



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** SYNFLORIX

**Other means of identification**

**Synonyms** PNEUMOCOCCAL CONJUGATE VACCINE (NON-TYPEABLE HAEMOPHILUS INFLUENZAE (NTHi) PROTEIN D, DIPHTHERIA OR TETANUS TOXOID CONJUGATES) ABSORBED

**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 phosphate	7784-30-7	0.1 - 1.5

Sodium chloride COMMON SALT HALITE ROCK SALT SODIUM MONOCHLORIDE Salt SEA SALT TABLE SALT SODIUM CHLORIDE (NaCl) CINa BULK INDUSTRIAL CRUDE SOLAR SALT, WHITE CRYSTALS, SOLAR OHS21105 RTECS VZ4725000 329 (GW ACN)	7647-14-5	0.1 - 1.5
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 18C CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN	Unassigned	<0.01
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 19F CONJUGATED TO DIPHTHERIA TOXOID CARRIER PROTEIN	Unassigned	<0.01
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPES 1,4,5,6B,7F,9V,14 AND 23F CONJUGATED TO NON-TYPEABLE HAEMOPHILUS INFLUENZAE (NTHi) PROTEIN D	Unassigned	<0.01
Other components below reportable levels		>95.0

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.

\*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).

## 4. First-aid measures

### Description of necessary first aid measures

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth thoroughly. Get medical advice/attention if you feel unwell. Do not induce vomiting.
<b>Personal protection for first-aid responders</b>	If you feel unwell, seek medical advice (show the label where possible). 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.
<b>Symptoms caused by exposure</b>	None known.
<b>Medical attention and special treatment</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

## 5. Fire-fighting measures

### Extinguishing media

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	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** 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.

<b>Hazchem Code</b>	Not available.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

<b>Environmental precautions</b>	Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
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<b>Methods and materials for containment and cleaning up</b>	Extinguish all flames in the vicinity.  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. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.
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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.

<b>Other issues relating to spills and releases</b>	Clean up in accordance with all applicable regulations.
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## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices. Use care in handling/storage. Handle and open container with care.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS). Do not freeze. Dispose of properly if frozen.

## 8. Exposure controls and personal protection

<b>Control parameters</b>	Follow standard monitoring procedures.
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### Occupational exposure limits

**GSK**  
Not established

### US. ACGIH Threshold Limit Values Components

Type	Value	Form
Aluminium phosphate (CAS 7784-30-7)	TWA	1 mg/m3 Respirable fraction.

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
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<b>Appropriate engineering controls</b>	No particular ventilation requirements. 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.
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### Individual protection measures, for example personal protective equipment (PPE)

<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
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#### Skin protection

<b>Hand protection</b>	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.
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#### Other

Wear suitable protective clothing.

<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.
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<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
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<b>Hygiene measures</b>	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.
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## 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	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions. DO NOT FREEZE - dispose of properly if frozen.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Do not freeze.
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	Expected to be a low ingestion hazard.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Symptoms related to exposure	None known.
Acute toxicity	Health injuries are not known or expected under normal use.

Components	Species	Test results
Sodium chloride (CAS 7647-14-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	3000 mg/kg

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

<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/irritation</b>	None known. Health injuries are not known or expected under normal use.
<b>Respiratory or skin sensitisation</b>	
<b>Skin sensitisation</b>	None known. This product is not expected to cause skin sensitisation.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.
<b>ACGIH Carcinogens</b>	
ALUMINUM PHOSPHATE (CAS 7784-30-7)	A4 Not classifiable as a human carcinogen.
<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction
<b>Specific target organ toxicity - single exposure</b>	None known.
<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not likely, due to the form of the product.
<b>Chronic effects</b>	Not expected to be hazardous by WHMIS criteria.
<b>Other information</b>	Caution - Pharmaceutical agent.

## 12. Ecological information

<b>Ecotoxicity</b>	Not expected to be harmful to aquatic organisms. The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
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Components	Species	Test results
Sodium chloride (CAS 7647-14-5)		
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EC50	Algae (Nitscheria linearis) 2430 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna) 3310 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus) 1295 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas) 6390 mg/l, 96 hours Static test
		Goldfish (Adult Carassius auratus) 7000 mg/l, 96 hours
		Mosquito fish (Adult Gambusia affinis) 17550 mg/l, 96 hours Static test

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

<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available for this product.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal methods</b>	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. 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.
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<b>Residual waste</b>	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). Not applicable.
<b>Contaminated packaging</b>	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

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

#### 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

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

#### 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**

SODIUM CHLORIDE (CAS 7647-14-5)

10 TONNES/YR Threshold Category: 1

**High Volume Industrial Chemicals (HVIC)**

Not listed.

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

Not listed.

**National Pollutant Inventory (NPI) substance reporting list**

Not listed.

**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 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. The product does not need to be labelled in accordance with EC directives or respective national laws.

**Stockholm Convention**

Not applicable.

**Rotterdam Convention**

Not applicable.

**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** 02-July-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.