

Dentalzym 5

1. Identification of the substance/mixture and of the company/undertaking

1.1: Product identifier

Product name: DENTALZYM 5
Product code: 903789

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

Identified uses: Enzymatic detergent for professional use

1.3: Details of the supplier of the safety data sheet

Company name: SMEG s.p.a.
Via Leonardo da Vinci 4,
42016 – GUASTALLA
ITALY
Telephone: +39-0522-8211
Fax: +39-0522-821592
e-mail: chemicals@smeg.it

1.4: Emergency telephone number

For urgent inquiries refer to: CAV (poison centre) Niguarda – MILAN Tel. +39 02-66101029

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is classified as hazardous according to EC Regulation 1272/2008 (CLP) (and subsequent amendments and adjustments). The product therefore requires a safety data sheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Classification and hazard identification:

Skin sensitisation, category 1A H317 May cause an allergic skin reaction.

2.2. Label elements.

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and adjustments.



Signal word: Warning

Hazards identification:

H317 May cause an allergic skin reaction
EUH208 Contains: alpha-amylase, lipase, protease subtilisin

May cause an allergic reaction

Precautionary statements:

P261 Avoid breathing dust / fumes / gas / mist / vapours / sprays.
P280 Wear protective gloves and eye protection / face protection.
P333+P313 If skin irritation or rash occurs: seek medical advice/attention.
P362+P364 Take off contaminated clothing and wash before reuse.

Contains: Corrosion inhibitor - Scale inhibitor
 Protease subtilisin

2.3. Other hazards.

Based on the data available, the product does not contain any PBT or vPvB substances in percentages greater than 0.1%.

SECTION 3. Composition/information on ingredients.**3.1. Substances.**

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Concentration %.	
Alcohols C12 – 14, ethoxylated propoxylated CAS. 68439-51-0 CE. - INDEX. —	5 - 15	Aquatic Chronic 3 H412
2-(2-BUTOXYETHOXY)ETHANOL CAS. 112-34-5 CE. 203-961-6 INDEX. 603-096-00-8	5 - 15	Eye Irrit. 2 H319
Corrosion inhibitor - Scale inhibitor CAS. 143239-08-1 CE. 410-800-5 INDEX. - Reg. No. 01-0000015829-57-0001	1 - 5	Skin Sens. 1 H317
Protease subtilisin CAS. 9014-01-1 CE. - INDEX. - Reg. No. 01-2119480434-38	0 - 1	Eye Irrit. 2 H319, Resp. Sens. 1 H334, Skin Sens. 1A H317, Aquatic Chronic 3 H412

EQUIPMENT

Normal firefighting equipment such as self-contained open-circuit compressed air breathing apparatus (EN 137), fire kit (EN 469), fire resistant gloves (EN 659) and firefighter boots (HO specification A29 or A30)

SECTION 6. Accidental release measures.**6.1. Personal precautions, protective equipment and emergency procedures.**

Stop leak if safe to do so.

Wear suitable protective equipment (including personal protective equipment referred to in section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These guidelines are valid for both production workers and for emergency personnel.

6.2. Environmental precautions.

The product must not enter sewer or drainage systems, surface water or groundwater.

6.3. Methods and material for containment and cleaning up.

Vacuum the spilt product into a suitable container. Evaluate the compatibility of the container to be used by checking section 10. Soak up any remaining product with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.**7.1. Precautions for safe handling.**

Handle the product only after having read all other sections of this safety data sheet. Avoid release to the environment. Do not eat, drink or smoke when using this product. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Keep only in the original container. Store in closed containers in a cool well-ventilated area, away from direct sunlight and other sources of heat. Store away from incompatible materials, see section 10.

SECTION 8. Exposure controls/personal protection.**8.1. Control parameters.**

Reference Standards:

DEU	Germany	MAK-und BAT-Werte-Liste 2012
ITA	Italy	Legislative Decree No. 81 of April 9 2008
EU	OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2017/164/EC; Directive 2000/39/EC; Directive 91/322/EEC
	TLV-ACGIH	ACGIH 2016

2-(2-BUTOXYETHOXY)ETHANOL**Threshold Limit Value.**

Type	Country	TWA/8h mg/m ³	ppm	STEL/15min mg/m ³	Ppm
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AGW	DEU	67	10	100.5	15
MAK	DEU	67	10	100.5	15
VLEP	ITA	67.5	10	101.2	15
OEL	EU	67.5	10	101.2	15
TLV-ACGIH		66	10		

