MAYNE ATRACURIUM BESYLATE

ChemWatch Material Safety Data Sheet
CHEMWATCH 59341
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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

MAYNE ATRACURIUM BESYLATE

STATEMENT OF HAZARDOUS NATURE

Not considered a hazardous substance according to OSHA 29 CFR 1910.1200.

SUPPLIER

Mayne Pharma (USA) Inc.
Mack Cali Centre II
650 From Rd.
Paramus, NJ 07652
USA
Phone: 1.888.606.2245
E-mail: medicalinformation@us.maynepharma.com

HAZARD RATINGS

Flammability: 1

Toxicity: 1

Body Contact: 0

Reactivity: 0

Chronic: 2

SCALE: Min/Nil=0 Low=1 Moderate=2 High=3 Extreme=4

PRODUCT USE

Neuromuscular blocking agent used as intermediate-duration, non- depolarising, skeletal muscle relaxant. Administered by intravenous injection. Used as an adjunct to general anaesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. WARNINGS: Should be used only by those skilled in the management of artificial respiration and only when facilities are instantly available for endotracheal intubation and for providing adequate ventilation of the patient, including the administration of oxygen under positive pressure and the elimination of carbon dioxide. The clinician must be prepared to assist or control respiration and anticholinesterase reversal agents should be immediately available. Atracurium besylate has the potential to cause histamine release and therefore there is a possibility of life threatening anaphylactic reactions. It is therefore essential that appropriate resuscitative equipment be immediately available. Do not give by intramuscular administration.

SYNONYMS

C53H72N2O12.2C6H5O3S Tracrium
muscle relaxant

Section 2 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
atracurium besylate	64228-81-5	>98

Section 3 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW

RISK

Cumulative effects may result following exposure*.
Possible skin sensitizer*.
* (limited evidence).

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Although ingestion is not thought to produce harmful effects the material, may still be damaging to the health of the individual following ingestion, especially where pre-existing organ(e.g. liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality (death) rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

EYE

Although the material is not thought to be an irritant, direct contact with the eye may produce transient discomfort characterized by tearing or conjunctival redness (as with windburn).

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good

hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

INHALED

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

CHRONIC HEALTH EFFECTS

Danger of cumulative effects.
Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population.

Principal routes of exposure are by accidental skin and eye contact and inhalation of generated dusts.
Exposure to small quantities may induce hypersensitivity reactions characterized by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic edema), running nose (rhinitis) and blurred vision . Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur. An individual may be predisposed to such anti-body mediated reaction if other chemical agents have caused prior sensitization (cross-sensitivity).
Although atracurium besylate is a less potent histamine releaser than d-tubocurarine, in common with most neuromuscular blocking agents the potential exists for histamine release in susceptible patients. Adverse reactions include skin flushing, transient hypotension, hypertension, tachycardia, bradycardia, bronchospasm and anaphylactoid reactions.

Section 4 - FIRST AID MEASURES

SWALLOWED

If poisoning occurs, contact a doctor or Poisons Information Center.
Poison Information Centres in each State capital city can provide additional assistance.

EYE

· If this product comes in contact with the eyes:
· Immediately hold the eyes open and wash with fresh running water.
· Ensure irrigation under the eyelids by occasionally lifting upper and lower lids.
· If pain persists or recurs seek medical attention.

· Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If product comes in contact with the skin:
· Immediately remove all contaminated clothing, including footwear (after rinsing with water).
· Wash affected areas thoroughly with water (and soap if available).
· Seek medical attention in event of irritation.

INHALED

· If fumes or combustion products are inhaled:
· Remove to fresh air.
· Lay patient down. Keep warm and rested.
· If breathing is shallow or has stopped, ensure clear airway and apply resuscitation. Transport to hospital, or doctor.

Section 5 - FIRE FIGHTING MEASURES

Flash Point (°F): Not applicable
Lower Explosive Limit (%): Not available
Upper Explosive Limit (%): Not available.
Autoignition Temp (°F): Not available

EXTINGUISHING MEDIA

Water spray or fog.
Foam.
Dry chemical powder.
BCF (where regulations permit).
Carbon dioxide.

FIRE FIGHTING

Alert Emergency Responders and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. Use water delivered as a fine spray to control fire and cool adjacent area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Solid which exhibits difficult combustion or is difficult to ignite.
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space. Dust may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion.
· Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
· Build-up of electrostatic charge may be prevented by bonding and grounding.
· Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
Combustion products include carbon dioxide (CO_2) , nitrogen oxides (NOx) and sulfur oxides (SOx)

FIRE INCOMPATIBILITY

Avoid contamination with strong oxidizing agents as ignition may result

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Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

· Remove all ignition sources.
· Clean up all spills immediately.
· Avoid contact with skin and eyes.
· Control personal contact by using protective equipment.
· Use dry clean up procedures and avoid generating dust.
· Place in a suitable labelled container for waste disposal.

