Safety Data Sheet

According to 1907/2006/EC, Article 31

Optitrol NAT HPV NEG/ Optitrol NAT HPV

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

1.1 Product identifier

Trade name: Optitrol NAT HPV NEG Article number: NT06013, NT06014
Optitrol NAT HPV Article number: NT06011, NT06012

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

In-vitro-Diagnostikum

1.3 Details of the supplier of the safety data sheet

Manufacturer/supplier

DiaMex GmbH
Siemensstrasse 38
69123 Heidelberg
Phone: +49 6221 4166-400
Fax: +49 6221 4166-490
Email: info@diamex.com

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

Flammable liquids, category 3, H226 Flammable liquid and vapour.
Acute toxicity, Category 3, H301 Toxic if swallowed.
Acute toxicity, Category 3, H311 Toxic in contact with skin.
Acute toxicity, Category 3, H331 Toxic if inhaled.
Specific target organ toxicity - single exposure, Category 1, H370 Causes damage to organs.

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: Danger

Hazard-determining components of labelling

Methanol

Hazard statements

H226 Flammable liquid and vapour
H301 + H311 + H331 Toxic if swallowed, in contact with skin or if inhaled.
H370 Causes damage to organs

Precautionary statements:
Prevention:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe mist or vapours.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
P370 + P378 In case of fire: use dry sand, dry chemical or alcohol-resistant foam to extinguish.

Storage:
P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

2.3 Other hazards
Ecological 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

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

CAS-Nr. EG-Nr.	Chemical name	Classification	Concentration (w/w)
67-56-1 200-659-6	Methanol	Flam. Liq. 2; H225 Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 STOT SE 1; H370 (Eyes) Specific concentration limit: >= 10 %: STOT SE 1; H370 3 – 10 %: STOT SE 2 H37	>= 30,0 - < 50 %

4. First aid measures

4.1 Description of first aid measures

General advice : Move out of dangerous area. Consult a physician. Show this safety data sheet to the doctor in attendance. Do not leave the victim unattended.

If inhaled : Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water. If on clothes, remove clothes.

In case of eye contact : Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital.
Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Alcohol-resistant foam
Carbon dioxide (CO_2)
Dry chemical

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. For safety reasons in case of fire, cans should be stored separately in closed containments. Use a water spray to cool fully closed containers.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment. Remove all sources of ignition.
Evacuate personnel to safe areas.
Refer to protective measures listed in sections 7 and 8. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low ventilated areas.

6.2 Enviromental precautions

Enviromental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods of cleaning up	:	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/ national regulations (section 13)

6.4 Reference to other sections

See Section 7 for safe handling information.

See Section 8 for information on personal protective equipment.

See Section 13 for disposal information.

7. Handling and storage

7.1 Precautions for safe handling

Avoid formation of aerosols.
Do not inhale dusts/vapors.
Avoid exposure, use personal protective equipment.
Avoid contact with eyes and skin.
Do not eat, drink or smoke in the area of application.
Take measures against electrostatic charges.
Provide adequate air exchange and/or exhaust in work areas.
Open tubes carefully.

Advice on protection against fire and explosion
Keep away from open flames, hot surfaces and ignition sources.

7.2 Conditions for safe storage, including any incompatibilities

No smoking. Keep container tightly closed in a dry and well- ventilated place. Containers which are opened must be care- fully resealed and kept upright to prevent leakage. Observe label precautions. Electrical installations / working materials must comply with the technological safety standards

Information on storage conditions can be found in the package insert and on the label.

Storage class
3, Flammable liquids

7.3 Specific end use

For In vitro diagnostic use

8. Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Methanol	67-56-1	TWA	200 ppm 260 mg/m3	2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin			
		AGW	100 ppm 130 mg/m3	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(II)			
	Further information: Skin absorption, when there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
Methanol	67-56-1	Methanol: 15 mg/l (Urine)	In case of long-term exposure: after more than one shift, Immediately after exposure or after working hours	TRGS 903

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Methanol	Workers	Dermal	Acute systemic effects	40 mg/kg
	Workers	Inhalation	Acute systemic effects	260 mg/m3
	Workers	Inhalation	Acute local effects	260 mg/m3
	Workers	Dermal	Long-term systemic effects	40 mg/kg
	Workers	Inhalation	Long-term systemic effects	260 mg/m3
	Workers	Inhalation	Long-term local effects	260 mg/m3
	Consumers	Dermal	Acute systemic effects	8 mg/kg
	Consumers	Inhalation	Acute systemic effects	50 mg/m3
	Consumers	Oral	Acute systemic effects	8 mg/kg
	Consumers	Inhalation	Acute local effects	50 mg/m3
	Consumers	Dermal	Long-term systemic effects	8 mg/kg
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
	Consumers	Oral	Long-term systemic effects	8 mg/kg
	Consumers	Inhalation	Long-term local effects	50 mg/m3

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Methanol	Fresh water	154 mg/l
Remarks:	Derivation of the PNEC	
	Fresh water sediment	570,4 mg/kg
	Marine water	15,4 mg/l
	Soil	23,5 mg/kg
	Sewage treatment plant	100 mg/l

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
In the case of vapour formation use a respirator with an approved filter.

Hand protection
The gloves are used for splash protection. For safety reasons, the gloves should be replaced immediately after wetting.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

This recommendation in no way replaces a suitability test by the user, which must be carried out in each case under the respective application conditions.

Eye protection
Tightly fitting safety goggles

Body protection
Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

9. Physical and chemicals properties

9.1 Information on basic physical and chemical properties

Physical state:	**liquid**
Colour:	**colourless**
Odour:	**No data available**
Odour Threshold:	**No data available**
Melting point/range:	**No data available**
Boiling point/range:	**64,5 °C**
Flammability:	**No data available**
Upper explosion limit:	**No data available**
Lower explosion limit:	**No data available**
Flashpoint:	**26,5 °C**
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**

10. Stability and reactivity

10.1 Reactivity
No relevant information available.

10.2 Chemical Stabilität
No decomposition if used and stored according to specifications

10.3 Possibility of hazardous reactions
No decomposition if used and stored according to specifications.

Vapours may form explosive mixture with air.

10.4 Conditions to avoid
Heat, flames and sparks

10.5 Incompatible materials
No relevant data available

10.6 Hazardous decomposition products
No relevant data available.

11. Toxicological information

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

Acute toxicity
Toxic if swallowed, in contact with skin or if inhaled.

Component: Methanol

Acute oral Toxicity:
LD50 (Rat): 1.187 mg/kg; Method: OECD guideline 401; GLP: no
Assessment: The component/mixture is toxic after single ingestion.

Acute inhalation toxicity:
LC50 (cat): 43,68 mg/l; Exposure time: 6 h; Test atmosphere: vapour; GLP: no information available.
Assessment: The component/mixture is toxic after short term inhalation.

Acute dermal Toxicity:
LD50 (Rabbit): 17.100 mg/kg; Method: No information available; GLP: No information available;
Assessment: The component/mixture is toxic after single contact with skin

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.

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 consid- ered 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
Solvents may degrease the skin.

12. Ecological information

12.1 Toxicity
component: Methanol

Toxicity to fish:
LC50 (Lepomis macrochirus (Bluegill sunfish)): 15.400 mg/l End point: mortality
Exposure time: 96 h Test Type: flow-through test Analytical monitoring: yes GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 18.260 mg/l End point: Immobilization
Exposure time: 96 h Test Type: semi-static test Method: OECD Test Guideline 202 GLP: No information available.

Toxicity to algae/aquatic plants
EC50 (Pseudokirchneriella subcapitata (green algae)): 22.000 mg/l
End point: Growth rate Exposure time: 96 h Test Type: static test
Method: OECD Test Guideline 201 GLP: No information available.

Toxicity to microorganisms
IC50 (activated sludge): > 1.000 mg/l End point: Growth rate Exposure time: 3 h Test Type: static test
Analytical monitoring: yes Method: OECD Test Guideline 209 GLP: No information available.

12.2 Persistence and degradability:
component: Methanol

Biodegradability:
Test Type: aerobic
Inoculum: activated sludge, non-adapted Concentration: 4 - 200 g/L
Result: Readily biodegradable. Biodegradation: 82,7 % Exposure time: 5 d
GLP: no

Biochemical Oxygen Demand (BOD):
Biochemical oxygen demand 600 - 1.120 mg/g Incubation time: 5 d

Chemical Oxygen Demand (COD):
1.420 mg/g

ThOD:
1.500 mg/g

BOD/ThOD:
76 %

12.3 Bioaccumulative potential:
component: Methanol

Bioaccumulation:
Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-Octanol/Wasser:
log Pow: -0,77 (20 °C)

12.4 Mobility in soil:
No data 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 consid- ered 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 data available

13. Disposal considerations

13.1 Waste treatment methods

Disposal
Do not empty into drains or water courses.

The product must be disposed of in accordance with local or national guidelines or regulations.

14. Transport information

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

14.1 UN Nummer

UN 1992

14.2 UN proper shipping name:

Flammable liquid, toxic, n.o.s. (Methanol-solution)

14.3 Transport hazard class

3

14.4 Packing group

III

14.3 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

15. Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major- accident hazards involving dangerous substances:
H2 ACUTE TOXIC
P5c FLAMMABLE LIQUIDS

Water hazard class (Germany): WGK 2 obviously hazardous to water

The product is subject to the supply restrictions of the Ordinance on the Prohibition of Chemicals

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

15.2 Chemical safety assessment
Chemical Safety Assessments for all substances in this product are either complete or not applicable.

16. Other information

Full-text of H-Statements
H226 Flammable liquid and vapour
H301 Toxic if swallowed
H311 Toxic in contact with skin.
H331 Toxic if inhaled.
H370 Causes damage to organs.

Note: The respective H-phrases apply to the pure substances

Abbrevations:
Acute Tox.: Acute Toxicity
Flam. Liq.: Flammable liquids
STOT SE: Specific target organ toxicity - single exposure

Further Information
The above information is based on the current state of our knowledge and does not constitute a guarantee of product properties and does not establish a contractual legal relationship. Existing laws and regulations must be observed by the recipient or user of our product at their own responsibility.

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