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	PENTOSTAM INJECTION
Registration number	-
Synonyms	PENTOSTAM INJECTION 100 MG/ML * PENTOSTAN INYECTABLE * STIBATIN INJECTION 100 MG/ML * SODIUM STIBOGLUCONATE, FORMULATED PRODUCT
Issue date	11-November-2013
Version number	07
Revision date	11-November-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 This product is non-flammable.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
SODIUM STIBOGLUCONATE	30 - < 40	16037-91-5 -	-	-	
Classification:	**DSD:** Xn;R20/22, N;R51/53				
	CLP: Acute Tox. 4;H302, Acute Tox. 4;H332, Aquatic Chronic 2;H411				
D-GLUCONIC ACID LACTONE CELL CULTURE TESTED	1 - < 3	90-80-2 202-016-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
SODIUM HYDROXIDE	1 - < 3	1310-73-2 215-185-5	-	011-002-00-6	
Classification:	**DSD:** C;R35				
	CLP: Skin Corr. 1A;H314				
4-CHLORO-M-CRESOL	< 0.2	59-50-7 200-431-6	-	604-014-00-3	
Classification:	**DSD:** Xn;R21/22, Xi;R41, R43, N;R50				
	CLP: Acute Tox. 4;H302, Acute Tox. 4;H312, Skin Sens. 1;H317, Eye Dam. 1;H318, Aquatic Acute 1;H400				
Other components below reportable levels	60 - < 70				

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 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.

4.1. Description of first aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate 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 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 Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. diarrhoea, anaemia and irritation.

4.3. Indication of any immediate medical attention and special treatment needed 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 non-flammable.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

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 Use standard firefighting procedures and consider the hazards of other involved materials. 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 Keep unnecessary personnel away. 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 Observe good industrial hygiene practices. No special control measures required for the normal handling of this product.

7.2. Conditions for safe storage, including any incompatibilities Store in original tightly closed container. 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
SODIUM STIBOGLUCONATE (CAS 16037-91-5)	OHC	2

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
SODIUM HYDROXIDE (CAS 1310-73-2)	STEL	2 mg/m3

Recommended monitoring procedures Follow standard monitoring procedures. A UK HSE Occupational Exposure Standard (OES) of 500 mcg/m3 (8hr TWA) has been established for antimony and antimony compounds.
A US OSHA Permissible Exposure Limit (PEL) of 500 mcg/m3 (8hr TWA) has been established for antimony and antimony compounds.

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	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Wear safety glasses with side shields (or goggles). (eg. EN 166) Eye wash fountain is recommended.
Skin protection	
- Hand protection	The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if no data are available and further guidance should be sought from your local safety department. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. (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. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

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	Liquid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	5.2 - 5.4
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

Percent volatile	67.6 % estimated

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.

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Harmful if inhaled.
Skin contact	May be irritating to the skin.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms	Adverse effects might occur in the following organ(s) following overexposure: Liver. Central nervous system. Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. and diarrhoea, anaemia, Irritation.

11.1. Information on toxicological effects

Acute toxicity	Harmful if inhaled. Harmful if swallowed.

Components	Species	Test results
4-CHLORO-M-CRESOL (CAS 59-50-7)		
Acute		
Oral		
LD50	Rat	1830 mg/kg
Subacute		
Oral		
NOAEL	Rat	400 mg/kg/day, 28 Day
Subchronic		
Oral		
NOAEL	Rat	150 ppm, 13 weeks, dietary study
SODIUM HYDROXIDE (CAS 1310-73-2)		
Acute		
Dermal		
LD50	Rabbit	1350 mg/kg
Oral		
LD50	Rat	104 - 340 mg/kg
SODIUM STIBOGLUCONATE (CAS 16037-91-5)		
Subacute		
Other		
	Human	> 500 mg/kg/day, Injected, every 3-7 days up to 5 doses

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	May be irritating to the skin.

Corrosivity

4-CHLORO-M-CRESOL	2 %, Literature data Result: Irritant Species: Human

Serious eye damage/eye irritation May be irritating to eyes.

Eye

4-CHLORO-M-CRESOL
0.1 %, Literature data
Result: Severe Irritant
Species: Rabbit

Respiratory sensitisation Due to lack of data the classification is not possible.

Skin sensitisation May be irritating to the skin.

