

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

Section 1: Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Substance / Trade name: Cleansing Tablets for Dental Prosthesis

Other means of identification: Fittydent Cleansing Tablets (Secure, Profast, Naturdent)

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

Relevant identified uses: Preparing a cleansing bath for dental prosthesis

For external use only, do not apply internally, causes skin burns when wet

No further relevant information available

1.3 Details of the supplier of the safety datasheet

Supplier

FITTYDENT INTERNATIONAL GmbH

Address

Carlbergergasse 38/Top 3/1 OG

Country code/ZIP/City

AT-1230 Vienna

Phone / Fax / E-Mail

Tel.: +43 1 381 81 81

Fax: +43 1 381 81 82

E Mail: office@fittydent.com

www.fittydent.com

1.4 EMERGENCY TELEPHONE NUMBER

+43 1 406 43 43 (Gesundheit Österreich GmbH, 24h)

Section 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



HS03 Flame over Circle
Oxidizing solid
Category 2

Danger

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1



Corrosive to metals
Danger

GHS05 Corrosion
Category 1B
H272 May intensify fire; oxidizer
Skin corrosion/burns
Severe eye damage



Warning

GHS07 Exclamation Mark
Category 4
Acute toxicity

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP/GHS) pictogram:



Labelling according to hazardous components

contains: Potassium Monopersulfate
Sulfamic Acid
Sodium Perborate Monohydrate
Sodium Carbonate Peroxyhydrate

Hazard statements:

H272 May intensify fire; oxidizer
H314 Causes skin burns and severe eye damage
H302 Harmful if swallowed

Precautionary statements:

P210 Keep away from heat/sparks/open flames/hot surfaces – No smoking
P220 Keep/Store away from clothing, combustible material
P221 Take any precaution to avoid mixing with combustibles
P280 Wear protective gloves/protective clothing/eye protection/face protection
P370+P378 In case of fire: Use water to extinction

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

- P501 Dispose of contents according to local/regional/national/international regulations
small amounts and empty containers may be disposed of with household waste
- P260 Do not breathe dust/fume/gas/mist/vapours//spray
P264 Wash thoroughly after handling
P301+P330+P331 IF SWALLOWED: Rinse Mouth. Do NOT induce vomiting
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing.
Rinse SKIN with water/shower
P363 Wash contaminated clothing before reuse
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P310 Immediately call a POISON CENTER or doctor/physician
P321 Specific treatment: rinse/wash/shower with plenty of water
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,
if present and easy to do, continue rinsing
- P405 Store locked up
- P270 Do not eat, drink or smoke when using this product
P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician IF you feel unwell
P330 Rinse mouth
P312 Call a POISON CENTER or doctor/physician if you feel unwell

Supplemental Hazard information

none

2.3 Other hazards

PBT and vPvB not applicable

Section 3: Composition/information on ingredients
3.1 Substances

This product is a mixture

Substance name	CAS No	UN Nr	Pictograms	Class Packing Group	% w/w
Potassium Monopersulfate	10058-23-8	UN3260	GHS05, GHS07	8 II	25 - 45
Sulfamic Acid	5329-14-6	UN2967	GHS05, GHS07	8 III	2,5 - 10
Sodium Perborate Monohydrate	10332-33-9	UN3377	GHS03, GHS07	5.1 III	1 - 10
Sodium Carbonate Peroxyhydrate	15630-89-4	UN3378	GHS03, GHS05, GHS07	5.1 II	< 1
Trisodium Phosphate	10101-89-0	none	GHS07	none	5 - 15
Sodium Carbonate	497-19-8	none	GHS07	none	5 - 15
Disodium EDTA	139-33-3	none	GHS07	none	< 1

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

Section 4: First aid measures**4.1 Description of first aid measures**

General information Remove contaminated clothes immediately
In case of discomfort seek medical advice

Following skin contact

Wash with plenty of water and soap

Following eye contact

Rinse cautiously with water for several minutes Remove contact lenses, rinse again with plenty of water, keep lid gap open; if necessary consult an eye specialist

Following ingestion

Immediately rinse mouth thoroughly, sip plenty of water (dilution effect). Do not vomit, do not apply neutralizing agents.

