

04.07.2024 Kit Components

Product code	Description

CSI084254 PROTEUS COLOR KIT

Components:

150233	proteus color OX 19 150233
150234	proteus color OX 2 150234
150235	proteus color OX K 150235
192673	Proteus color controllo positivo



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Revision: 04.07.2024

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024

Version number 1

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

- · 1.1 Diagnostic Reagent
- · Trade name: proteus color OX 19
- · Article number: 150233
- \cdot 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended

- · Application of the substance / the mixture Diagnostic reagent
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Sclavo Diagnostics International Via Po 26-28, Loc. Pian dei Mori CAP: 53018 - SOVICILLE - (SI) ITALY

- · Further information obtainable from: Product safety department.
- 1.4 Emergency telephone number: +39 0577 390 444 / 445

2 Hazards identification

- \cdot 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



GHS08 health hazard

Carc. 1B H350 May cause cancer.



GHS07

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





GHSU/ GHSU8

· Signal word Danger

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 19

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· Hazard-determining components of labelling:

formaldehyde

· Hazard statements

H317 May cause an allergic skin reaction.

H350 May cause cancer.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/

face protection/hearing protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

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

attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/

regional/national/international regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · 3.2 Mixtures
- · Description:

Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 50-00-0EINECS: 200-001-8Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H311; Acute Tox. 3, H331; Muta. 2, H341; Carc. 1B, H350; Skin Corr. 1B, H314; Skin Sens. 1, H317

Specific concentration limits:

SkinCorr. 1B; H314: $C \ge 25$ %

Skin Irrit. 2; H315: 5 % $\le C < 25$ %

Eye Irrit. 2; H319: 5 % $\le C < 25$ %

Skin Sens. 1; H317: $C \ge 0.2$ %

STOT SE 3; H335: $C \ge 5$ %

· Additional information:

For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · 4.1 Description of first aid measures
- · General information:

Immediately remove any clothing soiled by the product.

· After inhalation:

Supply fresh air and to be sure call for a doctor. In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Rinse opened eye for several minutes under running water.

· After swallowing: If symptoms persist consult doctor.

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX 19

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- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

- · 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions:

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

 \cdot 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13. Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

· Information about fire - and explosion protection:

Keep respiratory protective device available.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:
 No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:
- Keep container tightly sealed.
 7.3 Specific end use(s) No further relevant information available.

ΙE

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX 19

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8 Exposure controls/personal protection

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace: 50-00-0 formaldehyde

OEL Short-term value: 0.738 mg/m³, 0.6 ppm Long-term value: 0.37 0.62* mg/m³, 0.3 0.5* ppm Carc1B, Sens,*healthcare,funeral,embalm.:11.07.24

· Additional information:

The lists valid during the making were used as basis.

- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.

Store protective clothing separately.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Hand protection



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection



Tightly sealed goggles

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 19

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9 Physical and chemical prop	perties
\cdot 9.1 Information on basic physic	cal and chemical properties
· General Information	
· Physical state	Fluid
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling	ng
point and boiling range	Undetermined.
\cdot Flammability	Not applicable.
· Lower and upper explosion limit	t
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octano	1/
water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	7
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
\cdot 9.2 Other information	
· Appearance:	
· Form:	Fluid
· Important information on	
protection of health and	
environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion
	hazard.
· Solvent content:	
· Organic solvents:	1.0 %
· Water:	2.1 %
· VOC (EC)	0.22 %
· Solids content:	96.9 %
· Change in condition	
· Evaporation rate	Not determined.
\cdot Information with regard to	
physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 19

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		(
· Flammable solids	Void	
· Self-reactive substances and		
mixtures	Void	
· Pyrophoric liquids	Void	
· Pyrophoric solids	Void	
· Self-heating substances and		
mixtures	Void	
· Substances and mixtures, which		
emit flammable gases in contact		
with water	Void	
· Oxidising liquids	Void	
· Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
· Desensitised explosives	Void	

10 Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- \cdot 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further 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

Based on available data, the classification criteria are not met.

