



SAFETY DATA SHEET

1. Identification

Product identifier ENGERIX-B

Other means of identification

Synonyms

ENERGIX B ADULT INJECTION 20 MCG/ML * ENGERIX B PAEDIATRIC INJECTION 10 MCG/0.5 ML * HEPATITIS B SURFACE ANTIGEN VACCINE * HEPATITIS B (RECOMBINANT DNA) VACCINE (ADSORBED)

Recommended use of the chemical and restrictions on use

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.

Restrictions on use

No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia

Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
ALUMINIUM HYDROXIDE	21645-51-2	1
AF 260		
ALCOA 331		
ALCOA C 30BF		
ALUMIGEL		
ALUMINA HYDRATED		
ALUMINA TRIHYDRATE		
ALPHA-ALUMINA TRIHYDRATE		
ALUMINIC ACID		
ALUMINIUM HYDROXIDE		
ALUMINUM HYDRATE		
ALUMINUM(III) HYDROXIDE		
ALUMINUM HYDROXIDE GEL		
ALUMINUM OXIDE TRIHYDRATE		
ALUMINUM TRIHYDRATE		
ALUMINUM TRIHYDROXIDE		
ALUSAL		
AMBEROL ST 140F		
AMPHOJEL		
BACO AF 260		
BRITISH ALUMINUM AF 260		
C 31		
C 33		
C 31C		
C 4D		
C 31F		
C-31-F		
C.I. 77002		
GHA 331		
GHA 332		
H 46		
HIGILITE		
HIGILITE H 32		
HIGILITE H 42		
HIGILITE H 31S		
HYCHOL 705		
HYDRAL 705		
HYDRAL 710		
HYDRATED ALUMINA		
LIQUIGEL		
MARTINAL		
P 30BF		
PGA		
TRIHYDRATED ALUMINA		
TRIHIDROXYALUMINUM		
DISODIUM HYDROGEN PHOSPHATE	7558-79-4	1
DISODIUM HYDROGEN ORTHOPHOSPHATE		
PHOSPHORIC ACID, DISODIUM SALT		
DIBASIC SODIUM PHOSPHATE		
DISODIUM MONOHYDROGEN PHOSPHATE		
DSP		
EXSICCATED SODIUM PHOSPHATE		
SODA PHOSPHATE		
DISODIUM PHOSPHORIC ACID		
SODIUM MONOHYDROGEN PHOSPHATE		
DISODIUM ACID ORTHOPHOSPHATE		
DISODIUM HYDROPHOSPHATE		
HYDROGEN DISODIUM PHOSPHATE		
DISODIUM HYDROGEN PHOSPHATE ANHYDROUS		
SODIUM PHOSPHATE DIBASIC		
DISODIUM PHOSPHATE		
Trisodium phosphate		
HEPATITIS B VIRUS SURFACE ANTIGEN	Unassigned	<1

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT	54-64-8	0.1
MERCURATE(1-), ETHYL(2-MERCAPTOBENZOATE(2-)-O,S)-, SODIUM MERCURY, ETHYL(HYDROGEN O-MERCAPTOBENZOATO)-, SODIUM SALT ETHYLMERCURITHIOSALICYLIC ACID, SODIUM SALT SODIUM ETHYLMERCURITHIOSALICYLATE MERCUROTHIOLATE MERTHIOLATE SODIUM THIMEROSAL		

Other components below reportable levels

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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.

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

4. First-aid measures

Description of necessary first aid measures

Inhalation	In case of accident by inhalation: remove casualty to fresh air and keep at rest. Move to fresh air. If not breathing, give artificial respiration. Oxygen or artificial respiration if needed. If breathing is difficult, trained personnel should give oxygen. 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 if symptoms occur.
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance.

Personal protection for first-aid responders Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Take off contaminated clothing and shoes immediately. IF exposed or concerned: Get medical advice/attention.

Symptoms caused by exposure None known.

Medical attention and special treatment 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.

5. Fire-fighting measures

Extinguishing media

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 fire fighters Wear suitable protective equipment. 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.

Hazchem Code Not available.

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. For personal protection, see section 8.
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For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.
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. 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.
Other issues relating to spills and releases	Clean up in accordance with all applicable regulations.

