## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Issue date: 11/28/2022 Version: 1.0 SDS No: 13129-0030-005

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product form : Mixture

Product name : PROTECTASEPT SKIN UFI 8251-R0P4-100T-NPKX Type of product : Biocidal product

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

#### 1.2.1. Relevant identified uses

Use of the substance/mixture : Hand disinfection

1.2.2. Uses advised against

Restrictions on use : No additional information available

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

Supplier Manufacturer

MCD Medical Care Dental GmbH Laboratorium Dr. Deppe GmbH

Heinrich-Hertz-Str. 11 Hooghe Weg 35 50181 Bedburg 47906 Kempen Deutschland Germany

T 02272-401111 T +49 2152 55650 - F +49 2152 50849 info@nitras-medical.com - , www.nitras-medical.com sdb@drdeppe.de - www.drdeppe.de

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Germany	Giftinformationszentrum-Nord der Länder Bremen, Hamburg, Niedersachsen und Schleswig-Holstein (GIZ-Nord) Universitätsmedizin Göttingen - Georg- August-Universität	Robert-Koch Straße 40 37075 Göttingen	+49 (0) 551 19240	

### **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

## Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2 H225 H319 Serious eye damage/eye irritation, Category 2

Full text of H- and EUH-statements: see section 16

#### Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. Causes serious eye irritation.

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP) : Danger

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Hazard statements (CLP) : H225 - Highly flammable liquid and vapour.

H319 - Causes serious eye irritation.

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

P280 - Wear eye protection, face protection.

P337+P313 - If eye irritation persists: Get medical advice/attention.

Extra phrases : For professional users only.

### 2.3. Other hazards

Other hazards not contributing to the classification : Explosive vapour/air mixtures may be formed.

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## **SECTION 3: Composition/information on ingredients**

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol (Active substance (Biocide))	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002-00-5 REACH-no: 01-2119457610-	≥ 75 – < 80	Flam. Liq. 2, H225 Eye Irrit. 2, H319
Phosphoric acid Substance with a Community workplace exposure limit	CAS-No.: 7664-38-2 EC-No.: 231-633-2 EC Index-No.: 015-011-00-6 REACH-no: 01-2119485924- 24	≥ 0.3 - < 3	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318

Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
Ethanol (Active substance (Biocide))	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002-00-5 REACH-no: 01-2119457610-	( 50 ≤C ≤ 100) Eye Irrit. 2, H319	
Phosphoric acid	CAS-No.: 7664-38-2 EC-No.: 231-633-2 EC Index-No.: 015-011-00-6 REACH-no: 01-2119485924- 24	( 10 ≤C < 25) Eye Irrit. 2, H319 ( 10 ≤C < 25) Skin Irrit. 2, H315 ( 25 ≤C ≤ 100) Skin Corr. 1B, H314	

Full text of H- and EUH-statements: see section 16

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## **SECTION 4: First aid measures**

## 4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : The product is not considered to be irritating to the skin.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after eye contact : Eye irritation.

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

Treat symptomatically.

### **SECTION 5: Firefighting measures**

### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

Unsuitable extinguishing media : Strong water jet.

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

Fire hazard : Highly flammable liquid and vapour.

Hazardous decomposition products in case of fire : Toxic fumes may be released.

## 5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

## **SECTION** 6: Accidental release measures

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

### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Avoid contact with skin

and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

## 6.2. Environmental precautions

Avoid release to the environment.

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

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or

public waters.

Other information : Dispose of materials or solid residues at an authorized site.

### 6.4. Reference to other sections

For further information refer to section 13.

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### **SECTION 7: Handling and storage**

### 7.1. Precautions for safe handling

Additional hazards when processed

: In use, may form flammable vapour-air mixture. Precautions for safe handling

: Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof

equipment. Wear personal protective equipment. Avoid contact with eyes.

Hygiene measures Do not eat, drink or smoke when using this product. Always wash hands after handling the

product.

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

: Ground/bond container and receiving equipment. Technical measures

Storage conditions Store in a well-ventilated place. Keep cool. Keep container tightly closed.

Heat and ignition sources Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

### 7.3. Specific end use(s)

See Section 1.