· LD/LC50 val	· LD/LC50 values relevant for classification:		
ATE (Acute	ATE (Acute Toxicity Estimates)		
Oral	LD50	>89,286 mg/kg	
Dermal	LD50	133,929 mg/kg	
Inhalative	LC50/4 h	1,339 mg/l	
50-00-0 for	50-00-0 formaldehyde		
Oral	LD50	>200 mg/kg (rat)	

· Skin corrosion/irritation

Based on available data, the classification criteria are not met.

- · Serious eye damage/irritation
 - Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Germ cell mutagenicity

Based on available data, the classification criteria are not met.

- · Carcinogenicity May cause cancer.
- · Reproductive toxicity

Based on available data, the classification criteria are not met.

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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· STOT-single exposure

Based on available data, the classification criteria are not met.

· STOT-repeated exposure

Based on available data, the classification criteria are not met.

· Aspiration hazard

Based on available data, the classification criteria are not met.

- · 11.2 Information on other hazards
- · Endocrine disrupting properties

The product contains substances, which affect the thyroid system and other hormonal systems.

None of the ingredients is listed.

12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability

No further relevant information available.

· 12.3 Bioaccumulative potential

No further relevant information available.

- \cdot 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water $\ \ \,$

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

HP7 Carcinogenic

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

TE

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 19

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14 Transport information	
· 14.1 UN number or ID number · ADR, IMDG, IATA	not regulated
· 14.2 UN proper shipping name · ADR, IMDG, IATA	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group · ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
 14.7 Maritime transport in bulk according to IMO instruments 	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

- \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 28, 72
- · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

 None of the ingredients is listed.
- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

- · Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

 None of the ingredients is listed.
- · National regulations:
- · Information about limitation of use:

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 19

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· 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· Relevant phrases

- H301 Toxic if swallowed.
- H311 Toxic in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H331 Toxic if inhaled.
- H335 May cause respiratory irritation.
- H341 Suspected of causing genetic defects.
- H350 May cause cancer.
- · Department issuing SDS: Product safety department.
- · Contact:
- · Date of previous version: 01.07.2024
- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

ATE: Acute toxicity estimate values

Acute Tox. 3: Acute toxicity - Category 3

Skin Corr. 1B: Skin corrosion/irritation - Category 1B

Skin Sens. 1: Skin sensitisation - Category 1

Muta. 2: Germ cell mutagenicity - Category 2

Carc. 1B: Carcinogenicity - Category 1B

· * Data compared to the previous version altered.



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Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024

undertaking

Version number 1

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

- · 1.1 Diagnostic Reagent
- · Trade name: proteus color OX 2
- · Article number: 150234
- **UFI:** 1V31-E004-P00W-7WHW
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended

- · Application of the substance / the mixture Diagnostic reagent
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Sclavo Diagnostics International Via Po 26-28, Loc. Pian dei Mori CAP: 53018 - SOVICILLE - (SI) ITALY

- · Further information obtainable from: Product safety department.
- 1.4 Emergency telephone number: +39 0577 390 444 / 445

2 Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



GHS08 health hazard

Carc. 1B H350 May cause cancer.



GHS07

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





GHS07

GHS08

· Signal word Danger

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 2

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· Hazard-determining components of labelling:

formaldehyde

· Hazard statements

H317 May cause an allergic skin reaction.

H350 May cause cancer.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/

face protection/hearing protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

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

attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/

regional/national/international regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · 3.2 Mixtures
- · Description:

Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 50-00-0EINECS: 200-001-8Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Muta. 2, H341; Carc. 1B, H350; Skin Corr. 1B, H314; Skin Sens. 1, H317

Specific concentration limits:

SkinCorr. 1B; H314: $C \ge 25$ %

Skin Irrit. 2; H315: 5 % $\le C < 25$ %

Eye Irrit. 2; H319: 5 % $\le C < 25$ %

Skin Sens. 1; H317: $C \ge 0.2$ %

STOT SE 3; H335: $C \ge 5$ %

· Additional information:

For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · 4.1 Description of first aid measures
- · General information:

Immediately remove any clothing soiled by the product.

