

# Safety Data Sheet

according to 1907/2006/EC, Article 31

## Optitrol HEPR-1 / Optitrol HEPR-2

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### 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name: Optitrol HEPR-1 / HEPR-2

Article number: Optitrol HEPR-1: SR12045, SR12047; Optitrol HEPR-2: SR12055, SR12057

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

In Vitro Diagnostic Use

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

##### Manufacturer/supplier

DiaMex GmbH

Siemensstrasse 38

69123 Heidelberg, Germany

Phone: +49-6221-4166-400, Fax: +49-6221-4166-490, Email: info@diamex.com

##### Other supplier(s)

See section 16

#### 1.4 Emergency telephone number:

Tel.: +49-6221-4166-400 or the telephone number of your supplier in section 16

### 2. Hazards identification

#### 2.1 Classification of the substance or mixture

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

Skin Sens. 1 H317 May cause an allergic skin reaction.

#### 2.2 Label elements

##### Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

##### Hazard pictograms



**Signal word:** Warning

##### Hazard-determining components of labelling

2-Methyl-4-isothiazolin-3-one

##### Hazard statements

H317 May cause an allergic skin reaction.

##### Precautionary statements

P261 Avoid breathing mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing.

P501 Dispose of contents/container in accordance with local and national regulations.

P302 + P352 IF ON SKIN: Wash with soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

#### 2.3 Other hazards

The usual precautions when handling biological material or chemicals must be taken.

This product contains human-sourced materials and should be considered potentially infectious.

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### 3. Composition/information on ingredients

#### 3.2 Mixtures

##### Chemical characterization

Mixture

##### Additional information

For wording of the listed hazard statements, refer to section 16.

##### Dangerous components

CAS: 26628-22-8 EINECS: 247-852-1	Sodium azide	H300; EUH32; H400/H410	< 0.1%
CAS: 2682-20-4 EINECS: 220-239-6	2-methyl-4-isothiazolin-3-one	H331/H311/H301; H314; H317	0.013-0.015%

### 4. First aid measures

#### 4.1 Description of first aid measures

<b>After inhalation</b>	Supply fresh air and seek medical attention.
<b>After skin contact</b>	Wash affected area with soap and water. Take off any clothing that the product touched. Seek medical attention.
<b>After eye contact</b>	Rinse opened eye for several minutes under running water. Seek medical attention.
<b>After swallowing</b>	Seek medical attention and appropriate follow up.

#### 4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

#### 4.3 Indication of any immediate medical attention and special treatment needed

No relevant information available.

### 5. Fire fighting measures

#### 5.1 Extinguishing media

##### Suitable extinguishing agents

CO<sub>2</sub>, extinguishing powder, water jet or alcohol-resistant foam.

#### 5.2 Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

#### 5.3 Advice for firefighters

##### Protective equipment

Respiratory protection is normally not required.

### 6. Accidental release measures

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

Handle as a potentially infectious material.

Minimize exposure by using appropriate personal protective equipment as listed in Section 8.

#### 6.2 Environmental precautions

Do not allow to enter sewers, surface or ground water.

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### 6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Clean the spill area carefully. Suitable cleaners are: Disinfectant, warm water and cleansing agent.

### 6.4 Reference to other sections

Information on safe handling: Section 7

Information on personal protection equipment: Section 8

Information on disposal: Section 13

## 7. Handling and storage

### 7.1 Precautions for safe handling

Handle as potentially infectious material. Avoid contact with skin.

### Information about protection against explosions and fires

No special measures required.

### 7.2 Conditions for safe storage, including any incompatibilities

See label or package insert.

### Do not store together with

No restriction.

### 7.3 Specific end use(s)

No relevant information available.

## 8. Exposure controls/personal protection

### 8.1 Control parameters

#### Components with limit values that require monitoring at the workplace:

#### Sodium azide (CAS: 26628-22-8)

WEL (Great Britain)	Short-term value: 0,3 mg/m <sup>3</sup> Long-term value: 0,1 mg/m <sup>3</sup>	(as NaN <sub>3</sub> ), Sk
IOELV (European Union)	Short-term value: 0,3 mg/m <sup>3</sup> Long-term value: 0,1 mg/m <sup>3</sup>	Skin

### 8.2 Exposure controls

#### Personal protective equipment

#### General protective and hygienic measures

Follow the usual hygienic and precautionary measures for handling chemicals and potentially infectious materials.

#### Breathing equipment

Not necessary if room is well ventilated.

#### Hand protection

Gloves protect the user against splashes. For safety reasons, they should be changed immediately after wetting. This product is a preparation consisting of several substances. No specific information can be given regarding permeation breakthrough time. The choice of suitable gloves depends not only on the material, but also on other quality features and must be confirmed with the respective manufacturer. Per our knowledge, disposable gloves, e.g. made of nitriles, are suitable. This recommendation is not intended to replace a suitability test, which is essential and must be performed under the respective conditions of use.

#### Eye protection

Safety glasses

#### Body protection

Protective work clothing

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### 9. Physical and chemical properties

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

**Form**

Liquid

**Colour**

Yellowish

**Odour**

Odourless

#### 9.2 Other information

No relevant information available.

### 10. Stability and reactivity

#### 10.1 Reactivity

No relevant information available.

#### 10.2 Chemical stability:

No decomposition if used and stored according to specifications.

#### 10.3 Possibility of hazardous reactions

None known when used appropriately.

#### 10.4 Conditions to avoid

No relevant information available.

#### 10.5 Incompatible materials

No relevant information available.

#### 10.6 Hazardous decomposition products

No dangerous decomposition products known.

### 11. Toxicological information

#### 11.1 Information on toxicological effects

May cause an allergic skin reaction.

### 12. Ecological information

#### 12.1 Toxicity

No relevant information available.

#### 12.2 Persistence and degradability

No relevant information available.

#### 12.3 Bioaccumulative potential

No relevant information available.

#### 12.4 Mobility in soil

**General notes**

Water hazard class 1 (German Regulation): Slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

#### 12.5 Results of PBT and vPvB assessment

**PBT:** Not applicable

**vPvB:** Not applicable

#### 12.6 Other adverse effects

No relevant information available.

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### 13. Disposal considerations

#### 13.1 Waste treatment methods

##### Waste disposal

Dispose of waste in accordance to applicable local or national regulations.

### 14. Transport information

Optitrol HEPR-1 and Optitrol HEPR-2 contain IgG antibodies to HBs, HBe, HAV and HEV and are shipped as follows:

Classification according to current regulations (ADR/RID, IMDG, IATA/ICAO):

#### 14.1 UN number

UN 3373

#### 14.2 Proper shipping name

BIOLOGICAL SUBSTANCE, CATEGORY B

#### 14.3 Class

6.2

### 15. Regulatory information

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

##### National regulations

Water hazard class 1 (German Regulation): Slightly hazardous for water.

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### 16. Other information

#### Other supplier(s)

Australia:

National Reference Laboratory (NRL)

4th Floor, Healy Building

41 Victoria Parade

Fitzroy VIC 3065, Australia

Fax: +61 3 9418 1155

Phone: +61 3 9418 1111

Email: info@nrlquality.org.au

#### Relevant hazard statements

H300 Fatal if swallowed.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH 032 Contact with acids liberates very toxic gas.

Comment: The statements apply for the pure chemicals.

#### Further Information

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our product is responsible for ensuring that, where applicable, existing laws and guidelines are observed.