SAFETY DATA SHEET

1. Identification

Product identifier **HAVRIX JUNIOR**

Other means of identification

Synonyms HAVRIX PAEDIATRIC INJECTION 720 EL U/0.5 ML * HAVRIX 720 PAEDIATRIC * HAVRIX JUNIOR 720 U.E. SUSPENSIÓN INYECTABLE * HAVRIX VACUNA CONTRA LA HEPATITIS A 720 U/0,5 ML USO PEDIATRICO * HAVRIX 720 * HAVRIX 720 JUNIOR * HAVRIX JUNIOR 720 * HAVRIX 720 JUNIOR VACCINE * HAVRIX VACUNA CONTRA LA HEPATITIS A 720 U/0,5 ML USO PEDIATRICO * HAVRIX PAEDIATRIC INJECTION 360 EL U/0.5 ML * HAVRIX PAEDIATRIC * HAVRIX 360 * HAVRIX 360 PAEDIATRIC * HAVRIX 360 U.E. PEDIATRICO * HAVRIX JUNIOR * HAVRIX JUNIOR MONODOSE * HAV VACCINE * HEPATOVIRUS VACCINE * HEPATITIS A (INACTIVATED) VACCINE (ADSORBED)

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

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com
Website: www.gsk.com

CHEMTREC EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
Customer Number: CCN9484
US / International toll call +1 703 527 3887
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	%
2-PHENOXYETHANOL	AROSOL DOWANOL EP DOWANOL EPH EMERESSENCE 1160 EMERY 6705 ETHYLENE GLYCOL MONOPHENYL ETHER ETHYLENE GLYCOL PHENYL ETHER 2- FENOXYETHANOL (CZECH) FENYL-CELLOSOLVE (CZECH) FENYLCELOSOLV (CZECH) GLYCOL MONOPHENYL ETHER BETA-HYDROXYETHYL PHENYL ETHE R 1-HYDROXY-2-PHENOXYETHANE PHENOXETHOL PHENOXETOL PHENOXYETHANOL 2-PHENOXYETHANOL PHENOXYETHYL ALCOHOL PHENOXYTOL PHENYL CELLOSOLVE PHENYLMONOGLYCOL ETHER ROSE ETHER	122-99-6	1
SODIUM PHOSPHATE, DIBASIC	PHOSPHORIC ACID, DISODIUM SALT, HYDRATE	10140-65-5	1
HEPATITIS A VIRUS INACTIVATED	HEPATITIS A VIRUS INACTIVATED	Unassigned	<1
ALUMINIUM HYDROXIDE	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	21645-51-2	0.1
POTASSIUM CHLORIDE	POTASSIUM CHLORIDE (KCL) POTASSIUM MONOCHLORIDE SUPER K (SALT) POTASSIUM MURIATE	7447-40-7	0.1
POTASSIUM PHOSPHATE MONOBASIC	POTASSIUM ACID PHOSPHATE POTASSIUM DIPHOSPHATE POTASSIUM BIPHOSPHATE POTASSIUM ORTHOPHOSPHATE MONOPOTASSIUM PHOSPHATE POTASSIUM DIHYDROGEN PHOSPHAT E POTASSIUM DIHYDROGEN ORTHOPHOSPHATE POTASSIUM PHOSPHATE, MONOBASIC	7778-77-0	0.1
Other components below reportable levels			97.1

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

4. First-aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
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 center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. 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 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 non-flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. 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. 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 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	No special control measures required for the normal handling of this product. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store at 2 to 8 °C (36 to 46 °F). Do not freeze. Dispose of properly if frozen. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK Components	Type	Value	Note
POTASSIUM CHLORIDE (CAS 7447-40-7)	8 HR TWA	5000 mcg/m3	
	OHC	1	
POTASSIUM PHOSPHATE MONOBASIC (CAS 7778-77-0)	OHC	1	>1000 - </=5000 mcg/m3
SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5)	OHC	1	>1000 - </=5000 mcg/m3

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).

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Vial.
and
Pre-filled syringe.

Color Milky. White

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 applicable.

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

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

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.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

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. Direct contact with eyes may cause temporary irritation.

Ingestion Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics None known.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
POTASSIUM CHLORIDE (CAS 7447-40-7)		
Acute		
Oral		
LD50	Rat	2600 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. Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization No studies have been conducted.

Skin sensitization None known. 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 Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure Not assigned.

Aspiration hazard Not established.

Chronic effects Prolonged inhalation may be harmful.

Further information Occupational exposure to the substance or mixture may cause adverse effects.

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
POTASSIUM CHLORIDE (CAS 7447-40-7)			
Aquatic			
Acute			
Algae	NOEC	Green algae (Chlorella vulgaris)	600 mg/l, 4 months
Crustacea	EC50	Water flea (Daphnia magna)	83 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	951 mg/l, 96 hours Static test
		Channel catfish (Adult Ictalurus punctatus)	720 mg/l, 48 hours Static test
		Fathead minnow (Adult Pimephales promelas)	880 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	435 mg/l, 96 hours Static test

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

Persistence and degradability Not available.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

2-PHENOXYETHANOL	1.16

Mobility in soil Not available.

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

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

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Not available.

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

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

2-PHENOXYETHANOL (CAS 122-99-6)	Listed.
SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5)	Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

2-PHENOXYETHANOL (CAS 122-99-6)

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

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.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

2-PHENOXYETHANOL (CAS 122-99-6)

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

Country(s) or region	Inventory name	On inventory (yes/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 04-14-2014

Revision date 05-11-2017

Version # 05

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 This document has undergone significant changes and should be reviewed in its entirety.