Mivacurium chloride (cas 106861-44-3) MSDS

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material MIVACRON INJECTION

MIVACRON 2 MG/ML INJECTION * MIVACRON 10 MG/5 ML

Synonyms
INJEKTIONSLOSUNG * MIVACRON 20 MG/10 ML INJEKTIONSLOSUNG * MIVACURIUM CHLORIDE, FORMULATED PRODUCT

GliaxSmithKline, Corporate Environment, Health & Safety

Company Name
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Information and Advice: US number, available 24 hours
Multi-language response

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US General Information: +1-888-825-5249
Transport Emergency (non EU) +1-703-527-3887

US number, available 24 hours
Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Percentage
Ingredients CAS RN
MIVACURIUM CHLORIDE 0.22
106861-44-3

NON-HAZARDOUS INGREDIENTS 99.78
Unassigned

3. HAZARDS IDENTIFICATION

This product is classified as non-flammable.

Fire and Explosion
Health Caution - Pharmaceutical agent.
Exposure might occur via skin; eyes.
Pharmacological effects may occur following skin absorption.
Health effects information is based on hazards of components.
Environment No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES
**Ingestion**

Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

**Inhalation**

Physical form suggests that risk of inhalation exposure is negligible.

**Skin Contact**

Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

**Eye Contact**

Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

**NOTES TO HEALTH PROFESSIONALS**

**Medical Treatment**

Medical treatment in cases of overexposure should be treated as an overdose of neuromuscular blocking agent. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

**Medical Conditions**

None for occupational exposure.

**Caused or Aggravated by Exposure**

Antidotes

No specific antidotes are recommended.

**5. FIRE-FIGHTING MEASURES**

**Fire and Explosion**

Not expected for the product, although the packaging is combustible.

**Hazards**

Extinguishing Media

No special requirements needed.

Special Firefighting For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

**Hazardous Combustion**

Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

**Products**

**6. ACCIDENTAL RELEASE MEASURES**

**Personal Precautions**

Wear protective clothing and equipment consistent with the degree of hazard.

**Environmental Precautions**

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

**Clean-up Methods**

Collect and place it in a suitable, properly labelled container for recovery or disposal.

**Decontamination**

No specific decontamination or detoxification procedures have been identified for this product.

**Procedures**

**7. HANDLING AND STORAGE**

**HANDLING**

General Requirements

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**
MIVACURIUM CHLORIDE
INGREDIENT
2
GSK Occupational Hazard Category
GSK Occupational 500 mcg/m3 (15 MIN STEL) Exposure Limit
PERSONAL PROTECTIVE EQUIPMENT
Eye Protection Wear approved safety glasses with side shields if eye contact is possible.
Other Equipment or Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling. An eye wash station should be available.
Procedures

9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance
Solution.
Physical Form
4.5 to 6.5
pH of Aqueous Solutions

10. STABILITY AND REACTIVITY
Stability This product is expected to be stable.
Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION
Oral Toxicity Not expected to be toxic following ingestion.
Inhalation Toxicity No studies have been conducted.
Skin Effects Pharmacological effects may occur following skin absorption. Irritation is not expected following direct contact.
Eye Effects Direct contact with eyes might produce evidence of pharmacological effects. Irritation is not expected following direct contact with eyes.
Target Organ Effects No specific target organ effects have been identified.
Sensitisation Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Pharmacological Effects This product contains active ingredient(s) with the following activity: a muscle relaxant for use during anaesthesia.
Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION
Summary This material contains an active pharmaceutical ingredient that has had limited testing and no adverse environmental effects were observed in the tests conducted. Until there is additional testing to determine other potential adverse effects on the environment, appropriate precautions should be taken to limit release of this compound to the environment. Local regulations and procedures should be consulted prior to environmental release.
Specific information on the active pharmaceutical ingredient is provided below:
ECOTOXICITY
Aquatic
Activated Sludge This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
Respiration
IC50: > 1000 mg/l, 3 Hours, Activated sludge
* Daphnid This material contains an active pharmaceutical ingredient that is not toxic to daphnids.
EC50: 600 mg/l, 48 Hours, Daphnia magna, Static test
NOEL: 300 mg/l, 48 Hours, Daphnia magna, Static test

**MOBILITY**

**Solubility** This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

**Volutility** This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant 1.00E-16 atm m³/mol, Calculated

**Adsorption** This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. It may persist in soil or sediment if released directly to the environment.

**Soil Sediment Sorption** 4.26 to 4.5 at pH 4.9 to 8.2 (log Koc):

**Partitioning** This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

**PERSISTENCE/DEGRADATION**

**Photolysis** This material contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation.

UV/Visible Spectrum: 202 nm at pH 2 to 11

**Biodegradation** This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Ready

Percent Degradation: 2 %, 28 days, Sturm test, Activated sludge

Aerobic - Soil

Percent Degradation: < 36 %, 45 days

**BIOACCUMULATION** This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

13. DISPOSAL CONSIDERATIONS

SDS Number 123470 Approved/Revised 03-Apr-2007 Version 5

**MIVACRON INJECTION**

Material

Disposal Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

**UN Classification and Labelling**

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

**EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.


Classification This product is classified as hazardous according to the OSHA Hazard
Communication Standard.
Other US Regulations
TSCA Status Exempt

16. OTHER INFORMATION
References GSK Hazard Determination
Date Approved/Revised 03-Apr-2007 SDS Version Number 5

SDS Sections Updated
Sections Subsections
IDENTIFICATION OF SUBSTANCE / PREPARATION AN OF COMPANY
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.