7. Handling and storage

Precautions for safe handling	Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid exposure - obtain special instructions before use. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin. Avoid contact with eyes. Avoid prolonged exposure. Observe good industrial hygiene practices. When using do not eat or drink. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	CAUTION Avoid exposure - obtain special instructions before use. Keep away from heat, sparks and open flame. Store in original tightly closed container. Keep away from food, drink and animal feeding stuffs. Keep out of the reach of children. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters

Occupational exposure limits

GSK

Components

Type

Value

DISODIUM HYDROGEN
PHOSPHATE (CAS
7558-79-4)

8 HR TWA

5000 mcg/m3

OHC

1

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components

Type

Value

ETHYLMERCURITHIOSALI
CYLIC ACID SODIUM SALT
(CAS 54-64-8)

STEL

0.03 mg/m3

TWA

0.01 mg/m3

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components

Type

Value

ETHYLMERCURITHIOSALI
CYLIC ACID SODIUM SALT
(CAS 54-64-8)

STEL

0.03 mg/m3

TWA

0.01 mg/m3

US. ACGIH Threshold Limit Values

Components

Type

Value

Form

ALUMINIUM HYDROXIDE
(CAS 21645-51-2)

TWA

1 mg/m3

Respirable fraction.

ETHYLMERCURITHIOSALI
CYLIC ACID SODIUM SALT
(CAS 54-64-8)

STEL

0.03 mg/m3

TWA

0.01 mg/m3

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	4 mg/m ³	Inhalable dust.
		1.5 mg/m ³	Respirable dust.

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling time
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	20 µg/g	Total inorganic mercury	Creatinine in urine	*

* - For sampling details, please see the source document.

Exposure guidelines

Australia OELs: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Can be absorbed through the skin.
(CAS 54-64-8)

US ACGIH Threshold Limit Values: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Can be absorbed through the skin.
(CAS 54-64-8)

Appropriate engineering controls No special ventilation requirements.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection Wear safety glasses with side shields.

Skin protection

Hand protection Not normally needed.

Other No special protective equipment required.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not available.

Hygiene measures Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

Appearance

Physical state Liquid.
Form Vaccine.
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.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapour pressure Not available.

Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	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	Not available.
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. None under normal conditions.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on possible routes of exposure

Ingestion	Not established. Expected to be a low ingestion hazard.
Inhalation	Not established.
Skin contact	Not established.
Eye contact	Not established. Direct contact with eyes may cause temporary irritation.
Symptoms related to exposure	None known.

Acute toxicity	Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use.
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Components	Species	Test results
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)		
Acute		
Oral		
LD50	Rat	17 g/kg

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

Skin corrosion/irritation	Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use.
Serious eye damage/irritation	Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use.
Respiratory or skin sensitisation	
Respiratory sensitisation	Due to lack of data the classification is not possible.
Skin sensitisation	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

ALUMINIUM HYDROXIDE (CAS 21645-51-2) A4 Not classifiable as a human carcinogen.

Reproductive toxicity	Due to lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

Aspiration hazard Not available.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test results
ALUMINIUM HYDROXIDE (CAS 21645-51-2)			
Aquatic			
<i>Acute</i>			
Algae	NOEC	Green algae (Selenastrum capricornutum)	> 100 mg/l, 72 hours
Crustacea	NOEC	Water flea (Daphnia magna)	> 100 mg/l, 48 hours
Fish	NOEC	Brown trout (Adult Salmo trutta)	> 100 mg/l, 96 hours Static renewal test
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	252 mg/l

* 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 No data available.

Mobility in soil No data available.

Other adverse effects Not available.

13. Disposal considerations

Disposal methods Contract with a disposal operator licensed by the Law on Disposal and Cleaning. 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. Incinerate the material under controlled conditions in an approved incinerator. Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Dispose in accordance with all applicable regulations. When your own wastewater treatment plant is not available, collect entire waste and then charge to a licensed industrial waste management professional with manifests for industrial waste.

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). Avoid discharge into water courses or onto the ground.

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

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) For domestic use.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting., If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes., If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. in preparations for human external use For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once).

Australia Medicines & Poisons Appendix F

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) applies to all preparations in any concentration Strongly alkaline. Avoid contact with eyes., Avoid contact with skin.

Australia Medicines & Poisons Appendix G

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Mercury

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) for external use

Australia Medicines & Poisons Schedule 3

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) > 10

Australia Medicines & Poisons Schedule 4

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) in preparations for oral laxative use

Australia Medicines & Poisons Schedule 5

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 6

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) for non-domestic use. Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 7

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

Australia National Pollutant Inventory (NPI): Threshold quantity

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) 5 TONNES/YR Threshold Category: 1B

High Volume Industrial Chemicals (HVIC)

ALUMINIUM HYDROXIDE (CAS 21645-51-2)

10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting listETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT 2000 TONNES/YR Threshold Category: 2B
(CAS 54-64-8)**Prohibited Carcinogenic Substances**

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulationsThe 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.**Stockholm Convention**

Not applicable.

Rotterdam ConventionETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Pesticide
(CAS 54-64-8)**Kyoto protocol**

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
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**Issue date** 08-August-2014**Revision date** 08-August-2014**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

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: United States
GHS: Classification