



### Product: F10 Sterilant with Rust Inhibitor RTU

#### Revision date: 2022-09-26

### **EXPLANATORY NOTES**

This Safety Data Sheet has been compiled in accordance to the ECHA Guidelines (2020), European Regulation (EC) No. 1272/2008 (CLP), and Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (2021).

This Safety Data Sheet in its entirety applies to the product as a packed concentrate.

All packed products (sizes up to 5*l*) contain tamper proof heat induction seals.

Section 3 Hazard classification refers to the 100% raw material pure substance classification in the mixture and not the product mixture or the dilutions.

Section 16 Hazard statements are as per ECHA Pure Substance Classification and refers to the 100% raw material pure substance classification as specified in Section 3 and not the product mixture or dilutions.

# **SECTION 1: Chemical product and company identification**

#### Product identifier

Product form	Mixture
Trade name(s)	F10 Sterilant with Rust Inhibitor RTU (Ready to Use)
Relevant identified uses of the substance or mixtur	e and uses advised against
Relevant identified uses	For the rapid sterilization of heat-sensitive devices and surgical instruments. For the disinfection of all hard surfaces, non-porous surface and equipment in industrial, domestic and institutional areas. Safe for use on metals, plastics, rubber and latex.
Details of the supplier of the safety data sheet	
Manufacturer	Health and Hygiene (Pty) Ltd.
Address	Corner Leader and Hoefsmid Street, Stormill Ext. 10, Roodepoort, 1709, South Africa
Telephone number	+27 (0) 11 474 1668
E- mail address	info@healthandhygiene.co.za / info@f10products.com
Emergency contact number(s)	+27 (0) 11 474 1668

Country	Organisation	Website	Emergency number
Australia	Poisons Information Centre	https://www.health.gov.au/contacts/poisons-information-centre	13 11 26
Belgium	Centre Anti-Poisons/ Antigifcentrum	https://www.poisoncentre.be/	+32 70 245 245
Canada	BC Drug and Poison Information Center	https://infopoison.ca/centres/	+1 604 707 2789
China	National Poison Control Center	https://www.chinacdc.cn/en/	+86 24 25718881
Czech Republic	Toxicological Information Centre	https://www.cenia.cz/odborna-podpora/reach/bezpecnostni-listy/	+420 22 49 192 93
Finland	Poison Information Centre	https://www.hus.fi/en/medical-care/medical- services/Poison%20Information%20Centre/Pages/default.aspx	0800 147 111 09 471 977

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France	Centre antipoison et de toxicovigilance de Paris	https://reach-info.ineris.fr/Numero_orfila	+33 (0)1 45 42 59 59
Germany	Clinical Toxicology and Berlin Poison Information Centre	https://www.reach-clp-biozid- helpdesk.de/DE/REACH/Sicherheitsdatenblatt/Sicherheitsdatenblatt-EN/Emergency- Telephone-number.html	+49 30 192 40
Hong Kong	Hong Kong Poison Information Centre	https://www.hkpcn.org.hk/eng/HKPIC.html	+852 3949 5089
Iceland	Eitrunarmiðstöð Landspítali	http://www.landspitali.is/?PageID=14556	+354 543 22 22
Iraq	Poisoning consultation centre		+964 (0)780 191 3821
Ireland	National Poison Information Centre	https://www.poisons.ie	+353 1 8092566
Italy	Poison Centre – Catholic University School of Medicine	https://preparatipericolosi.iss.it/cav.aspx	+39 06 305 43 43
Malta	Medicines & Poisons Info Office	https://deputyprimeminister.gov.mt/en/Pages/health/aspx	112
Netherlands	Nationaal Vergiftigingen Informatie Centrum Uitsluitend bestemd om artsen te informeren bij accidentele vergiftigingen	https://www.umcutrecht.nl/nl/Subsites-nl/Nationaal-Vergiftigingen-Informatie-Centrum- (NVIC)/Productinformatie/Informationsheet-product-notification	+31 30 274 88 88 +31 (0)88 755 8000
New Zealand	The National Poisons Centre	https://poisons.co.nz/	0800 764 766 0800 POISON
Philippines	National Poison Management & Control Center	https://m.facebook.com/upnpmcc	+632 544 8400 local 3726
Qatar	Qatar Poison Centre		+974 4003 1111
Saudi Arabia	Drug and Poison Information Center	https://beta.sfda.gov.sa/en/toxicinfo-dept	+966 11 232 4180
South Africa	Tygerberg Poison Information Centre	https://www.sun.ac.za/english/faculty/healthsciences/Clinical%20Pharmacology/poison- information-centre	+27 (0)861 555 777
Spain	Servicio de Información Toxicológica	https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/productos- guimicos/portal-reach-clp/novedades/detalle_novedades.aspx?id=tcm:30-193752-16	+34 91 562 0420
Switzerland	Swiss Toxicological Information Centre	https://toxinfo.ch/startseite_en	+41 44 251 51 51 (in Switzerland dial 145)
United Arab Emirates	Health Poison and Drug Information Center	https://u.ae/en/information-and-services/justice-safety-and-the-law/handling- emergencies	+971 8 449 3333
United Kingdom	National Poisons Information Service	https://www.npis.org/	844 892 0111
USA	National Capital Poison Center	https://www.poison.org/	1-800-222-1222

