE	Ames Result: Negative Chromosomal aberration assay Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay Result: Positive in vivo cytogenetics assay Result: Negative Species: Rat
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Carcinogenicity	Not classifiable as to carcinogenicity to humans.
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Reproductive toxicity	Knowledge about health hazard is incomplete.
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CIS-ATRACURIUM BESYLATE	5 mg/kg/day Embryofetal Development Result: Maternal toxicity; Foetal NOAEL Species: Rabbit
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Specific target organ toxicity - single exposure	Nervous system.
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Specific target organ toxicity - repeated exposure	None known.
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Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
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Chronic effects

Prolonged inhalation may be harmful.

12. Ecological information**Ecotoxicity**

Components	Species	Test Results
CIS-ATRACURIUM BESYLATE (CAS 96946-42-8)		
Aquatic		
Acute		
Activated Sludge Respiration	IC50	Residential sludge > 4000 mg/l, 3 hours, Nominal, OECD 209
	NOEC	Residential sludge 320 mg/l
Crustacea	EC50	Water flea (Daphnia magna) 14 mg/l, 48 hours, Nominal, OECD 202
	NOEC	Water flea (Daphnia magna) 5.6 mg/l
Microtox	MIC	Azotobacter chroococcum 300 mg/l
		Chaetomium globosum > 1000 mg/l
		Pseudomonas fluorescens > 1000 mg/l
Other	MIC	Anabaena flos-aquae > 1000 mg/l
		Aspergillus clavatus > 1000 mg/l
		Bacillus megaterium > 1000 mg/l
		Penicillium canescens > 1000 mg/l

* 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)**

CIS-ATRACURIUM BESYLATE

2.45 Days Measured, pH 5 Buffer Solution

UV/visible spectrum wavelength

CIS-ATRACURIUM BESYLATE

280 nm

Hydrolysis**Half-life (Hydrolysis-acidic)**

CIS-ATRACURIUM BESYLATE

19 Days Measured

Half-life (Hydrolysis-basic)

CIS-ATRACURIUM BESYLATE

< 4 Minutes Measured

Half-life (Hydrolysis-neutral)

CIS-ATRACURIUM BESYLATE

6.4 Hours Measured

Bioaccumulative potential

No data available.

Partition coefficient n-octanol / water (log Kow)

CIS-ATRACURIUM BESYLATE

-2.3

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. 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
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SARA 302 Extremely hazardous substance	No
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SARA 311/312 Hazardous chemical	No
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NFPA ratings	Health: 2 Flammability: 0 Instability: 0
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HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
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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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Food and Drug Administration (FDA)	Not regulated.
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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

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

Issue date	11-28-2013
Revision date	11-28-2013
Version #	09
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 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.
Revision Information	Fire-fighting measures: Unsuitable extinguishing media Regulatory Information: United States Other information, including date of preparation or last revision: Further information