



# 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

**COMPANY NAME** GlaxoSmithKline US  
**Address:** 5 Moore Drive  
Research Triangle Park, NC 27709 USA  
**Telephone:** +1-888-825-5249 (General Inquiries)  
**Email:** msds@gsk.com  
**Website:** www.gsk.com

### EMERGENCY CONTACTS

**Telephone:** CHEMTREC EMERGENCY NUMBERS  
+(1) 703 527 3887 (International)  
24/7; multi-language response  
**Contract Number:** CCN9484  
**Telephone:** VERISK 3E GLOBAL INCIDENT RESPONSE  
+(1) 760 476 3971 (In country)  
+(1) 760 476 3962 or +(1) 866 519 4752 (International)  
24/7; multi-language response  
**Contract Number:** 334878

## 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	90
ALUMINUM PHOSPHATE	ALUMINUM PHOSPHATE ALUMINIUM PHOSPHATE TRIBASIC ALUMINIUM ORTHOPHOSPHATE	7784-30-7	4
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 MYCERIN 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 (CO<sub>2</sub>).

**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**

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.

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 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 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.

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>	<b>Note</b>
NEOMYCIN SULFATE (CAS 1405-10-3)	8 HR TWA	2000 mcg/m <sup>3</sup>	
	OHC	1	SKIN SENSITISER
		1	REPRODUCTIVE HAZARD
SODIUM CHLORIDE (CAS 7647-14-5)	OHC	1	
<b>US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>			
<b>Components</b>	<b>Type</b>	<b>Value</b>	
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.

<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions. DO NOT FREEZE - dispose of properly if frozen.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	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)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	> 8000 mg/kg
SODIUM CHLORIDE (CAS 7647-14-5)		
<b>Acute</b>		
<b>Oral</b>		
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.

#### 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

NEOMYCIN SULFATE

No studies have been conducted.

Literature search  
Result: Positive

### Skin sensitization

#### Sensitization

NEOMYCIN SULFATE

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

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
<b>ALUMINIUM HYDROXIDE (CAS 21645-51-2)</b>		
<b>Aquatic</b>		
<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
<b>NEOMYCIN SULFATE (CAS 1405-10-3)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Other	MIC	Bacteria 0.12 mg/l
<b>SODIUM CHLORIDE (CAS 7647-14-5)</b>		
<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.

**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)
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FORMALDEHYDE 35% SOLUTION	50-00-0	100	500		
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**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



Country(s) or region	Inventory name	On inventory (yes/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

<b>Issue date</b>	05-29-2018
<b>Revision date</b>	05-29-2018
<b>Version #</b>	20
<b>Further information</b>	This material has not been assessed for HMIS or NFPA ratings.
<b>HMIS® ratings</b>	Health: 1 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision information</b>	This document has undergone significant changes and should be reviewed in its entirety.