### **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

### 8.1.1 National occupational exposure and biological limit values

Phosphoric acid (7664-38-2)		
EU - Indicative Occupational Exposure Limit (IOEL)		
Local name	Orthophosphoric acid	
IOEL TWA	1 mg/m³ 1 mg/m³	
IOEL STEL	2 mg/m³ 2 mg/m³	
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC COMMISSION DIRECTIVE 2000/39/EC	

#### 8.1.2. Recommended monitoring procedures

No additional information available

## 8.1.3. Air contaminants formed

No additional information available

### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

### Appropriate engineering controls:

Ensure good ventilation of the work station.

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#### 8.2.2. Personal protection equipment

#### Personal protective equipment symbol(s):







### 8.2.2.1. Eye and face protection

### Eye protection:

Safety glasses

#### 8.2.2.2. Skin protection

#### Skin and body protection:

Wear suitable protective clothing

#### Hand protection:

Protective gloves

### 8.2.2.3. Respiratory protection

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

### **Environmental exposure controls:**

Avoid release to the environment.

Relative vapour density at 20°C

Particle characteristics

## **SECTION 9: Physical and chemical properties**

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

Physical state : Liquid Colourless. Colour Appearance Clear. Odour Not available Odour threshold Not available Melting point Not available Freezing point : Not available : ≈ 79 °C **Boiling point** Flammability (solid, gas) : Not applicable

Explosive properties : Product is not explosive. Flammable or explosive vapour/air mixtures may be formed.

Oxidising properties : Non oxidizing. **Explosive limits** : Not available Lower explosive limit (LEL) Not available : Not available Upper explosive limit (UEL) Flash point : 19 °C Auto-ignition temperature : Not available Decomposition temperature : Not available : 2.5 - 2.9 pН Viscosity, kinematic : Not available Solubility : Not available Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50°C : Not available Density : 0.862 - 0.872 g/cm<sup>3</sup> Relative density : Not available

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: Not available

: Not applicable

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#### 9.2. Other information

### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Refractive index : 1.36 - 1.37 (20°C)

## **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

Highly flammable liquid and vapour.

### 10.2. Chemical stability

Stable under normal conditions.

## 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### **SECTION 11: Toxicological information**

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

Acute toxicity (oral) : Not classified Acute toxicity (dermal) : Not classified Acute toxicity (inhalation) : Not classified

Ethanol (64-17-5)		
LD50 oral	6200 mg/kg	
LD50 dermal	20000 mg/kg	
Phosphoric acid (7664-38-2)		
LD50 dermal	1071 mg/kg	
ATE CLP (oral)	500 mg/kg bodyweight	

Skin corrosion/irritation : Not classified

pH: 2.5 - 2.9

Serious eye damage/irritation : Causes serious eye irritation.

pH: 2.5 - 2.9

Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified : Not classified Carcinogenicity Reproductive toxicity : Not classified STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard : Not classified

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#### 11.2. Information on other hazards

No additional information available

## **SECTION 12: Ecological information**

### 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse

effects in the environment.

Hazardous to the aquatic environment, short-term

: Not classified

Hazardous to the aquatic environment, long-term

(chronic)

: Not classified

### 12.2. Persistence and degradability

No additional information available

## 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## **SECTION 13: Disposal considerations**

### 13.1. Waste treatment methods

Waste treatment methods Additional information

: Dispose of contents/container in accordance with licensed collector's sorting instructions.

Flammable vapours may accumulate in the container.

## **SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	ADR IMDG IATA ADN		RID		
14.1. UN number or ID n	14.1. UN number or ID number				
UN 1170 UN 1170		UN 1170	UN 1170	UN 1170	
14.2. UN proper shippin	14.2. UN proper shipping name				
ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	Ethanol solution	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	

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ADR	IMDG	IATA	ADN	RID		
Transport document descr	Transport document description					
UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II, (D/E)	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II	UN 1170 Ethanol solution, 3, II	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II		
14.3. Transport hazard	class(es)					
3	3	3	3	3		
3	3	3	3	3		
14.4. Packing group						
II	II	II	II	II		
14.5. Environmental hazards						
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No		
No supplementary information	No supplementary information available					

