SAFETY DATA SHEET

1. Identification

Product identifier **ANECTINE INJECTION**

Other means of identification Not available.

Synonym(s) ANECTINE INJECTION 20MG/ML * ANECTINE INJECTION 50MG/ML * ANECTINE INJECTABLE * SUXAMETHONIUM 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

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
SUXAMETHONIUM CHLORIDE	SUCCINYLCHOLINE CHLORIDE SCOLINE CHLORIDE SUCCINIC ACID BIS(BETA-DIMETHYLAMINOEHTYL) ESTER, DIHYDROCHLORIDE	71-27-2	2.3 -5.3
METHYL PARABEN	GR30517X METHYL P-HYDROXYBENZOATE P-HYDROXYBENZOIC ACID, METHYL ESTER 4-HYDROXYBENZOIC ACID, METHYL ESTER METHYL P-OXYBENZOATE METHYL PARAHYDROXYBENZOATE C8H8O3 OHS14677 RTECS DH2450000 NIPOGIN U124	99-76-3	0.1
Other components below reportable levels			>94.0

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

4. First-aid measures

Inhalation
In case of accident by inhalation: remove casualty to fresh air and keep at rest. If not breathing, give artificial respiration. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention immediately.

Skin contact
Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.

Eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion
Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed
May cause allergic respiratory reaction.

The following adverse effects have been noted with therapeutic use of this material: changes in heart rate or pulse; changes in blood pressure; respiratory depression; interference with control of muscle contraction; pain; salivation; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically. Symptoms may be delayed. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

General information
Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting respiratory symptoms and including respiratory function testing.
In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting respiratory conditions and other allergy symptoms.

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. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of vapors or mists. 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 entry into waterways, sewer, basements or confined areas. 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 discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
Avoid breathing mist or vapor. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

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

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
SUXAMETHONIUM CHLORIDE (CAS 71-27-2)	15 MIN STEL	100 mcg/m3	
	OHC	3	RESPIRATORY SENSITISER

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

Appropriate engineering controls 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.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed.

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 Use personal protective equipment as required.

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 Solution.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH Not available.

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	Health injuries are not known or expected under normal use. Prolonged inhalation may be harmful. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Avoid inhaling this material.
Skin contact	Health injuries are not known or expected under normal use. May be harmful in contact with skin.
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; respiratory depression; interference with control of muscle contraction; pain; salivation.

Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use. May be harmful if swallowed. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components	Species	Test Results
METHYL PARABEN (CAS 99-76-3)		
Acute		
Oral		
LD50	Mouse	> 8 g/kg
SUXAMETHONIUM CHLORIDE (CAS 71-27-2)		
Acute		
Oral		
	Mouse	125 mg/kg
Other		
	Mouse	0.43 mg/kg, Intravenous route
	Rabbit	0.24 mg/kg, Intravenous route

* 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.

Irritation Corrosion - Skin

SUXAMETHONIUM CHLORIDE	SAR / QSAR, DEREK, Lhasa, UK Result: Positive

Serious eye damage/eye irritation	Avoid contact with eyes.

Eye

SUXAMETHONIUM CHLORIDE	SAR / QSAR, DEREK, Lhasa, UK Result: Positive; potential irritant

Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization	Not established.

Sensitization

SUXAMETHONIUM CHLORIDE	Clinical use Result: Anaphylaxis Species: Human Result: Cardiac anaphylaxis, induction of serum antibodies. Species: Guinea pig

Sensitization

SUXAMETHONIUM CHLORIDE	SAR / QSAR, DEREK, Lhasa, UK Result: Positive

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

SUXAMETHONIUM CHLORIDE	2.5 mg/kg Chromosomal Aberration Assay In Vivo, Intravenous dosing. Result: Positive Species: Mouse 2.5 mg/kg In vivo meiotic study, Intravenous dosing. Result: structural abnormalities, sperm head abnormalities. Species: Mouse Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Positive Clinical use, 100 mg - Intravenous dosing Result: Negative Species: Human Organ: Blood, lymphocytes

Carcinogenicity Knowledge about carcinogenicity is incomplete.

Reproductive toxicity Knowledge about health hazard is incomplete.

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

Specific target organ toxicity - repeated exposure Not established.

Aspiration hazard Not applicable.

Chronic effects Prolonged inhalation may be harmful.

Further information None known.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
SUXAMETHONIUM CHLORIDE (CAS 71-27-2)			
Aquatic			
Acute			
Algae	EC50	Algae	> 100 mg/l, 96 hours, QSAR Estimate
Crustacea	EC50	Daphnia	> 100 mg/l, 48 hours, QSAR Estimate
Fish	EC50	Fish	> 100 mg/l, 96 hours, QSAR Estimate

* 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.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SUXAMETHONIUM CHLORIDE	-8.16 (Calculated).
METHYL PARABEN	1.96

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. Dispose of contents/container in accordance with local/regional/national/international regulations.

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 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: 1
Flammability: 1
Instability: 0

HMIS® ratings

Health: 1
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)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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)	Yes
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 This material has not been assessed for HMIS or NFPA ratings. HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 1
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 1
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
Fire-fighting measures: Unsuitable extinguishing media
Regulatory Information: United States