

1. Identification

Product identifier**BOOSTRIX****Other means of identification****Synonyms**

BOOSTRIX DTPa * BOOSTRIX DTPa JERINGA * BOOSTRIX FERTIGSPRITZE * BOOSTRIX INJECTION * BOOSTRIX JERINGA PRELLENADA * BOOSTRIX PFS * BOOSTRIX SIRINGA PRERIEMPITA * BOOSTRIX Tdpa IMPFSTOFF ZUR AUFFRISCHUNG * REFORTRIX * DIPHTHERIA, TETANUS AND ACELLULAR PERTUSSIS ADSORBED VACCINE

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**

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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

Chemical name	Common name and synonyms	CAS number	%
ALUMINIUM HYDROXIDE	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 * TRIHYDROXYALUMINUM	21645-51-2	1
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	1
DIPHTHERIA TOXOID		Unassigned	<1
FILAMENTOUS HAEMAGGLUTININ		Unassigned	<1
PERTACTIN (69 KDA OUTER MEMBRANE PROTEIN-69K)		Unassigned	<1
PERTUSSIS TOXIN	HISTAMINE-SENSITIZING FACTOR * IAP * ISLET ACTIVATING PROTEIN * LYMPHOCYTOSIS-PROMOTING FACTOR	70323-44-3	<1
TETANUS TOXOID		Unassigned	<1
Other components below reportable levels			91

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

4. First-aid measures

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	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.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. Get medical advice/attention if you feel unwell. Do not induce vomiting.
Most important symptoms/effects, acute and delayed	None known.
Indication of immediate medical attention and special treatment needed	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.
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.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO ₂). Water.
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	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	This product is expected to be non-combustible.

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
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 to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

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

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
PERTUSSIS TOXIN (CAS 70323-44-3)	OHC	5	PROVISIONAL

US. ACGIH Threshold Limit Values Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	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.
Individual protection measures, such as personal protective equipment	
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
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.
Skin protection	
Other	Wear suitable protective clothing.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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.
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Form	Pre-filled syringe. or Vial.
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)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Percent volatile	91 % estimated

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 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	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 the physical, chemical and toxicological characteristics None known.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components **Species** **Test Results**

SODIUM CHLORIDE (CAS 7647-14-5)

Acute

Oral

LD50 Rat 3000 mg/kg

* 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.

Serious eye damage/eye irritation Health injuries are not known or expected under normal use.

Respiratory or skin sensitization

Respiratory sensitization Not established.

Skin sensitization This product is not expected to cause skin sensitization.

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

Carcinogenicity Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not likely, due to the form of the product.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity 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.

Components **Species** **Test Results**

ALUMINIUM HYDROXIDE (CAS 21645-51-2)

Aquatic

Acute

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

SODIUM CHLORIDE (CAS 7647-14-5)

Aquatic

Acute

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.

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 instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
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 dangerous goods.
IMDG
Not regulated as dangerous goods.
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 One or more components are not listed on TSCA.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
2-PHENOXYETHANOL	122-99-6	1

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.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

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)	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, including date of preparation or last revision

Issue date	07-02-2014
Revision date	07-02-2014
Version #	12
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 Flammability: 0 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	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Transport Information: Material Transportation Information Regulatory Information: United States GHS: Classification