SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	ANECTINE INJECTION
Registration number	-
Synonyms	ANECTINE INJECTION 20MG/ML * ANECTINE INJECTION 50MG/ML * ANECTINE INJECTABLE * SUXAMETHONIUM CHLORIDE, FORMULATED PRODUCT
Issue date	28-November-2013
Version number	09
Revision date	28-November-2013
Supersedes date	28-June-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information Not applicable.

2.3. Other hazards Caution - Pharmaceutical agent. This product is expected to be non-combustible.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
SUXAMETHONIUM CHLORIDE	2.3 -5.3	71-27-2 200-747-4	-	-	
Classification:	**DSD:** T;R23/24/25, R42				
	CLP: Acute Tox. 3;H301, Acute Tox. 3;H311, Acute Tox. 3;H331, Resp. Sens. 1;H334				
METHYL PARABEN	0.1	99-76-3 202-785-7	-	-	
Classification:	**DSD:** Xi;R36, R43				
	CLP: Skin Sens. 1;H317, Eye Irrit. 2;H319				

Other components below reportable levels >94.0

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Take off immediately all contaminated clothing. In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Wash contaminated clothing before reuse. 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.

4.1. Description of 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. For minor skin contact, avoid spreading material on unaffected skin.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do. Continue rinsing.

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

4.2. Most important symptoms and effects, both 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).

4.3. Indication of any immediate medical attention and special treatment needed 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. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards This product is expected to be non-combustible.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO_2).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Immediately evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Fully encapsulating, vapour protective clothing should be worn for spills and leaks with no fire. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of vapours or mists. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material 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 in original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Do not taste or swallow. Avoid breathing vapour. Avoid contact with skin. Avoid contact with eyes. Avoid prolonged exposure. Avoid contact with clothing. Use only outdoors or in a well-ventilated area. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Wash contaminated clothing before reuse.
7.2. Conditions for safe storage, including any incompatibilities	Store locked up. 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).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived No Effect Level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

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

General information	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Not normally needed.
Skin protection	
- 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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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.

Environmental exposure controls

Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Solution.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability Material is stable under normal conditions.

10.3. Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid Contact with incompatible materials.

10.5. Incompatible materials Strong oxidising agents.

10.6. Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion May be harmful if swallowed.

Inhalation Health injuries are not known or expected under normal use. Harmful if inhaled. 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 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.

11.1. 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 sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation Not established.

Sensitisation

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

Germ cell mutagenicity

Mutagenicity

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.

Mixture versus substance information Not available.

Other information None known.

SECTION 12: Ecological information

12.1. Toxicity 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.

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

METHYL PARABEN	1.96
SUXAMETHONIUM CHLORIDE	-8.16 (Calculated).

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil No data available.

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste 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.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information 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.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Read safety instructions, SDS and emergency procedures before handling.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations	Young people under 18 years old are not allow to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R20/21/22 Harmful by inhalation, in contact with skin and if swallowed. R23/24/25 Toxic by inhalation, in contact with skin and if swallowed. R36 Irritating to eyes. R42 May cause sensitization by inhalation. R43 May cause sensitization by skin contact. H301 Toxic if swallowed. H311 Toxic in contact with skin. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H331 Toxic if inhaled. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Revision information	SECTION 5: Firefighting measures: Unsuitable extinguishing media Regulatory Information: United States
Training information	Follow training instructions when handling this material.
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.