

**Optitrol NAT Controls**

Version: 2.2

Page 1/5

Last alteration on: 2021-08-18

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

**1.1 Product identifier**

Trade name: Optitrol NAT HBV Screening, Optitrol NAT HBV Viral Load, Optitrol NAT HCV Screening, Optitrol NAT HCV Viral Load, Optitrol NAT HIV Screening, Optitrol NAT HIV Viral Load, Optitrol NAT Triplex, Optitrol NAT NEG

Article number: NT01011, NT01012 (Optitrol NAT HBV Screening)  
NT01013, NT01014 (Optitrol NAT HBV Viral Load)  
NT01021, NT01022 (Optitrol NAT HCV Screening)  
NT01023, NT01024 (Optitrol NAT HCV Viral Load)  
NT01031, NT01032 (Optitrol NAT HIV Screening)  
NT01033, NT01034 (Optitrol NAT HIV Viral Load)  
NT01041, NT01042 (Optitrol NAT Triplex)  
NT01053, NT01054 (Optitrol NAT NEG)

**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**

The product is not classified according to the CLP regulation.

**2.2 Label elements**

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

The usual precautionary measures for handling biological material or chemicals must be taken. The product does not have to be labeled according to the CLP regulation.

**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.

**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**

Not applicable.

**Optitrol NAT Controls**

Version: 2.2

Page 2/5

Last alteration on: 2021-08-18

**4. First aid measures**

**4.1 Description of first aid measures**

**After inhalation** Supply fresh air and seek medical attention  
**After skin contact** In general the product is not irritating to the skin  
**After eye contact** Rinse opened eye for several minutes under running water. Seek medical attention  
**After swallowing** Seek medical attention and appropriate follow up.

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

No relevant information available

**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.

**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.

(Continued on page 3)

**Optitrol NAT Controls**

Version: 2.2

Page 3/5

Last alteration on: 2021-08-18

(Continued from page 2)

**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**

The product does not contain relevant quantities of substances with limit values that require monitoring at the workplace.

**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

**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.

(Continued on page 4)

# Safety Data Sheet

according to 1907/2006/EC, Article 31

## Optitrol NAT Controls

Version: 2.2

Page 4/5

Last alteration on: 2021-08-18

(Continued from page 3)

### 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

The product does not have to be labeled according to the CLP regulation.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

## 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 (German Regulation): Generally not hazardous to water.

### 12.5 Results of PBT and vPvB assessment

**PBT:** Not applicable

**vPvB:** Not applicable

### 12.6 Other adverse effects

No relevant information available.

## 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 NAT Triplex controls contain HBV DNA, HCV RNA and HIV RNA, Optitrol NAT HBV Screening and Optitrol NAT HBV Viral Load controls contain HBV DNA, Optitrol NAT HCV Screening and Optitrol NAT HCV Viral Load controls contain HCV RNA, Optitrol NAT HIV Screening and Optitrol NAT HIV Viral Load controls contain HIV RNA and are shipped as follows:

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

### 14.1 UN number

UN 3373

(Continued on page 5)

# Safety Data Sheet

according to 1907/2006/EC, Article 31

## Optitrol NAT Controls

Version: 2.2

Page 5/5

Last alteration on: 2021-08-18

(Continued from page 4)

### 14.2 Proper shipping name

BIOLOGICAL SUBSTANCE, CATEGORY B

### 14.3 Class

6.2

Optitrol NAT NEG is no dangerous good according according to current regulations (ADR/RID, IMDG, IATA/ICAO).

## 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

### 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.