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In the case of country not listed above, contact your nearest local Poison Centre.

For further information refer to ECHA website for Poison Centres (https://poisoncentres.echa.europa.eu/).

## **SECTION 2: Hazards identification**

# Classification of the substance or mixture Not classified Label elements Labelling according to Regulation (EC) No 1272/2008 [CLP] Hazard pictogram(s) None Signal word None Hazard statements None **Precautionary statements** P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P103 Read label before use. P264 Wash hands thoroughly after handling. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P317 If eye irritation persists: Get emergency medical help. P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of container in suitable manner as is required by country legislation. **Supplemental Hazard information**

Not applicable

#### Other hazards

None

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

# Substances

Not applicable

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#### **Mixtures**

Substance name	CAS No EC No	Classification according Regulation (EC) No 1278/ 2008 [CLP] (100% raw material pure substance classification)	Formulated Concentration (packed product) (% w/w)
Di-decyl dimethyl-ammonium Chloride	7173-51-5 230-525-2	Acute Tox.; 3; H301/ Skin Corr.; 1B; H314 Aquatic Acute; 1; H400	0.005 – 0.05 %
Benzyl (C12-16) Alkyl Dimethyl Ammonium chloride	68424-85-1 270-325-2	Acute Tox.; 4; H302/ Skin Corr.; 1B; H314 Aquatic Acute; 1; H400/ Aquatic Chronic; 1; H410	0.005 – 0.05 %
Poly (hexamethylene biguanide) Hydrochloride	27083-27-8	Acute Tox.; 4; H302/ Acute Tox.; 2; H330 Eye Dam.; 1; H318/ Skin Sens.; 1B; H317/ Carc.; 2; H351/ STOT RE1; H372/ Aquatic Acute; 1; H400/ Aquatic Chronic; 1; H410	0.001 – 0.007 %
Ingredients determined not to be hazardous			Balance

#### Additional information:

For full text of H- and EUH-statements, refer to SECTION 16.

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

#### Description of first aid measures

#### **General information**

In case of concern or doubt, call a doctor or physician.

#### **Following inhalation**

Move the person to fresh air. Contact a physician if required.

#### Following skin contact

Remove all contaminated clothing immediately. Wash affected area thoroughly with soap and water. Wash contaminated clothing before reuse or discard.

#### Following eye contact

If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses if present. Continue flushing for at least 15 minutes, or until advised to stop by the Poisons Information Centre or a doctor. Seek immediate medical attention.

#### **Following ingestion**

Do not induce vomiting. Wash out mouth thoroughly with water.

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

#### Symptoms/ effects following inhalation

None

#### Symptoms/ effects following skin contact

None

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#### Symptoms/ effects following eye contact

May be some pain and reddening of the eye which will moderate after some time.

#### Symptoms/ effects following ingestion

Ingestion of the concentrate may cause irritation to mouth, throat and digestive tract.

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

If you feel unwell, seek medical advice immediately and show label if possible.

Note to the doctor/ physician

Treat symptomatically.

# **SECTION 5: Firefighting measures**

#### **Extinguishing media**

#### Suitable extinguishing media

Use appropriate fire extinguisher for surrounding environment.

#### Unsuitable extinguishing media

Do not extinguish with water under high pressure.

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

# Hazardous combustion products

This product is non-combustible. However, heating can cause expansion or decomposition leading to violent rupture of containers.

#### Advice for firefighters

Fire fighters should wear full protective clothing and self-contained breathing apparatus (SCBA) operated in positive pressure mode. Fight fire from safe distance and location.

