SAFETY DATA SHEET

1. Identification

Product identifier **MIVACRON INJECTION**

Other means of identification

Synonyms MIVACRON 2 MG/ML INJECTION * MIVACRON 10 MG/5 ML INJEKTIONSLOSUNG * MIVACRON 20 MG/10 ML INJEKTIONSLOSUNG * MIVACURIUM CHLORIDE, 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	%
MIVACURIUM CHLORIDE	1090U81 DICHLORIDE * (R)-1,2,3,4-TETRAHYDRO-2-(3-HYDROXYPROPYL)-6,7-DIMETHOXY-2-METHYL-1-(3,4,5-TRIMETHOXYBENZYL)ISOQUINOLINIUM CHLORIDE, (E)-4-OCTENEDIOATE (2:1) * MVCD * MVCE * GW297632A * 1609 (GW ACN)	106861-44-3	0.22
HYDROCHLORIC ACID	HYDROCHLORIC ACID SOLUTIONS * RTECS MW4025000 * MURIATIC ACID * AQUEOUS HYDROGEN CHLORIDE * CHLOROHYDRIC ACID * HCL	7647-01-0	0.01
Other components below reportable levels			99.77

*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. If breathing is difficult, trained personnel should give oxygen. 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 The following adverse effects have been noted with therapeutic use of this material: interference with control of muscle contraction; flushing.

Indication of immediate medical attention and special treatment needed 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 Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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 Foam. Dry chemical powder. Carbon dioxide (CO2). Water.

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 No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

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.

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
MIVACURIUM CHLORIDE (CAS 106861-44-3)	15 MIN STEL	500 mcg/m3

GSK

Components	Type	Value
	OHC	2

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

Components	Type	Value
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	7 mg/m3
		5 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	2 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	7 mg/m3
		5 ppm

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

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.

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Skin protection

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. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

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 Vial.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH 4.5 - 6.5

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	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 cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	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. 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: interference with control of muscle contraction; flushing.

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
HYDROCHLORIC ACID (CAS 7647-01-0)		
Acute		
Inhalation		
LC50	Mouse	1108 ppm, 1 Hours
	Rat	3124 ppm, 1 Hours
LCL0	Guinea pig	4416 ppm, 30 minutes
	Human	3000 ppb, 5 minutes
		1300 ppm, 30 minutes
	Rabbit	4416 ppm, 30 minutes
NOEL	Human	<= 1.8 ppm, 45 minutes No effect on respiratory function in asthmatics.

Components	Species	Test Results
Oral		
LD50	Rabbit	900 mg/kg
	Rat	700 mg/kg
Chronic		
Inhalation		
LOAEL	Rat	10 ppm, 128 weeks
Subacute		
Oral		
LD	Rat	34.1 mg/kg/day, 9 weeks
LOEL	Rat	10.2 mg/kg/day, 9 weeks
Subchronic		
Inhalation		
LOEC	Rat	10 ppm, 3 months Inflammation of lips and nasal cavity.
NOAEC	Rat	20 ppm, 3 months
MIVACURIUM CHLORIDE (CAS 106861-44-3)		
Acute		
Oral		
LD50	Rat	165 mg/kg
Subacute		
Other		
Evident Toxicity	Rat	> 0.8 mg/kg/day, 14 days 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

HYDROCHLORIC ACID	OECD 404 Result: Corrosive Species: Rabbit Test Duration: 1 Hours

Irritation Corrosion - Skin

MIVACURIUM CHLORIDE	SAR / QSAR, DEREK, Lhasa, UK Result: Plausible

Serious eye damage/eye irritation Health injuries are not known or expected under normal use.

Eye

HYDROCHLORIC ACID	OECD 405 Result: Corrosive effects/irritation Species: Rabbit
MIVACURIUM CHLORIDE	SAR / QSAR, DEREK, Lhasa, UK Result: Plausible

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization Not applicable.

