

21/2/2024
Version 1.0

Safety Data Sheet

Denfiz Racina SH

SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

- 1.1 Product Identifier
Product name : Denfiz Racina SH
- 1.2 Relevant identified uses of the substance or mixture and uses advised against
- Relevant identified uses:
Product Code : BCC1001
Main use category : Professional use
Function or use category : Root Canal Rinsing Solution
- Uses advised against : No additional information available
- 1.3 : Details of the supplier of the safety data sheet
Supplier
Safecare Medical Industries
KIZAD KHIA 8-18
P.O. Box 133685, Abu Dhabi
United Arab Emirates
- Contact person: Regulatory Affairs – tel. +971 2 506 7333

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture
Not a hazardous substance or mixture according to regulation (EC) No 1272/2008.
- 2.2 Label elements
Signal word (CLP) : None Required
Pictogram : None Required
Hazard statements (CLP) : None Required
Precautionary Phrases : None Required
Precautionary statements (CLP) : None Required

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

- 3.1 Substances : Not applicable
- 3.2 Mixtures

Name	Product Identifier	%	Classification according to Regulations (EC) No. 1272/2008 (CLP)
Water and non-hazardous ingredients	Mixture	98-100%	NA
Sodium Hypochlorite	7681-52-9	<5%	Skin Corr. 1B H31 Acute aquatic toxicity Category 1; H400

SECTION 4: FIRST AID MEASURES

- 4.1 Description of first aid measures

- First-aid measures after inhalation : Acute effects following exposure to this product via inhalation are not expected during normal use.
- First-aid measures after skin contact: The use of gloves is recommended when handling this product. Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
- First-aid measures after eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice / attention.
- First-aid measure after ingestion : If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER or doctor/physician if you feel unwell.
- 4.2 Most important symptoms and effects, both acute and delayed symptoms/effects
: In all cases of doubt, or when symptoms persist, seek medical attention.
Symptoms/effects after skin contact: Causes skin irritation
Symptoms/effects after eye contact: Causes eye irritation.
- 4.3 Indication of any immediate medical attention and special treatment needed
: Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

- 5.1 Extinguishing media : Use extinguishing media appropriate for surrounding fire. Water fog, Foam, carbon dioxide (CO2) and powder.
Unsuitable extinguishing media : None known
- 5.2 Special hazards arising from the substance or mixture
Fire hazard : Not flammable or combustible
Explosion hazard : Product is not explosive
Hazardous decomposition products in case of fire : Carbon and sodium oxides
- 5.3 Advice for firefighters
Firefighting instructions : Use personal protective equipment
Specific Extinguishing Methods : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. In the event of fire and/or explosion do not breathe fumes

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- General measures : Wear appropriate personal protective equipment - see Section 8.
Avoid contact with skin and eyes.
- For non-emergency personnel** : No additional information available
- For emergency responders** : No additional information available
- 6.2. Environmental precautions** : Discharging into rivers and drains is forbidden.
- 6.3. Methods and material for containment and cleaning up**
For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.
- Methods for cleaning up : Do not reuse towelette. Pick up wipe and place in an appropriate container for disposal. If used, please in a container for infectious waste disposal. Do not flush in toilet.

6.4. Reference to other sections : For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for safe handling : Keep container tightly closed. Avoid contact with skin and eyes.
 Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Keep only in original container. Do not expose to temperatures exceeding 50 °C/ 122 °F. Keep cool. Keep out of reach of children. Store in suitable, labelled containers.

Incompatible materials : None known

7.3. Specific end use(s)

Specific uses: : Medical devices. Automatic and manual processes

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Components	CAS-No.	Form of Exposure	Permissible Concentration	Basis
Water and non-hazardous ingredients	Various	TWA (Particles)	10mg/m ³	UKCOSSTD

DNEL

Water and non-hazardous ingredients	Various	None Established
Sodium Hypochlorite	7681-52-9	1.55 mg/m ³

PNEC

Water and non-hazardous ingredients	Various	None Established
Sodium Hypochlorite	7681-52-9	4.69 mg/l

8.2 Exposure Controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Personal protective equipment : No special protective equipment required.

Hand protection : Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/ impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Eye protection : Safety glasses with side-shields

Skin and body protection : No special protective equipment required

Respiratory protection : No special respiratory protection equipment is recommended under normal

conditions of use with adequate ventilation.

Other Information : Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking when leaving work.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	: Clear, colorless liquid on a polyester towelette
Colour	: Clear
Odor	: Slight Bleach odor
Odor threshold	: Not determined
pH	: 10.5-12.5
Relative evaporation rate	: Not determined
Melting point	: Not determined
Freezing point	: Not determined
Boiling point	: 100°C
Flash point	: Not determined
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined
Flammability (solid, gas)	: Not determined
Vapour pressure	: Not determined
Relative vapour density at 20°C	: Not determined
Relative density	: 1.04
Solubility	: Not determined
Log Pow	: Not determined
Viscosity, kinematic	: Not determined
Viscosity, dynamic	: Not determined
Explosive properties	: Product is not explosive.
Oxidising properties	: Not determined
Explosive limits	: Not determined

9.2 Other Information

Addition Information : None to our knowledge

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under conditions of normal use

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

No decomposition if stored and used normally.

Thermal decomposition generates: Carbon monoxide. Carbon dioxide. Nitrogen Oxides, Sulphur Oxides, metal oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity : Not classified
 Skin corrosion/irritation : Causes severe skin burns and eye damage.
 Serious eye damage/irritation : Causes serious eye damage.
 Respiratory or skin sensitisation : Not classified
 Germ cell mutagenicity : Not classified
 Carcinogenicity : Not classified
 Reproductive toxicity : Not classified
 STOT-single exposure : Not classified
 STOT-repeated exposure : Not classified
 Aspiration hazard : Not classified

11.2

Product: Oral rat LD50>5000 mg/kg (no mortalities), inhalation rat LC50 > 2.2mg/L/4 hr (no mortalities), Dermal rat LD50 >5800 mg/kg (no mortalities)

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology – general : No toxicity data available for product.

Sodium Hypochlorite	
Toxicity	96 hr LC50 Oncorhynchus mykiss 1.65 mg/L, 48 hr EC50 daphnia magna 141 ug/L

12.2 Persistence and degradability

Denfiz Racina SH	
Persistence and degradability	No data available

12.3 Bio accumulative potential

Denfiz Racina SH	
Log Pow	Not determined
Bio-accumulative potential	No data available

12.4 Mobility in Soil

Denfiz Racina SH	
Ecology – soil	No data available

12.5 Results of PBT and vPvB assessment

Denfiz Racina SH	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6 Other adverse effects

Other adverse effects : None to our knowledge
 Additional Information : No other effects known

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) : Dispose as hazardous waste.
 Waste treatment methods : Recover the product with absorbent material. Dispose of contents/container in accordance with licensed collector’s sorting instructions.
 Product/Packaging disposal

recommendations : Do not reuse containers. Dispose in a safe manner in accordance with local/national regulations.
 Ecology - waste materials : Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

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

ADR	IMDG	IATA	RID
14.1 UN Number			
1791	1791	1791	1791
14.2 Transport document description			
Sodium Hypochlorite Solution	Sodium Hypochlorite Solution	Sodium Hypochlorite Solution	Sodium Hypochlorite Solution
14.3 Transport hazard class(es)			
8	8	8	8
14.4 Packaging group			
II	II	II	II
14.5 Environmental hazards			
Dangers for Environment: No	Dangers for Environment: No Marine pollutant: No	Dangers for Environment: No	Dangers for Environment: No
No supplementary information available			

SECTION 15: REGULATORY INFORMATION

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

According to Detergents Regulation EC 648/2004: Less than 5% bleach, Potassium Hydroxide.

15.2 Chemical Safety Assessment

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet when needed.

SECTION 16: OTHER INFORMATION

Indication of changes: Identification of the substance/mixture and of the company/undertaking. Relevant identified uses.

1.0	Composition / Information on Ingredients	Modified
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 Version 1.0
 Signature Regulatory Affairs

The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.