4.2 Most important symptoms and effects, both acute and delayed

No additional information available

4.3 Indication of any immediate medical attention and special treatment needed

See precautionary statements under 2.2

Section 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media: water spray jet, foam, carbon dioxide, extinguishing powder, atomized spray (water)

Unsuitable extinguishing media: Do not apply water full jet in order to avoid further proliferation of the fire

5.2 Special hazards arising from the substance or mixture

In case of fire hazardous combustion products like carbon monoxide, carbon dioxide and sulfur dioxide may be formed.

5.3 Advice for fire-fighters

Wear suitable protective equipment and use self-contained breathing apparatus inside the hazard area.

Arising vapors may be precipitated with water.

Avoid intrusion of firefighting water into surface water, ground water and soil

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel
Adequate ventilation of the affected area
Do not inhale gases/aerosols
Wear protective equipment

For emergency responders
Wear protective equipment according to section 8

6.2 Environmental precautions

Avoid intrusion of firefighting water into surface water, ground water and soil, cover sewer inlets.

6.3 Methods and material for containment and cleaning up

Collect scrap and contaminated material in suitable containers, care for proper disposal according to local regulations.

6.4 Reference to other sections

For protective measures see also sections 7, 8 and 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

Store in tightly closed containers in ventilated and dry storage room.

Fire preventions

Take care of proper ventilation
Keep away from ignition sources
Take measures against electrostatically charge

Aerosol and dust generation precautions

Not to be expected, if handled and processed appropriate

Environmental precautions

Use dry storage room with impermeable flooring

Advice on general occupational hygiene

Do not eat, drink or smoke in working areas
After skin contact wash with water and soap.

7.2 Conditions for safe storage, including any incompatibilities

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

Technical measures and storage conditions

Recommended storage temperature: room temperature
Do not store together with substances liable to spontaneous combustion or substances, which form flammable gases or with organic peroxides.
Avoid heat/hot surface/direct sunlight.

Requirements for storage rooms and vessels

Store in ventilated and dry rooms with impermeable flooring, keep vessels tightly closed.

Storage class: none

Specific end uses

Preparation of cleansing bath for dental prosthesis. See product folder or www.fittydent.com

Section 8: Exposure controls / personal protection

8.1 Control parameters

none

Occupational exposure limits

none

8.2 Exposure controls

none

Appropriate engineering controls

Take care of appropriate ventilation.

Personal protective equipment

Eye / Face protection

Use of Safety goggles with protective side shields according to EN 166 2001

Skin protection

Gloves: Nitrile rubber, thickness of the glove material min. 0,7 mm

Environmental exposure controls

See sections 6 and 7

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

Section 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance	
- Physical state:	solid
- Color:	blue
Odor:	specific
Odor threshold:	no data available
pH aqueous solution:	approx.. 9
Melting point/freezing point:	not determined Initial boiling
point/boiling range:	not applicable
Flash point:	not applicable
Evaporation rate:	not applicable
Flammability (solid, gas):	not determined
Upper/lower explosive limits:	not applicable
Vapor pressure:	not applicable
Vapor density:	not applicable
Relative density:	not applicable
Solubility(ies):	soluble in water
Partition Coefficient: n-octanol/water:	not applicable
Auto-ignition temperature:	not applicable
Decomposition temperature:	not determined
Viscosity:	not applicable
Explosive properties:	not applicable
Oxidizing properties:	not determined

9.2 Other information

No additional information available

Section 10: Stability and reactivity**10.1 Reactivity**

This product is not reactive under normal environmental conditions.

10.2 Chemical stability

This product is chemically stable under normal environmental conditions.

10.3 Possibility of hazardous reactions

Reaction and heat buildup with strong reducing agents and strong acids.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, open flames and other ignition sources.

10.5 Incompatible materials

Strong reduction agents

10.6 Hazardous decomposition products

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

There are no hazardous decomposition products to be expected, in case of fire hazardous combustion products may be formed. See section 5 of this safety data sheet.