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

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

#### For non-emergency personnel

Wear appropriate personal protective equipment and clothing to prevent exposure to clothing, skin and eyes. Increase ventilation.

# For emergency responders

Have a copy of the SDS available. Use appropriate personal protective equipment.

#### **Environmental precautions**

In case of entry into sewers or waterways, inform the responsible authorities in accordance with relevant regulations.

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

#### For containment

Contain the spill with appropriate material and techniques.

#### For cleaning up

Clean spillages immediately. Do not dilute material but contain it. Place inert absorbent material onto spillage. Collect the material and place into a suitable container.

#### Reference to other sections

Refer to SECTIONS 8 and 13 for exposure control/ personal protection equipment and disposal considerations.

# **SECTION 7: Handling and storage**

#### Precautions for safe handling

Avoid skin and eye contact. Keep containers sealed when not in use. Use in well-ventilated area. Wash hands and other exposed areas with soap and water prior to eating, drinking and smoking. Handle in accordance with good hygiene and safety procedures.

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

Store in a cool, dry, well-ventilated area. Protect from direct sunlight. Store in suitable, labelled containers. Keep containers tightly closed. Ensure that storage conditions comply with applicable local and national regulations.

## Specific end use(s)

Refer to SECTION 1 for identified end use(s).

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

#### Control parameters

#### **Occupational exposure limits**

No exposure standards have been established for the mixture. However, over-exposure to some chemicals may result in enhancement of pre-existing medical conditions and/ or allergic reactions and should be kept to the least possible levels.

#### **Biological limit values**

No biological limits allocated.

#### Exposure limits at intended use

DNEL/ PNEC – values — No data available

#### Exposure controls

#### Appropriate engineering controls

Handle in premises with good ventilation. Eye rinsing facilities shall be available at the workplace.

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#### Personal protection equipment

## Eye and face protection

None required. Care should be exercised to prevent contact with eyes.

#### Skin protection

None required. Care should be exercised to prevent contact with skin.

#### **Respiratory protection**

No respiratory protection required.

### **Environmental exposure controls**

Refer to SECTION 12 for limitations on environmental exposure.

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

# Information on basic physical and chemical properties

Appearance	_	clear, colourless liquid
Odour	_	characteristic odour
Odour threshold	—	not available
Melting point/ freezing point	_	not available
Boiling point	_	100°C
Flammability	_	not combustible
Lower and upper explosion limit	_	not available
Flash point	_	not available
Auto-ignition temperature	_	not available
Decomposition temperature	_	not available
pH (undiluted)	_	7.5
Viscosity	_	not available
Solubility in water	_	soluble
Partition coefficient	_	not known
Vapour pressure	_	not available
Density	_	1.0g/cm <sup>3</sup>
Vapour density (air = 1)	_	not available

## Other information

No other data available

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# **SECTION 10: Stability and reactivity**

#### Reactivity

The product contains no substances which could lead to hazardous reactions during normal use, handling and storage.

#### **Chemical stability**

Stable when handled and stored under normal ambient conditions.

#### Possibility of hazardous reactions

No hazardous reactions when handled and stored under normal ambient conditions.

#### **Conditions to avoid**

Protect from direct sunlight.

#### Incompatible materials

Do not mix with anionic detergents and other chemicals.

#### Hazardous decomposition products

No known hazardous decomposition products.

# **SECTION 11: Toxicological information**

#### Information on hazard classes as defined in Regulation (EC) No 1272/ 2008 & EPA Guidelines\*\*

**	Category 1	_	High Toxicity	Category 2	_	Moderate Toxicity
	Category 3	_	Low Toxicity	Category 4	_	Very Low Toxicity

#### Data as per non-diluted Packed Concentrated Product

•		
Acute toxicity (oral) (rat)	—	None
Acute toxicity (dermal) (rat)	—	None
Skin corrosion/ irritation	—	None
Serious eye damage/ irritation	—	None
Respiratory or skin sensitisation	—	None
Germ cell mutagenicity	—	None predicted based on data for the raw materials
Carcinogenicity	—	None predicted based on data for the raw materials
Reproductive toxicity	—	None predicted based on data for the raw materials
STOT-single exposure	—	No known hazards for occasional exposure
STOT-repeated exposure	—	No known hazards for repeated exposure
Aspiration hazard	—	Not expected to be an aspiration hazard
Inhalation toxicity	—	> 2 mg / L for 4-hour exposure

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#### Information on other hazards

None

## **SECTION 12: Ecological information**

#### Toxicity

Acute (short-term) toxicity	—	None
Chronic (long-term) toxicity		None

#### Persistence and degradability

Product is readily biodegradable, and the product is neither persistent nor problematic metabolites are produced. The product is hydrolytically stable, and hydrolytic processes do not contribute to its degradation in the environment, it is neither volatile nor is it expected to be present in the air. It can be considered immobile in soil.

