



SAFETY DATA SHEET

1. Identification

Product identifier TWINRIX ADULT

Other means of identification
Synonyms

TWINRIX ADULT INJECTION 720 EL U AND 20 MCG/ML * TWINRIX SUSPENSION FOR INJECTION * TWINRIX ADULT PRE-FILLED SYRINGE * TWINRIX ERWACHSENE AMPULLE MIT 1 ML SUSPENSION * TWINRIX ERWACHSENE FERTIGSPRITZE MIT 1 ML SUSPENSION * HAB ADULT (720/20) * COMBINED HEPATITIS A/HEPATITIS B VACCINE * TWINRIX VACUNA COMBINADA ANTIHEPATITIS A Y B * TWINRIX VACUNA CONTRA LA HEPATITIS A Y B * TWINRIX ADULTO * AMBIRIX * HEPATITIS A VIRUS ANTIGEN (HM175) AND r-DNA HEPATITIS B SURFACE ANTIGEN (HBsAg) COMBINED 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

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	%
ALUMINUM PHOSPHATE	ALUMINUM PHOSPHATE ALUMINIUM PHOSPHATE TRIBASIC ALUMINIUM ORTHOPHOSPHATE	7784-30-7	4

Chemical name	Common name and synonyms	CAS number	%
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	0.5
FORMALDEHYDE 35% SOLUTION	FORMALIN FORMIC ALDEHYDE FORMALIN, (METHANOL-FREE) METHANAL METHYL ALDEHYDE METHYLENE GLYCOL METHYLENE OXIDE TETRAOXYMETHYLENE OXOMETHANE OXYMETHYLENE METHALDEHYDE	50-00-0	< 0.1
NEOMYCIN SULFATE	NEOMYCIN, SULFATE (SALT) NEOMYCIN SULPHATE MYGERIN SULPHATE 242 (GW ACN) MYCIGUENT NEOMIX NEOMYCIN SULFATE USP POWDER 50/50	1405-10-3	< 0.1
HEPATITIS A VIRUS ANTIGEN (HM175 STRAIN)	HEPATITIS A VIRUS INACTIVATED	Unassigned	Not Applicable
r-DNA HEPATITIS B VIRUS SURFACE ANTIGEN (HBsAg)		Unassigned	Not Applicable
Other components below reportable levels			> 90.0

*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

The following adverse effects have been noted with therapeutic use of this material: fever; nausea; vomiting; diarrhoea; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

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. 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.
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	<p>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.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills in original containers for re-use. For waste disposal, see section 13 of the SDS.</p>
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 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
NEOMYCIN SULFATE (CAS 1405-10-3)	8 HR TWA	2000 mcg/m3	
	OHC	1	SKIN SENSITISER
		1	REPRODUCTIVE HAZARD

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Components	Type	Value
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)	STEL	2 ppm
	TWA	0.75 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.
ALUMINUM PHOSPHATE (CAS 7784-30-7)	TWA	1 mg/m3	Respirable fraction.
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)	Ceiling	0.3 ppm	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)	Ceiling	0.1 ppm
	TWA	0.016 ppm

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 Vaccine.Pre-filled syringe.Vial.

Color Cloudy. 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 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 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 Hazardous polymerization does not occur.

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
NEOMYCIN SULFATE Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Literature search
Result: May cause irritation

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 The following adverse effects have been noted with therapeutic use of this material: fever; nausea; vomiting; diarrhoea; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

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
NEOMYCIN SULFATE (CAS 1405-10-3)		
Acute		
Oral		
LD50	Mouse	> 8000 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.

Corrosivity
NEOMYCIN SULFATE Literature search
Result: Irritant

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye
NEOMYCIN SULFATE Literature search
Result: Irritant

Respiratory or skin sensitization

ACGIH sensitization
FORMALDEHYDE (CAS 50-00-0) Dermal sensitization
Respiratory sensitization

Respiratory sensitization No studies have been conducted.
NEOMYCIN SULFATE Literature search
Result: Positive

Skin sensitization None known. This product is not expected to cause skin sensitization.

Sensitization
NEOMYCIN SULFATE Literature search
Result: Positive

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. Carcinogenic effects are not expected as a result of occupational exposure.

NEOMYCIN SULFATE 25 mg/kg/day, Auditory toxicity, no evidence of carcinogenicity.
Species: Rat
Observation Period: 104 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0) 1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0) Cancer

US. National Toxicology Program (NTP) Report on Carcinogens

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0) Known To Be Human Carcinogen.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction**Reproductivity**

NEOMYCIN SULFATE

100 mg/kg/day Embryo-foetal development, Intra-muscular administration.

Result: Auditory toxicity in offspring.

Species: Rat

Notes: Shepherd's Catalogue of Teratogenic Agents.

25 mg/kg/day 3-generation study, Dietary study.

Result: NOAEL (maximum dose)

Species: Rat

Notes: WHO Food Additive Series

25 mg/kg/day, Dietary study.

Result: No adverse foetal effects observed.

Species: Rat

Notes: WHO Food Additive Series

4 g/l Embryo-foetal development, Administered in drinking water.

Result: No malformations.

Species: Mouse

Notes: Shepherd's Catalogue of Teratogenic Agents.

Embryo-foetal development

Result: No malformations.

Species: Rabbit

Notes: Reprotox

Specific target organ toxicity - single exposure Not assigned.**Specific target organ toxicity - repeated exposure** Not assigned.

NEOMYCIN SULFATE

Organ: Auditory system, kidneys.

Aspiration hazard Not established.**Chronic effects** Prolonged inhalation may be harmful.**Further information** Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.**12. Ecological information****Ecotoxicity** No information is available about the potential of this product to produce adverse environmental effects.

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
NEOMYCIN SULFATE (CAS 1405-10-3)			
Aquatic			
<i>Acute</i>			
Other	MIC	Bacteria	0.12 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.**Partition coefficient n-octanol / water (log Kow)**

FORMALDEHYDE 35% SOLUTION 0.35

Mobility in soil No data 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.
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 Not applicable.

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)

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0) Listed.

SARA 304 Emergency release notification

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0) Cancer
 Skin sensitization
 Respiratory sensitization
 Eye irritation
 Skin irritation
 respiratory tract irritation
 Acute toxicity
 Flammability

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

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
FORMALDEHYDE 35% SOLUTION	50-00-0	100	500		

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
FORMALDEHYDE 35% SOLUTION	50-00-0	< 0.1

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****US - California Proposition 65 - CRT: Listed date/Carcinogenic substance**

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0) Listed: January 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

NEOMYCIN SULFATE (CAS 1405-10-3) Listed: October 1, 1992

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

FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)

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	07-01-2014
Revision date	05-06-2017
Version #	20
Further information	This material has not been assessed for HMIS or NFPA ratings.
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.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.