Section 11: Toxicological information

11.1 Information on toxicological effects

Acute Toxicity

Skin corrosion/irritation

no data available

Eye damage/irritation

no data available

Sensitisation to the respiratory tract/skin

no data available

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

Specific target organ-toxicity (single exposure)

no data available

Specific target organ-toxicity (repeated exposure)

no data available

Aspiration hazard

not applicable

Component information

Component	LD50 oral mg/kg	LD50 dermal mg/kg	LC50 Inhalation
Sodium perborate monohydrate	770 – 2100 (Rat)	>2000 (Rabbit)	Not listed
Sodium carbonate peroxyhydrate	2200 (Mouse)	>2000 (Rabbit)	No data available

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

Symptoms related to the physical, chemical and toxicological characteristics
In addition: Information about toxicokinetics, metabolism and dispersion

no data available

Section 12: Ecological information

12.1 Toxicity

no data available

12.2 Persistence and degradability

no relevant data available

12.3 Bioaccumulative potential

no relevant data available

12.4 Mobility in soil

no relevant data available

12.5 Results of PBT- and vPvB-assessment

not applicable

12.6 Other adverse effects

no relevant data available

Section 13: Disposal considerations

13.1 Waste treatment methods
Directive 2008/98/EC (Waste Framework Directive)

Prevent intrusion in the sewer system. Dispose of product and uncleaned vessels according to local/regional/national/international regulations.

Treatment of uncleaned packaging

Uncleaned packaging is to be treated the same way as the product.

Waste code according to European waste catalogue (AVV)

180104 wastes whose collection and disposal is not subject to special requirements in order to prevent infection.

Small amounts from private households may be disposed of with municipal waste.

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

Section 14: Transport information

14.1 UN-Number

UN3084

14.2 Proper shipping name

ADR/RID

UN3084

CORROSIVE SOLID, OXIDIZING N.O.S.

IMDG-Code / ICAO-TI / IATA-DGR

UN3084

CORROSIVE SOLID, OXIDIZING N.O.S.

14.3 Transport hazard class

8+5.1

Labels



Signal word:

Danger

Warning

14.4 Packing group

II

14.5 Limited quantities

1 kg



ADR/IMDG



IATA DGR

14.6 Excepted quantities



14.7 Environmental hazards

Label environmental hazard

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: yes / no

Marine Pollutant: jyes / no

14.8 Special precautions for users

See sections 6 to 8

14.9 Transport in bulk according to annex II of MARPOL-73/78 and IBC-Code

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

The product will not be transported in bulk.

Section 15: Regulatory information

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

Regulation (EC) No 1005/2009 (on substances that deplete the ozone layer):

not applicable

Regulation (EC) No 850/2004 (persistent organic pollutants):

not applicable

Regulation (EC) No 689/2008 (concerning the export and import of dangerous chemicals):

not applicable

Regulation (EC) No 689/2008 (concerning medical devices):

The product is classified, registered and labelled as medical device class 1 according to this regulation

Restrictions according to Title VIII of the Regulation (EC) No 1907/2006:

none

National Regulations e.g.

Water hazard classe

No data available

Lösemittelverordnung (31. BImSchV)

not applicable

Störfallverordnung (12. BImSchV)

not applicable

Technische Anleitung Luft (TA-Luft)

not applicable

Other relevant Regulations

United States Federal Food, Drug, and Cosmetic Act

The product is classified as 510k exempt according to the above set of laws.

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

Section 16: Other information

Safety Data Sheet according to Regulation (EC) No 1 1907/2006

Print Date	1/17/20201/20/20201/20/20201/20/202020.01.20201/20/20	Revision Date	1/20/2020
Version	2.0 E	Replaces Version	1

Modifications with respect to the previous version

Declaration as dangerous good, actualization of labelling, additional information "excepted/limited quantities.

Abbreviations

Key literature references and sources for data

REACH Regulation (EC) No 1907/2006, last amendment Regulation (EU) 2018/675

CLP-Regulation (EC) No 1272/2008, last amendment Regulation (EU) 29178/669

Methods according to Artikel 9 of the regulation (EC) No 1272/2008 used for classification

Health and Environmental hazards: calculation method

Relevant P-, H- and EUH-phrases (number and full text)

See section 2.2

Training advice

For this product no training advice has to be provided