

Safety Data Sheet

according to 1907/2006/EC, Article 31

Optitrol NAT Blood Bank Controls

Version: 3.0

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Last alteration on: 22.12.2022

Date of first issue: 20.01.2020

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 HIV-2, Optitrol NAT Triplex, Optitrol NAT NEG

Article number: Optitrol NAT HBV Screening: NT01011, NT01012
Optitrol NAT HBV Viral Load: NT01013, NT01014
Optitrol NAT HCV Screening: NT01021, NT01022
Optitrol NAT HCV Viral Load: NT01023, NT01024
Optitrol NAT HIV Screening: NT01031, NT01032
Optitrol NAT HIV Viral Load: NT01033, NT01034
Optitrol NAT HIV-2: NT01035, NT01036
Optitrol NAT Triplex: NT01041, NT01042
Optitrol NAT NEG: NT01051, NT01052

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 product is not classified and not labelled according to the CLP regulation.

Hazard pictograms

Not applicable

Signal word: Not applicable

Hazard-determining components of labelling

Not applicable

Hazard statements

Not applicable

Precautionary statements

Not applicable

2.3 Other hazards

Ecological/toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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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

No relevant information available.

Dangerous components

Not applicable

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

CO₂, 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.

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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)

In Vitro Diagnostic Use.

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 protection

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

Physical state:	Liquid
Colour:	Yellowish
Odour:	Odourless
Odour Threshold:	No data available
Melting point/range:	No data available

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Boiling point/range:	No data available
Flammability:	No data available
Upper explosion limit:	No data available
Lower explosion limit:	No data available
Flashpoint:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH-Wert:	No data available
Kinematic viscosity:	No data available
Water solubility:	completely miscible
Solubility in other solvents:	No data available
Partition coefficient n-Octanol/Wasser:	No data available
Vapour pressure:	No data available
Relative Density:	No data available
Relative vapour density:	No data available
Particle properties:	Not applicable

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye Irritation

Not classified based on available information.

Respiratory or skin sensitisation

Not classified based on available information.

Component: Not applicable

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Germ cell mutagenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Specific target organ toxicity at single exposure.

Not classified based on available information.

Specific target organ toxicity in repeated exposure.

Assessment: The substance or mixture is not classified as target organ toxicant in case of repeated exposure.

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

11.2.2 Further information

No relevant information available.

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

No relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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

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

14.1 UN number

UN 3373

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14.2 UN proper shipping name
BIOLOGICAL SUBSTANCE, CATEGORY B

14.3 Transport hazard class
6.2

14.4 Packing group
Not applicable

14.5 Environmental hazards

ADR
Environmental hazardous: no

IMDG
Marine pollutant: no

14.6 Special precautions for users
No data available.

14.7 Marine transport in bulk according to IMO instruments
Not applicable

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
No relevant information available.

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out. Not applicable.

16. Other information

Other supplier(s)
Contact and emergency telephone number in 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.