Corrosion inhibitor - Scale inhibitor

Predicted No Effect Concentration (environment) - PNEC

Reference value in freshwater	2	mg/l
Reference value in seawater	0.2	mg/l
Reference value for freshwater sediment	18.98	mg/kg
Reference value for seawater sediment	1.9	mg/kg
Reference value of STP microorganisms	100	mg/l
Reference value for the terrestrial compartment	2.6	mg/kg

Health - Derived no effect level - DNEL / DMEL

Route of exposure	Effects on consumers			Effects on workers			Chronic systemic 10 mg/m3
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	
Inhalation							VND

protease subtilisin**Threshold limit value**

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm
TLV-ACGIH		0.00006			

Key:

(C) = CEILING ; INALAB = Inhalable Fraction ; RESPIR = Breathable Fraction ; TORAC = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available; NEA = no anticipated exposure; NPI = no identified risk.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

If necessary, seek advice from your chemical suppliers regarding the choice of personal protective equipment.

Personal protective equipment must carry the CE mark to show that it complies with the applicable regulations.

Provide safety shower with eyewash station.

HAND PROTECTION

Protect hands with category III work gloves (ref. standard EN 374).

The choice of work glove material should take into consideration: compatibility, degradation, breakage times and permeation.

Work glove resistance to chemical agents should be checked before use as it can be unpredictable. The gloves have a durability that depends on how long and how they are used.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN ISO 20344). Wash with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight goggles (ref. standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (ref. standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.), combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (ref. standard EN 137) or external air-intake breathing apparatus (ref. standard EN 138). For the correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties.**9.1. Information on basic physical and chemical properties.**

Physical State/Appearance	liquid
Colour	yellow
Odour	Characteristic, slightly pungent
Odour threshold.	Not available.
pH.	8.3
Melting point/freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Lower flammability limit.	Not available.
Upper flammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density.	Not available.
Relative density.	1.02
Solubility	Soluble
Partition coefficient: n-octanol/water:	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information.

VOC (Directive 2010/75/EC):	0
VOC (volatile carbon) :	0

SECTION 10. Stability and reactivity.

Corrosion inhibitor - Scale inhibitor
Decomposes above 367 degrees.

10.1. Reactivity.

There are no particular risks of reaction with other substances under normal conditions of use.

10.2. Chemical stability.

The product is stable under normal conditions of storage and use.

10.3. Possibility of hazardous reactions.

There are no known hazardous reactions under normal conditions of storage and use.

2-(2-BUTOXYETHOXY)ETHANOL: may react with oxidizing agents. May form peroxides with atmospheric oxygen. May react with aluminium to form hydrogen. May form explosive mixtures with air.

10.4. Conditions to avoid.

Avoid overheating
2-(2-BUTOXYETHOXY)ETHANOL: avoid contact with air.

10.5. Incompatible materials.

Strong reducing agents and oxidants, strong bases and acids, high temperature materials.

2-(2-BUTOXYETHOXY)ETHANOL: oxidants, strong acids and alkaline metals.

10.6. Hazardous decomposition products.

2-(2-BUTOXYETHOXY)ETHANOL: may give off hydrogen.

SECTION 11. Toxicological information.

Product is not genotoxic.
May cause sensitisation by skin contact.
Not irritating to the eyes.
Irritating to respiratory system.

11.1. Information on toxicological effects.

There is no toxicological data available for the product as such. The potential health risks of the product are evaluated on the basis of the properties of the substances it contains, according to the criteria provided in the reference standards for the classification. Consider therefore the concentration of each hazardous substance, if mentioned in section 3, in order to assess the toxicological effects resulting from exposure to the product.

The product contains sensitiser(s) and may therefore cause an allergic reaction.

Metabolism, toxicokinetics, mode of action and other information

No information available

Information on likely routes of exposure

2-(2-BUTOXYETHOXY)ETHANOL

WORKERS: inhalation; contact with the skin.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

2-(2-BUTOXYETHOXY)ETHANOL

May be absorbed by inhalation, ingestion and skin contact; it is a skin irritant and especially to the eyes. May cause damage to the spleen. Due to its low vapour pressure, inhalation is unlikely at room temperature.

Interactive effects

No information available

ACUTE TOXICITY

LC50 (Inhalation - vapours) of the mixture: LC50 (Inhalation - vapours) of the mixture:

Not classified (no significant component)

LC50 (Inhalation - mists / dusts) of the mixture: LC50 (Inhalation - mists / dusts) of the mixture:

Not classified (no significant component)

LD50 (Oral) of the mixture: LD50 (Oral) of the mixture:

Not classified (no significant component)

LD50 (Dermal) of the mixture: LD50 (Dermal) of the mixture:

Not classified (no significant component)

2-(2-BUTOXYETHOXY)ETHANOL

3384 mg/kg Rat

LD50 (Oral)

2700 mg/kg Rabbit

LD50 (Dermal)

Lipase

> 2000 mg/kg

LD50 (Oral)

protease subtilisin

1800 mg/kg

LD50 (Oral)

SKIN CORROSION / IRRITATION

Does not meet the criteria for classification in this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the criteria for classification in this hazard class

RESPIRATORY OR SKIN SENSITISATION

Skin sensitiser

May cause an allergic reaction.