Sensitization

MIVACURIUM CHLORIDE	SAR / QSAR, DEREK, Lhasa, UK Result: Plausible

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

Mutagenicity

HYDROCHLORIC ACID	<= 10 mmol/L Chromosomal Aberration Assay In Vitro, CHO cells, IUCLID Result: Positive
MIVACURIUM CHLORIDE	Ames Assay, GLP assay Result: Negative

Mutagenicity

HYDROCHLORIC ACID	Ames, IUCLID Result: Negative
MIVACURIUM CHLORIDE	Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Negative Cytogenetic Analysis In Vivo, bone marrow, GLP assay; maximum dose = 0.8 mg/kg, subcutaneous injection Result: Negative Species: Rat
HYDROCHLORIC ACID	E coli Pol-A repair assay, IUCLID Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay, IUCLID Result: Negative
MIVACURIUM CHLORIDE	Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Negative
HYDROCHLORIC ACID	Yeast Mutation Assay, IUCLID Result: Negative

Carcinogenicity Not classifiable as to carcinogenicity to humans.

HYDROCHLORIC ACID	10 ppm Inhalation Result: Negative Species: Rat Observation Period: 128 months Notes: IUCLID
MIVACURIUM CHLORIDE	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

IARC Monographs. Overall Evaluation of Carcinogenicity

HYDROCHLORIC ACID (CAS 7647-01-0) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Reproductivity

HYDROCHLORIC ACID	302 ppm Embryo-foetal development, IUCLID Result: Maternal toxicity, resorptions, foetal malformations. Species: Rat
MIVACURIUM CHLORIDE	Embryo-foetal development - Subcutaneous Result: NOAEL = 0.5 mg/kg/day, subcutaneous (maximum dose); no adverse maternal or foetal effects Species: Mouse Embryo-foetal development - Subcutaneous Result: NOAEL = 0.8 mg/kg/day, subcutaneous (maximum dose); no adverse maternal or foetal effects Species: Rat

Specific target organ toxicity - single exposure Nervous system.

HYDROCHLORIC ACID Result: Respiratory irritation/corrosion.

Specific target organ toxicity - repeated exposure Not established.

Aspiration hazard Not likely, due to the form of the product.

Further information Caution - Pharmaceutical agent.

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
MIVACURIUM CHLORIDE (CAS 106861-44-3)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours OECD 209

Components		Species	Test Results
Crustacea	EC50	Water flea (Daphnia magna)	600 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	300 mg/l, 48 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

UV/visible spectrum wavelength

MIVACURIUM CHLORIDE 202 nm, pH 2-11

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

MIVACURIUM CHLORIDE < 36 %, 45 days

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

MIVACURIUM CHLORIDE 0.015

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

MIVACURIUM CHLORIDE 4.26 - 4.5, pH 4.9-8.2

Mobility in general Not available.

Volatility

Henry's law

MIVACURIUM CHLORIDE 0 atm m^3/mol Calculated

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)

HYDROCHLORIC ACID (CAS 7647-01-0) Listed.

SARA 304 Emergency release notification

HYDROCHLORIC ACID (CAS 7647-01-0) 5000 LBS

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

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity	Threshold planning quantity	Threshold planning quantity, lower value	Threshold planning quantity, upper value
HYDROCHLORIC ACID	7647-01-0	5000	500 lbs		

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

HYDROCHLORIC ACID (CAS 7647-01-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

HYDROCHLORIC ACID (CAS 7647-01-0)

Safe Drinking Water Act (SDWA) Not regulated.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2)

HYDROCHLORIC ACID (CAS 7647-01-0)

DEA Essential Chemical Code Number

HYDROCHLORIC ACID (CAS 7647-01-0) 6545

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

HYDROCHLORIC ACID (CAS 7647-01-0) 20 %WV

DEA Exempt Chemical Mixtures Code Number

HYDROCHLORIC ACID (CAS 7647-01-0) 6545

US state regulations

US. Massachusetts RTK - Substance List

HYDROCHLORIC ACID (CAS 7647-01-0)

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

HYDROCHLORIC ACID (CAS 7647-01-0)

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

HYDROCHLORIC ACID (CAS 7647-01-0)

US. Rhode Island RTK

HYDROCHLORIC ACID (CAS 7647-01-0)

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

Country(s) or region	Inventory name	On inventory (yes/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 08-14-2014

Revision date 08-14-2014

Version # 07

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.

Revision Information
Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Toxicological Information:
Ecological Information: GSK Environmental Hazard Assessment Concentration
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: United States
GHS: Classification