MAJOR SPILLS

· Clean up all spills immediately.
· Wear protective clothing, safety glasses, dust mask, gloves.
· Secure load if safe to do so. Bundle/collect recoverable product.
· Use dry clean up procedures and avoid generating dust.
· Vacuum up.
· Water may be used to prevent dusting.
· Collect remaining material in containers with covers for disposal.
· Flush spill area with water.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

· Avoid generating and breathing dust
· Avoid contact with skin and eyes.
· Wear nominated personal protective equipment when handling.
· Use in a well-ventilated area.
· Use good occupational work practices.
· Observe manufacturer's storing and handling recommendations.

RECOMMENDED STORAGE METHODS

Packaging as recommended by manufacturer.
Check that containers are clearly labele
Plastic container

STORAGE REQUIREMENTS

· Store in original containers.
· Keep containers securely sealed.
· No smoking, naked lights or ignition sources.
· Store in a cool, dry, well-ventilated area.
· Store away from incompatible materials and foodstuff containers.
· Protect containers against physical damage and check regularly for leaks.
· Observe manufacturer's storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

No exposure limits set by NOHSC or ACGIH

PERSONAL PROTECTION



EYE

No special equipment needed when handling small quantities of substance.
For bulk handling wear:
Chemical goggles or

Face shield.

HANDS/FEET

Rubber gloves
PVC gloves
Protective shoe covers
Head covering.

OTHER

No special equipment when handling small quantities of substance otherwise:
Coveralls
For Emergencies:
Vinyl suit
Safety shower

RESPIRATOR

High Efficiency Dust Respirator (P2, P3)
For non-routine emergencies wear full face mask self-contained breathing apparatus.

ENGINEERING CONTROLS

Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.
Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.
The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.
Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the

"capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Mixes with water.

Molecular Weight: 1243.49
Boiling Range (°F): Not available
Melting Range (°F): 185 - 194
Specific Gravity (water=1): Not available
Solubility in water (g/L): Miscible
pH (as supplied): Not applicable
pH (1% solution): Not available
Vapor Pressure (kPa): Negligible
Volatile Component (%vol): Negligible
Evaporation Rate: Not applicable
Relative Vapor Density (air=1): >1
Flash Point (°F): Not applicable
Lower Explosive Limit (%): Not available
Upper Explosive Limit (%): Not available.
Autoignition Temp (°F): Not available
Decomposition Temp (°F): Not available
State: Divided solid

APPEARANCE

Off-white freeze dried powder; soluble in water.

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

· Presence of incompatible materials.
· Product is considered stable.
· Hazardous polymerization will not occur.

STORAGE INCOMPATIBILITY

Avoid storage with oxidizers
Be sure container is tightly closed when not in use.

Section 11 - TOXICOLOGICAL INFORMATION

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atracurium besylate

No significant acute toxicological data identified in literature search.

Section 12 - ECOLOGICAL INFORMATION

Section 13 - DISPOSAL CONSIDERATIONS

US EPA Waste Number & Descriptions

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.
· Recycle wherever possible. Special hazard may exist - specialist advice may be required.
· Consult manufacturer for recycling options.
· Consult Waste Management Authority for disposal.
· Bury or incinerate residue at an approved site.
· Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
· Puncture containers to prevent re-use and bury at an authorized landfill.

Section 14 - TRANSPORTATION INFORMATION

DOT Information
Shipping Name:
NONE
Hazard Class: None
UN/NA Number: None
Packing Group: None
Labels Required:
Additional Shipping Information:
International Transport Regulations:
IMO: None

Section 15 - REGULATORY INFORMATION

US Federal Regulations

A. General Product Information

In addition to Federal and State regulation, local regulations may apply. Check with your local regulatory authorities.

The substance (atracurium besylate) appears on the TSCA Inventory

B. Component Information
This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 455 Appendix A) SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4):

State Regulations

A. General Product Information
No component(s) require labeling under California Proposition 65

B. Component Information
The following components appear on one or more of the following state hazardous substance lists.

Component	CAS No	CA	FL	MA	MN	NJ	PA
atracurium besylate	64228-81-5	N	N	N	N	N	N

Other Regulations

A. General Product Information
Component listed in the European Inventory of New and Existing Chemical Substances (EINECS)
B. Component Information
CANADA
Component found on the Canadian Domestic Substances List.

Section 16 - OTHER INFORMATION

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