· After inhalation:

Supply fresh air and to be sure call for a doctor. In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Rinse opened eye for several minutes under running water.

· After swallowing: If symptoms persist consult doctor.

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 2

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- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

- · 5.2 Special hazards arising from the substance or mixture
 No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 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).

Dispose contaminated material as waste according to section 13. Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

· Information about fire - and explosion protection:

Keep respiratory protective device available.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:
 No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep container tightly sealed.
- · 7.3 Specific end use(s) No further relevant information available.

ΙE

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX 2

(Contd. of page 3)

8 Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace: 50-00-0 formaldehyde

OEL Short-term value: 0.738 mg/m³, 0.6 ppm Long-term value: 0.37 0.62* mg/m³, 0.3 0.5* ppm Carc1B, Sens,*healthcare,funeral,embalm.:11.07.24

· Additional information:

The lists valid during the making were used as basis.

- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. Store protective clothing separately.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Hand protection



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection



Tightly sealed goggles

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 2

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9 Physical and chemical prop	perties
\cdot 9.1 Information on basic physic	cal and chemical properties
· General Information	
· Physical state	Fluid
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling	ng
point and boiling range	Undetermined.
\cdot Flammability	Not applicable.
· Lower and upper explosion limit	t
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octano	1/
water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	7
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
\cdot 9.2 Other information	
· Appearance:	
· Form:	Fluid
· Important information on	
protection of health and	
environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion
	hazard.
· Solvent content:	
· Organic solvents:	1.0 %
· Water:	2.1 %
· VOC (EC)	0.22 %
· Solids content:	96.9 %
· Change in condition	
· Evaporation rate	Not determined.
\cdot Information with regard to	
physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void

(Contd. on page 6)

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX 2

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		(oonoa. or page
· Flammable solids	Void	
· Self-reactive substances and		
mixtures	Void	
· Pyrophoric liquids	Void	
· Pyrophoric solids	Void	
· Self-heating substances and		
mixtures	Void	
· Substances and mixtures, which		
emit flammable gases in contact		
with water	Void	
· Oxidising liquids	Void	
· Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
· Desensitised explosives	Void	

10 Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- \cdot 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further 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

Based on available data, the classification criteria are not met.

\cdot LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimates)		
Oral	LD50	>89,286 mg/kg
Dermal	LD50	133,929 mg/kg
Inhalative	LC50/4 h	1,339 mg/l
50-00-0 formaldehyde		
Oral	LD50	>200 mg/kg (rat)

- · Skin corrosion/irritation
 - Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation

Based on available data, the classification criteria are not met.

- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Germ cell mutagenicity

Based on available data, the classification criteria are not met.

- · Carcinogenicity May cause cancer.
- · Reproductive toxicity

Based on available data, the classification criteria are not met.

(Contd. on page 7)

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX 2

(Contd. of page 6)

· STOT-single exposure

Based on available data, the classification criteria are not met.

· STOT-repeated exposure

Based on available data, the classification criteria are not met.

· Aspiration hazard

Based on available data, the classification criteria are not met.

- · 11.2 Information on other hazards
- · Endocrine disrupting properties

The product contains substances, which affect the thyroid system and other hormonal systems.

None of the ingredients is listed.

12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability

No further relevant information available.

· 12.3 Bioaccumulative potential

No further relevant information available.

- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water $\ \ \,$

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

HP7 Carcinogenic

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

TE

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX 2

(Contd. of page 7)

14 Transport information	
· 14.1 UN number or ID number · ADR, IMDG, IATA	not regulated
· 14.2 UN proper shipping name · ADR, IMDG, IATA	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group · ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

- \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 28, 72
- · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

 None of the ingredients is listed.
- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

- · Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

 None of the ingredients is listed.
- · National regulations:
- · Information about limitation of use:

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX 2

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· 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· Relevant phrases

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H341 Suspected of causing genetic defects.

H350 May cause cancer.

- · Department issuing SDS: Product safety department.
- · Contact: -
- · Date of previous version: 01.07.2024
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative ATE: Acute toxicity estimate values Acute Tox. 3: Acute toxicity - Category 3 Skin Corr. 1B: Skin corrosion/irritation - Category 1B Skin Sens. 1: Skin sensitisation - Category 1

Carc. 1B: Carcinogenicity - Category 1B

* * Data compared to the previous version altered.

Muta. 2: Germ cell mutagenicity - Category 2



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Revision: 04.07.2024

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024

Version number 1

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

- · 1.1 Diagnostic Reagent
- · Trade name: proteus color OX K
- · Article number: 150235
- **UFI:** 1X31-X0DJ-000E-V83Y
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended

- · Application of the substance / the mixture Diagnostic reagent
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Sclavo Diagnostics International Via Po 26-28, Loc. Pian dei Mori CAP: 53018 - SOVICILLE - (SI) ITALY

- · Further information obtainable from: Product safety department.
- 1.4 Emergency telephone number: +39 0577 390 444 / 445

2 Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS08 health hazard

H350 May cause cancer. Carc. 1B



GHS07

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





GHS07

GHS08

· Signal word Danger

(Contd. on page 2)

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX K

(Contd. of page 1)

· Hazard-determining components of labelling:

formaldehyde

· Hazard statements

H317 May cause an allergic skin reaction.

H350 May cause cancer.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/

face protection/hearing protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

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

attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/

regional/national/international regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · 3.2 Mixtures
- · Description:

Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 50-00-0EINECS: 200-001-8Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H311; Acute Tox. 3, H331; Muta. 2, H341; Carc. 1B, H350; Skin Corr. 1B, H314; Skin Sens. 1, H317

Specific concentration limits:

SkinCorr. 1B; H314: $C \ge 25$ %

Skin Irrit. 2; H315: 5 % $\le C < 25$ %

Eye Irrit. 2; H319: 5 % $\le C < 25$ %

Skin Sens. 1; H317: $C \ge 0.2$ %

STOT SE 3; H335: $C \ge 5$ %

· Additional information:

For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · 4.1 Description of first aid measures
- · General information:

Immediately remove any clothing soiled by the product.

· After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for

transportation.
• After skin contact:

Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Rinse opened eye for several minutes under running water.

· After swallowing: If symptoms persist consult doctor.

(Contd. on page 3)

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX K

(Contd. of page 2)

- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

- · 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 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).

Dispose contaminated material as waste according to section 13. Ensure adequate ventilation.

- · 6.4 Reference to other sections
 - See Section 7 for information on safe handling.
 - See Section 8 for information on personal protection equipment.
 - See Section 13 for disposal information.

7 Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

 \cdot Information about fire - and explosion protection:

Keep respiratory protective device available.

- 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:
 No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:
 - Keep container tightly sealed.
- · 7.3 Specific end use(s) No further relevant information available.

ΙE

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX K

(Contd. of page 3)

8 Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace: 50-00-0 formaldehyde

OEL Short-term value: 0.738 mg/m³, 0.6 ppm Long-term value: 0.37 0.62* mg/m³, 0.3 0.5* ppm Carc1B, Sens,*healthcare,funeral,embalm.:11.07.24

· Additional information:

The lists valid during the making were used as basis.

- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. Store protective clothing separately.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Hand protection



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection



Tightly sealed goggles

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX K

(Contd. of page 4)

9 Physical and chemical prop	perties
· 9.1 Information on basic physic	cal and chemical properties
· General Information	de due cuemical properties
· Physical state	Fluid
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling	
point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octanol	•
water (log value)	Not determined.
· Vapour pressure:	Not determined.
 Density and/or relative density 	7
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	
· Appearance:	
· Form:	Fluid
· Important information on	
protection of health and	
environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion
	hazard.
· Solvent content:	
· Organic solvents:	1.0 %
· Water:	2.1 %
· VOC (EC)	0.22 %
· Solids content:	96.9 %
· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to	
physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	
· Aerosols · Oxidising gases	Void
	Void
· Gases under pressure	Void
· Flammable liquids	Void
	(Contd. on page 6)

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according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

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Trade name: proteus color OX K

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· Flammable solids	Void
· Self-reactive substances and	
mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and	
mixtures	Void
· Substances and mixtures, which	
emit flammable gases in contact	
with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

10 Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- \cdot 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further 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

Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:				
ATE (Acute Toxicity Estimates)				
Oral	LD50	>89,286 mg/kg		
Dermal	LD50	133,929 mg/kg		
Inhalative	LC50/4 h	1,339 mg/l		
50-00-0 for	maldehyde			

50-00-0 for	maldehyde	
Oral	LD50	>200 mg/kg (rat)

· Skin corrosion/irritation

Based on available data, the classification criteria are not met.

- · Serious eye damage/irritation
 - Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Germ cell mutagenicity

Based on available data, the classification criteria are not met.

- · Carcinogenicity May cause cancer.
- · Reproductive toxicity

Based on available data, the classification criteria are not met.

(Contd. on page 7)

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX K

(Contd. of page 6)

· STOT-single exposure

Based on available data, the classification criteria are not met.

· STOT-repeated exposure

Based on available data, the classification criteria are not met.

· Aspiration hazard

Based on available data, the classification criteria are not met.

- · 11.2 Information on other hazards
- · Endocrine disrupting properties

The product contains substances, which affect the thyroid system and other hormonal systems.

None of the ingredients is listed.

12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability

No further relevant information available.

· 12.3 Bioaccumulative potential

No further relevant information available.

- \cdot 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water $\ \ \,$

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

HP7 Carcinogenic

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

TE

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX K

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14 Transport information	
· 14.1 UN number or ID number · ADR, IMDG, IATA	not regulated
· 14.2 UN proper shipping name · ADR, IMDG, IATA	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group	
· ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

- \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 28, 72
- · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

 None of the ingredients is listed.
- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

- · Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

 None of the ingredients is listed.
- · National regulations:
- · Information about limitation of use:

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

(Contd. on page 9)

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024 Version number 1 Revision: 04.07.2024

Trade name: proteus color OX K

(Contd. of page 8)

· 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· Relevant phrases

- H301 Toxic if swallowed.
- H311 Toxic in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H331 Toxic if inhaled.
- H335 May cause respiratory irritation.
- H341 Suspected of causing genetic defects.
- H350 May cause cancer.
- · Department issuing SDS: Product safety department.
- · Contact: -
- · Date of previous version: 01.07.2024
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

ATE: Acute toxicity estimate values

Acute Tox. 3: Acute toxicity - Category 3

Skin Corr. 1B: Skin corrosion/irritation - Category 1B

Skin Sens. 1: Skin sensitisation - Category 1

Muta. 2: Germ cell mutagenicity - Category 2

Carc. 1B: Carcinogenicity - Category 1B

· * Data compared to the previous version altered.