## 14.6. Special precautions for user

### **Overland transport**

Classification code (ADR) : F1 : 144, 601 Special provisions (ADR) Limited quantities (ADR) : 11 Excepted quantities (ADR) : E2

Packing instructions (ADR) : P001, IBC02, R001

: MP19 Mixed packing provisions (ADR) Transport category (ADR) 2 Hazard identification number (Kemler No.) 33 :

Orange plates

1170 Tunnel restriction code (ADR) : D/E

Transport by sea

Special provisions (IMDG) : 144 : 1L Limited quantities (IMDG) Excepted quantities (IMDG) : E2 : P001 Packing instructions (IMDG) IBC packing instructions (IMDG) : IBC02 : T4 Tank instructions (IMDG) : TP1 Tank special provisions (IMDG) : F-E EmS-No. (Fire) EmS-No. (Spillage) : S-D Stowage category (IMDG) : A

Air transport

PCA Excepted quantities (IATA) : E2 : Y341 PCA Limited quantities (IATA) PCA limited quantity max net quantity (IATA) : 1L : 353 PCA packing instructions (IATA) : 5L PCA max net quantity (IATA)

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CAO packing instructions (IATA) : 364
CAO max net quantity (IATA) : 60L

Special provisions (IATA) : A3, A58, A180

ERG code (IATA) : 3L

Inland waterway transport

: F1 Classification code (ADN) : 144, 601 Special provisions (ADN) Limited quantities (ADN) · 11 Excepted quantities (ADN) : E2 Carriage permitted (ADN) : T : PP, EX, A Equipment required (ADN) Ventilation (ADN) : VE01 Number of blue cones/lights (ADN) : 1

Rail transport

Classification code (RID) : F1
Special provisions (RID) : 144, 601
Limited quantities (RID) : 1L
Excepted quantities (RID) : E2

Packing instructions (RID) : P001, IBC02, R001

Transport category (RID) : 2
Hazard identification number (RID) : 33

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

### **SECTION 15: Regulatory information**

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

### 15.1.1. EU-Regulations

### **REACH Annex XVII (Restriction List)**

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

#### **REACH Annex XIV (Authorisation List)**

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

### **REACH Candidate List (SVHC)**

Contains no substance(s) listed on the REACH Candidate List

### **PIC Regulation (Prior Informed Consent)**

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

## **POP Regulation (Persistent Organic Pollutants)**

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### **Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

## **Drug Precursors Regulation (273/2004)**

Contains substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

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### **Seveso Directive (Disaster Risk Reduction)**

Seveso III Part I (Categories of dangerous substances)	Qualifying quantity (tonnes)	
	Lower-tier	Upper-tier
P5c FLAMMABLE LIQUIDS Flammable liquids, Categories 2 or 3 not covered by P5a and P5b	5000	50000

## 15.1.2. National regulations

No additional information available

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## **SECTION 16: Other information**

Abbreviations and acr	onyms:
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

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Abbreviations and acronyms:		
STP	Sewage treatment plant	
ThOD	Theoretical oxygen demand (ThOD)	
TLM	Median Tolerance Limit	
VOC	Volatile Organic Compounds	
CAS-No.	Chemical Abstract Service number	
N.O.S.	Not Otherwise Specified	
vPvB	Very Persistent and Very Bioaccumulative	
ED	Endocrine disrupting properties	
DOT	Department of Transport	
TDG	Transportation of Dangerous Goods	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals	
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships	
ADG	Transport of Australian Dangerous Goods	

### Other information

: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Full text of H- and EUH-statements:		
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Flam. Liq. 2	Flammable liquids, Category 2	
H225	Highly flammable liquid and vapour.	
H290	May be corrosive to metals.	
H302	Harmful if swallowed.	
H314	Causes severe skin burns and eye damage.	
H315	Causes skin irritation.	
H318	Causes serious eye damage.	
H319	Causes serious eye irritation.	
Met. Corr. 1	Corrosive to metals, Category 1	
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	

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Classification and pro	Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Flam. Liq. 2	H225	On basis of test data	
Eye Irrit. 2	H319	Calculation method	

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.