Sensitisation

4-CHLORO-M-CRESOL
OECD 406 - Maximisation test, Literature data
Result: positive
Species: Guinea pig

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Mutagenicity

4-CHLORO-M-CRESOL
125 mg/kg In vivo Micronucleus, Intra-peritoneal injection.
Result: negative
Species: Mouse
Organ: Bone marrow
Ames
Result: Equivocal
HPRT gene mutation in human lymphocytes
Result: negative

SODIUM STIBOGLUCONATE
SAR / QSAR
Result: negative

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

4-CHLORO-M-CRESOL
104 mg/kg/day, Literature data
Result: NOAEL for renal necrosis and fibrosis
Species: Rat

Reproductive toxicity Due to inconclusive data the classification criteria are not met.

Reproductive toxicity

Reproductivity

SODIUM STIBOGLUCONATE
300 - 900 mg/kg/day Embryofetal Development, No maternal Toxicity, embryolethality and increased incidence of atlas bone abnormality (spontaneous at low frequencies in rat test species) noted
Result: Fetal lethality
Species: Rat
Teratogenicity, Chicks, rats, mice and sheep
Result: negative

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure. Central nervous system. Liver.

SODIUM STIBOGLUCONATE
Epidemiology, Overexposure
Species: Human
Organ: Central nervous system
Epidemiology, Overexposure
Species: Human
Organ: Liver

Aspiration hazard Not available.

Mixture versus substance information No information available.

Other information Not available.

SECTION 12: Ecological information

12.1. Toxicity No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test results
SODIUM HYDROXIDE (CAS 1310-73-2)			
Aquatic			
Acute			
Fish	EC50	Mosquito fish (Adult Gambusia affinis)	125 mg/l, 96 hours, Static test

Components	Species	Test results
	Rainbow trout (Adult Oncorhyncus mykiss)	45.4 mg/l, 96 hours, Static test

* Estimates for product may be based on additional component data not shown.

12.2. Persistence and degradability Not available.

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

4-CHLORO-M-CRESOL	2.78 - 3.1 3.1
SODIUM STIBOGLUCONATE	-0.402 (Calculated).

12.4. Mobility in soil Not available.

Mobility in general Not 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.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN3082
14.2. UN proper shipping name	Environmentally hazardous substances, liquid, n.o.s. (SODIUM STIBOGLUCONATE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	Yes
Tunnel code	Not available.
Labels required	9
Additional information:	
Special Provisions	8, 146, 335, IB3, T4, TP1, TP29

IATA

14.1. UN number	UN3082
14.2. UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (SODIUM STIBOGLUCONATE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
Labels required	9
Additional Information:	
Passenger & cargo	Allowed.
Packaging Instruction	964
Pkg Inst cargo only	964
Pkg Inst pasenger & cargo	Y964
LQ	
SP See 44	A97,A158
Max net qty pkg	450 L

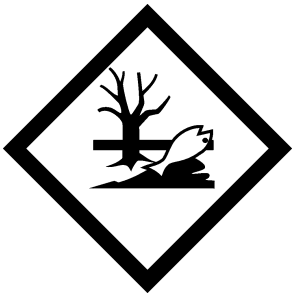
Max net qty pkg cargo only	450 L
Max net qty pkg LQ	30 kg G

IMDG

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SODIUM STIBOGLUCONATE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	No
Labels required	9
EmS	F-A, S-F
14.6. Special precautions for user	Not available.
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.

ADR; IATA; IMDG

Marine pollutant



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

4-CHLORO-M-CRESOL (CAS 59-50-7)
SODIUM HYDROXIDE (CAS 1310-73-2)

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

4-CHLORO-M-CRESOL (CAS 59-50-7)
SODIUM HYDROXIDE (CAS 1310-73-2)

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	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	R20/22 Harmful by inhalation and if swallowed. R21/22 Harmful in contact with skin and if swallowed. R35 Causes severe burns. R36/38 Irritating to eyes and skin. R41 Risk of serious damage to eyes. R43 May cause sensitization by skin contact. R50 Very toxic to aquatic organisms. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H302 Harmful if swallowed. H312 Harmful in contact with skin. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H332 Harmful if inhaled. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients EXPOSURE CONTROLS/PERSONAL PROTECTION: Physical & Chemical Properties: Transport Information: Product Shipping Name/Packing Group Regulatory Information: United States GHS: Classification
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.