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Revision: 04.07.2024

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Printing date 04.07.2024

Version number 1

ne substance/mixture and of the company/

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

- · 1.1 Diagnostic Reagent
- · Trade name: Proteus color controllo positivo
- · Article number: 192673
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant Identified Uses: For laboratory use only Uses advised against: Uses other than those recommended

- · Application of the substance / the mixture Diagnostic reagent
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Sclavo Diagnostics International Via Po 26-28, Loc. Pian dei Mori CAP: 53018 - SOVICILLE - (SI) ITALY

- · Further information obtainable from: Product safety department.
- 1.4 Emergency telephone number: +39 0577 390 444 / 445

2 Hazards identification

- \cdot 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 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · 3.2 Mixtures
- · Description:

Mixture of substances listed below with nonhazardous additions.

· Dangerous components: Void

(Contd. on page 2)

according to Regulation (EC) No 1907/2006, Article 31 including amending Regulation EU/2020/878

Version number 1 Revision: 04.07.2024 Printing date 04.07.2024

Trade name: Proteus color controllo positivo

(Contd. of page 1)

· Additional information:

For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- · After inhalation:

Supply fresh air; consult doctor in case of complaints.

- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact:

Rinse opened eye for several minutes under running water.

- · After swallowing: If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

- · 5.2 Special hazards arising from the substance or mixture
 - No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 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).
- · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection:

No special measures required.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

No special requirements.

· Information about storage in one common storage facility: Not required.

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- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:
 The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- · Additional information:

The lists valid during the making were used as basis.

- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · Respiratory protection: Not required.
- · Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection Goggles recommended during refilling

9 Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

· Physical state Fluid

· Colour: According to product specification

Odour: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: Undetermined.

· Boiling point or initial boiling

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.

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· рН	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
Dynamic:	Not determined.
· Solubility	
water:	Not miscible or difficult to mix.
Partition coefficient n-octanol/	•
water (log value)	Not determined.
· Vapour pressure:	Not determined.
Density and/or relative density	
· Density:	Not determined.
Relative density	Not determined.
· Vapour density	Not determined.
9.2 Other information	
Appearance:	
Form:	Fluid
Important information on	
protection of health and	
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion
	hazard.
· Solvent content:	
· VOC (EC)	0.00 %
· Solids content:	99.0 %
· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to	
physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and	V O T Q
mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void Void
	νοτα
Self-heating substances and	170101
mixtures	Void
Substances and mixtures, which	
emit flammable gases in contact	
with water	Void
· Oxidising liquids	Void
	T 7 - 4 -1
Oxidising solids	Void
· Oxidising solids · Organic peroxides	void Void
Oxidising solids	

10 Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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· 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further 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

Based on available data, the classification criteria are not met.

· Skin corrosion/irritation

Based on available data, the classification criteria are not met.

· Serious eye damage/irritation

Based on available data, the classification criteria are not met.

· Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

· Germ cell mutagenicity

Based on available data, the classification criteria are not met.

· Carcinogenicity

Based on available data, the classification criteria are not met.

· Reproductive toxicity

Based on available data, the classification criteria are not met. · STOT-single exposure

Based on available data, the classification criteria are not met.

· STOT-repeated exposure

Based on available data, the classification criteria are not met.

- · Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards · Endocrine disrupting properties

The product contains substances, which affect the thyroid system and other hormonal systems.

None of the ingredients is listed.

12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability

No further relevant information available.

· 12.3 Bioaccumulative potential

No further relevant information available.

- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

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- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water $\ \ \,$

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Smaller quantities can be disposed of with household waste.

- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

14 Transport information

 14.1 UN number or ID number ADR, IMDG, IATA not regulated 14.2 UN proper shipping name ADR, IMDG, IATA not regulated
,,
· 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA · Class not regulated
· 14.4 Packing group · ADR, IMDG, IATA not regulated
· 14.5 Environmental hazards: Not applicable.
· 14.6 Special precautions for user Not applicable.
 14.7 Maritime transport in bulk according to IMO instruments Not applicable.
· UN "Model Regulation": not regulated

15 Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

None of the ingredients is listed.

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· REGULATION (EU) 2019/1148

· Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- · Department issuing SDS: Product safety department.
- · Contact: -
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative