

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 03.01.2017

Version number 5

Revision: 20.12.2016

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

1.1 Product identifier

Trade name: **NitraClean**

1.2 Relevant identified uses of the substance or mixture and uses advised against
Application of the substance / the mixture Tablets for cleaning DAC Autoclaves

1.3 Details of the supplier of the safety data sheet

Supplier:

Sirona Dental A/S
Rho 10
DK-8382 Hinnerup
Tel.: +45 87 43 90 60
Fax: +45 87 43 90 61
E-Mail: contact.hygiene@sirona.com

Manufacturer:

O2-Tabs Desinfektion GmbH
- Member of the Medea Group -
Silberhofstr. 88
D-09599 Freiberg

Further information obtainable from:

Tel.: +49 4331 69620 0
Fax: +49 4331 69620 22
E-Mail: info@medeagroup.de

1.4 Emergency telephone number:

Giftinformationen
Bispebjerg Hospital
DK-2400 København NV
Tel.: +45 82 12 12 12

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Eye Irrit. 2 H319 Causes serious eye irritation.

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

Signal word Warning

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

P102 Keep out of reach of children.

(Contd. on page 2)

EU

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 03.01.2017

Version number 5

Revision: 20.12.2016

Trade name: NitraClean

(Contd. of page 1)

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

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 77-92-9 EINECS: 201-069-1 Reg.nr.: 01-2119457026-42-xxxx	citric acid Eye Irrit. 2, H319	25-50%
CAS: 497-19-8 EINECS: 207-838-8 Index number: 011-005-00-2 Reg.nr.: 01-2119485498-19-xxxx	sodium carbonate Eye Irrit. 2, H319	25-50%
CAS: 120313-48-6	Fatty alcohol alkoxyolate Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 2, H411; Skin Irrit. 2, H315	0,25-<2,5%

Regulation (EC) No 648/2004 on detergents / Labelling for contents

non-ionic surfactants <5 %

anionic surfactants <5 %

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

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: No special measures required.

After inhalation: Supply fresh air.

After skin contact: Immediately rinse with water.

After eye contact:

Rinse opened eye for several minutes under running water.

Seek medical treatment.

After swallowing:

Rinse out mouth and then drink plenty of water.

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.

EU

(Contd. on page 3)

Safety data sheet according to 1907/2006/EC, Article 31

Printing date: 03.01.2017

Version number 5

Revision: 20.12.2016

Trade name: NitraClean

(Contd. of page 2)

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:CO₂, powder or water spray. Fight larger fires with water spray.

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: Mouth respiratory protective device.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Product forms slippery surface when combined with water.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Wash residues with water.

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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Prevent formation of dust.

Avoid contact with the eyes and skin.

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:** Store only in the original receptacle.**Information about storage in one common storage facility:** Not required.**Further information about storage conditions:** Protect from humidity and water.**7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical facilities: No further data; see item 7.

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.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 03.01.2017

Version number 5

Revision: 20.12.2016

Trade name: NitraClean

(Contd. of page 3)

8.2 Exposure controls

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.
 Avoid contact with the eyes and skin.

Respiratory protection: In case of dust formation use respiratory protective device.

Protection of hands: Protective gloves

Material of gloves

Nitrile rubber, NBR

Recommended thickness of the material: $\geq 0,11$ mm

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.

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 protection: Tightly sealed goggles

Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	Tablets
Colour:	Blue
Odour:	Characteristic
Odour threshold:	Not determined.

pH-value:	(1 g/150 ml, 20 °C) 6,0-7,0
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Change in condition

Melting point/freezing point:	Not determined.
Initial boiling point and boiling range:	Not determined.

Flash point:	Not applicable.
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Flammability (solid, gas):	Not determined.
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Ignition temperature:

Decomposition temperature:	Not determined.
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Auto-ignition temperature:	Product is not selfigniting.
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Explosive properties:	Product does not present an explosion hazard.
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Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

Vapour pressure:	Not applicable.
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Density:	Not determined.
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(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 03.01.2017

Version number 5

Revision: 20.12.2016

Trade name: NitraClean

(Contd. of page 4)

Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with water:	Easily soluble.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
Organic solvents:	0,0 %
VOC (EC)	0,00 %
9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability Stable if stored according to specifications.

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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Dermal	LD50	10000 mg/kg (rabbit)
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Primary irritant effect:

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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.

EU

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 03.01.2017

Version number 5

Revision: 20.12.2016

Trade name: NitraClean

(Contd. of page 5)

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

77-92-9 citric acid

LC50/48h 440 mg/l (fish)

LC50/24h 1535 mg/l (Daphnia magna)

497-19-8 sodium carbonate

EC50/96h 300 mg/l (Lepomis macrochirus)

120313-48-6 Fatty alcohol alkoxyate

LC50/96h >0,1-<1 mg/l (Leuciscus idus)

EC50/48h >1-<10 mg/l (Daphnia magna)

12.2 Persistence and degradability The contained surfactants are easily biodegradable.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.**vPvB:** Not applicable.
12.6 Other adverse effects No further relevant information available.

SECTION 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.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.**Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA not regulated

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class not regulated

(Contd. on page 7)

EU

Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 5

Revision: 20.12.2016

Trade name: NitraClean

(Contd. of page 6)

14.4 Packing group ADR, IMDG, IATA	not regulated
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

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

Labelling according to Regulation (EC) No 1272/2008 GHS label elements

Directive 2012/18/EU
Named dangerous substances - ANNEX I None of the ingredients is listed.

National regulations:

The product is subject to be labeled according to the prevailing version of the regulations on hazardous substances.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

Relevant phrases

- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H400 Very toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.

Department issuing SDS: Department R&D

Contact: Dr. Niels Ole Vesteraager

Abbreviations and acronyms:

ADR: Accord européen sur le transport 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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

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Trade name: NitraClean

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

* **Data changed with respect to previous version.**

(Contd. of page 7)

EU