

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name or designation of the mixture	ROTARIX
Registration number	-
Synonyms	NDC NO. 58160-805-11 * HUMAN ROTAVIRUS (HRV) VACCINE * LIVE ATTENUATED HUMAN ROTAVIRUS (HRV) VACCINE
Issue date	11-April-2014
Version number	05
Revision date	11-April-2014

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Identified uses** 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.

**Uses advised against** No other uses are advised.

### 1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK  
980 Great West Road  
Brentford, Middlesex TW8 9GS UK  
UK General Information (normal business hours): +44-20-8047-5000  
Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)

### 1.4. Emergency telephone number

TRANSPORT EMERGENCIES::  
UK In-country toll call: + (44)-870-8200418  
International toll call: +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

#### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

#### Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### 2.2. Label elements

#### Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Supplemental label information** Not applicable.

### 2.3. Other hazards

Assume that this product is capable of sustaining combustion.  
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

## General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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HUMAN ROTAVIRUS, LIVE ATTENUATED, RIX4414 STRAIN	<1		-	-	
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**Classification:**     **DSD:** -  
                              **CLP:** -

Other components below reportable levels   99.9

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

## SECTION 4: First aid measures

**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.

### 4.1. Description of 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.

**4.2. Most important symptoms and effects, both acute and delayed**                   None known.

**4.3. Indication of any 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.

## SECTION 5: Firefighting measures

**General fire hazards**                   Assume that this product is capable of sustaining combustion.

### 5.1. Extinguishing media

**Suitable extinguishing media**                   Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>). Water.

**Unsuitable extinguishing media**                   None known.

**5.2. Special hazards arising from the substance or mixture**                   During fire, gases hazardous to health may be formed.

### 5.3. Advice for firefighters

**Special protective equipment for firefighters**                   Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Special fire fighting procedures**                   Move containers from fire area if you can do so without risk.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel**                   Keep unnecessary personnel away. For personal protection, see section 8.

**For emergency responders**                   Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

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

**6.3. Methods and material for containment and cleaning up**                   Stop the flow of material, if this is without risk. Following product recovery, flush area with water.

**6.4. Reference to other sections**                   For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
<b>7.3. Specific end use(s)</b>	Medicinal Product

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

##### GSK

Components	Type	Value
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D-SORBITOL (CAS 50-70-4)	OHC	1
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##### UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
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Sucrose (CAS 57-50-1)	STEL	20 mg/m <sup>3</sup>
	TWA	10 mg/m <sup>3</sup>

**Recommended monitoring procedures** Follow standard monitoring procedures.

**Derived No Effect Level (DNEL)** Not available.

**Predicted no effect concentrations (PNECs)** Not available.

### 8.2. Exposure controls

**Appropriate engineering controls** No particular ventilation requirements.

#### Individual protection measures, such as personal protective equipment

**General information** Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

##### Skin protection

##### - 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

##### - Other

Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

##### Respiratory protection

No personal respiratory protective equipment normally required.

##### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

#### Hygiene measures

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.

#### Environmental exposure controls

**Hazard guidance and control recommendations** Not available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

**Physical state** Solid.

**Form** Lyophilised powder. Vial.

**Colour** Not available.

**Odour** Not available.

**Odour threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</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.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	Contact with incompatible materials.
<b>10.5. Incompatible materials</b>	Strong oxidising agents.
<b>10.6. Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## SECTION 11: Toxicological information

<b>General information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
<b>Information on likely routes of exposure</b>	
<b>Ingestion</b>	Expected to be a low ingestion hazard.
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Symptoms</b>	None known.
<b>11.1. Information on toxicological effects</b>	
<b>Acute toxicity</b>	Health injuries are not known or expected under normal use.
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use.
<b>Respiratory sensitisation</b>	Not established.
<b>Skin sensitisation</b>	This product is not expected to cause skin sensitisation.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.
<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction
<b>Specific target organ toxicity - single exposure</b>	None known.

<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not likely, due to the form of the product.
<b>Mixture versus substance information</b>	No information available.
<b>Other information</b>	Caution - Pharmaceutical agent.

## SECTION 12: Ecological information

<b>12.1. Toxicity</b>	Not expected to be harmful to aquatic organisms.
<b>12.2. Persistence and degradability</b>	No data is available on the degradability of this product.
<b>12.3. Bioaccumulative potential</b>	No data available.
<b>12.4. Mobility in soil</b>	No data available.
<b>Mobility in general</b>	Not available.
<b>12.5. Results of PBT and vPvB assessment</b>	Not available.
<b>12.6. Other adverse effects</b>	Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Residual waste</b>	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).
<b>Contaminated packaging</b>	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.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Special precautions</b>	Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

<b>ADR</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	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.

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**  
Not listed.
- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**  
Not listed.
- Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**  
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**  
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**  
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**  
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**  
Not listed.

**Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry**

Not listed.

**Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA**

Not listed.

**Authorisations**

**Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**

Not listed.

**Restrictions on use**

**Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**

Not listed.

**Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work**

Not listed.

**Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding**

Not listed.

**Other EU regulations**

**Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**

Not listed.

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Not listed.

**Directive 94/33/EC on the protection of young people at work**

Not listed.

**Other regulations**

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

**National regulations**

Follow national regulation for work with chemical agents.

**15.2. Chemical safety assessment**

No Chemical Safety Assessment has been carried out.

**SECTION 16: Other information**

**List of abbreviations**

Not available.

**References**

GSK Hazard Determination

**Information on evaluation method leading to the classification of mixture**

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

**Full text of any statements or R-phrases and H-statements under Sections 2 to 15**

None.

**Revision information**

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
Regulatory Information: United States  
GHS: Classification

**Training information**

Follow training instructions when handling this material.

**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.