

1. Identification

Product identifier

HAVRIX ADULT

Other means of identification

Synonyms

HAVRIX ADULT INJECTION 1440 EL U/ML * HAVRIX 1440 * HAVRIX MONODOSE * VIRAXIN ADULT INJECTION 1440 EL U/ML * NDC NO. 58160-826-11 * NDC NO. 58160-826-46 * 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

Manufacturer

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
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
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	%
SODIUM CHLORIDE	COMMON SALT * ROCK SALT * SODIUM MONOCHLORIDE * SALT * SEA SALT * TABLE SALT * SALT, WHITE CRYSTALS, SOLAR	7647-14-5	1
HEPATITIS A VIRUS INACTIVATED	HEPATITIS A VIRUS INACTIVATED	Unassigned	<1

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	0.1
POTASSIUM CHLORIDE	POTASSIUM CHLORIDE (KCL) * POTASSIUM MONOCHLORIDE * SUPER K (SALT) * POTASSIUM MURIATE	7447-40-7	0.1
Other components below reportable levels			98.8

*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	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 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. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions**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).

8. Exposure controls/personal protection**Occupational exposure limits****GSK****Components****Type****Value**

POTASSIUM CHLORIDE
(CAS 7447-40-7)

8 HR TWA

5000 mcg/m3

OHC

1

**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.

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.

Hand protection

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

Skin protection**Other**

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

Respiratory protection

No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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.
or
Pre-filled syringe.

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.

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.
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
POTASSIUM CHLORIDE (CAS 7447-40-7)		
Acute		
<i>Oral</i>		
LD50	Rat	2600 mg/kg

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
Acute		
<i>Oral</i>		
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	Due to partial or complete lack of data the classification is not possible.
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 Not expected to be harmful to aquatic organisms.

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
POTASSIUM CHLORIDE (CAS 7447-40-7)		
Aquatic		
<i>Acute</i>		
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
SODIUM CHLORIDE (CAS 7647-14-5)		
Aquatic		
<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

Components		Species	Test Results
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 - Yes 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	08-08-2014
Revision date	08-08-2014
Version #	18
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 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.