#### **Bioaccumulative potential**

No additional information available.

#### Mobility in soil

Not mobile in soil.

#### Results of PBT vPvB assessment

None of the substances in this mixture is considered to be persistent, bioaccumulating and toxic or considered to be very persistent and very bioaccumulating.

#### **Endocrine disrupting properties**

No additional information available.

#### Other adverse effects

No additional information available.

# **SECTION 13: Disposal considerations**

#### Waste treatment methods

Waste should not be disposed of by release to sewers. Dispose of this material and its container in a safe manner in accordance with relevant and applicable local and national regulations and/ or legislation. Avoid release to the environment.

# **SECTION 14: Transport information**

#### UN number or ID number

None allocated. Not classified as dangerous goods.

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UN proper shipping name

None allocated.

Transport hazard class(es) None allocated.

Packing group Not applicable.

Environmental hazards

Not applicable.

Special precautions for user

None necessary.

Maritime transport in bulk according to IMO instruments

Not applicable.

# **SECTION 15: Regulatory information**

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

Classified as Hazardous according to SANS 10234:2019 Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Safety, health and environmental regulations/ legislation specific for the substance or mixture:

South Africa — NRCS VC8054:2017 — Compulsory Specification for Chemical Disinfectants

United Kingdom — HSE Health Directorate HD D4 (Biocides and Pesticides Assessment Unit) — Safety of raw materials

During international product registration (refer countries below), of the F10<sup>®</sup> product range, all safety, health and environmental aspects are considered by the relevant authorities.

Australia (APVMA)	China	Czech Republic	France (ANSES)	Germany (BAUA)
Hong Kong	Iraq (Ministry of Health)	Kuwait	Namibia	Philippines
Qatar	Singapore	UAE (Dubai Municipality,	MoChAe)	United Kingdom (HSE)
USA (EPA, FDA)				

### Chemical safety assessment

Chemical Safety Assessment based on study data of base formulation and dilutions.

# SECTION 16: Other information

#### Indication of changes

New format to comply with all international legislation.

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Addition of explanatory notes.

Section 15 revised.

### Abbreviations and acronyms

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CAS	—	Chemical Abstracts Service Number
CLP	—	Classification Labelling Packaging Regulation
DNEL	—	Derived No Effect Level
EC	—	European Community
EPA	—	Environmental Protection Agency
ECHA	—	European Chemicals Agency
GHS	—	Globally Harmonized System
HSE	_	Health and Safety Executive
IMO	—	International Maritime Organisation
NRCS	—	National Regulator for Compulsory Specifications
OPPTS	_	Office of Prevention, Pesticides and Toxic Substances
PBT	—	Persistent Bioaccumulative and Toxic Substance
PNEC	_	Predicted No Effect Concentration(s)
SANS	—	South African National Standards
SDS	_	Safety Data Sheet
STOT	_	Specific Target Organ Toxicity
UN	_	United Nations
vPvB	_	Very Persistent and Very Bioaccumulative
w/w	_	Weight by Weight

#### Key literature references and sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, Regulation (EC) 1272/ 2008 Annex I, as well as from actual test data performed on the product itself.

#### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

All classifications were done as per available test data based on Health Effects Guideline OPPTS and EPA Guidelines or as per official European classification as listed per CLP and GHS regulations.

# Relevant H- and EUH-statements (number and full text)

#### The following refers to the 100% raw material pure substance classification

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H318	—		Causes se	erious eye dama	je		
H317	_		May cause an allergic skin reaction				
H314	_		Causes severe skin burns and eye damage				
H302	—		Harmful if swallowed				
H301	—		Toxic if swallowed				





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H330	_	Fatal if inhaled
H351	—	Suspected of causing cancer
H372	—	Causes damage to organs through prolonged or repeated exposure
H400	—	Very toxic to aquatic life
H410	_	Very toxic to aquatic life with long lasting effects

# Training advice

All personnel handling this product must be made aware of the content of the SDS and hazards of the product if any.

# **Further information**

Not applicable.

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