Contains:

Alpha-amylase

Lipase

protease subtilisin

GERM CELL MUTAGENICITY

Does not meet the criteria for classification in this hazard class

CARCINOGENICITY

Does not meet the criteria for classification in this hazard class

REPRODUCTIVE TOXICITY

Does not meet the criteria for classification in this hazard class

SPECIFIC TARGET ORGAN TOXICITY (STOT) - SINGLE EXPOSURE

Does not meet the criteria for classification in this hazard class

SPECIFIC TARGET ORGAN TOXICITY (STOT) - REPEATED EXPOSURE

Does not meet the criteria for classification in this hazard class

ASPIRATION HAZARD

Does not meet the criteria for classification in this hazard class

SECTION 12. Ecological information.

As there is no data available for the product, use according to good working practices, avoid release to the environment. Prevent the product from contaminating soil or from entering sewer or drainage systems or watercourses. Inform the relevant authorities should the product reach watercourses or sewers or contaminate soil or vegetation. Take measures to minimise the effect on groundwater.

12.1. Toxicity.

Corrosion inhibitor - Scale inhibitor

LC50 - Fish	> 100 mg/l/96h Fish: Leporis Macrochirus
EC50 - Crustaceans	> 1000 mg/l/48h Daphnia magna
EC50 - Algae / aquatic plants	> 1000 mg/l/72h Bacteria: activated sludge

Lipase

LC50 - Fish	> 68.3 mg/l/96h
EC50 - Crustaceans	> 37.4 mg/l/48h Daphnia
EC50 - Algae / aquatic plants	

protease subtilisin

LC50 - Fish	8.2 mg/l/96h
EC50 - Crustaceans	586 ug/l/48h Daphnia
EC50 - Algae / aquatic plants	

12.2. Persistence and degradability.

Corrosion inhibitor - Scale inhibitor

NOT Readily Biodegradable.

Alcohols C12 – 14,
ethoxylated propoxylated
Readily Biodegradable.

2-(2-BUTOXYETHOXY)ETHANOL

Solubility in water. mg/l 1000 - 10000
Readily biodegradable.

Lipase
Readily Biodegradable.

Protease subtilisin
Readily Biodegradable.

12.3. Bioaccumulative potential.

2-(2-BUTOXYETHOXY)ETHANOL

Partition coefficient: 1
n-octanol/water.

Protease subtilisin
Partition coefficient: < 0
n-octanol/water.

12.4. Mobility in soil.

No information available.

12.5. Results of PBT and vPvB assessment.

Based on the data available, the product does not contain any PBT or vPvB substances in percentages greater than 0.1%.

12.6. Other adverse effects.

No information available.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, if possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.

14.1. UN number

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. Transport hazard class(es).

Not applicable.

14.4. Packing group.

Not applicable.

14.5. Environmental hazards.

Not applicable.

14.6. Special precautions for user.

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code.

Information not relevant.

SECTION 15. Regulatory information:**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.**

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.

Point. 3

Contained substances.

Point. 55 2-(2-BUTOXYETHOXY)ETHANOL

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substance subject to export notification procedure EU Regulation 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

Workers exposed to this chemical agent must undergo health checks according to the provisions of article 41 of Legislative Decree no. 81 of 9 April 2008 unless the risk to the safety and health of the worker is considered negligible according to article 224 paragraph 2.

15.2. Chemical safety assessment.

No chemical safety assessment has been carried out for this mixture or the substances it contains.

SECTION 16. Other information.

Full text of hazard (H) statements referred to in sections 2-3 of the sheet:

Eye Irrit. 2 Eye irritation, category 2
Resp. Sens. 1 Respiratory sensitisation, category 1

Skin Sens. 1	Skin sensitisation, category 1
Skin Sens. 1A	Skin sensitisation, category 1A
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic, category 3
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.

KEY:

- ADR: European Agreement concerning the international carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service number
- EC50: The concentration where 50% of the population tested exhibits a response.
- EC NUMBER: (ESIS) European chemical Substances Information System ID number
- CLP: EC Regulation 1272/2008
- DNEL: Derived no-effect level
- EmS: Emergency Schedule
- GHS: Globally harmonised system of classification and labelling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulations
- IC50: The inhibitory concentration where 50% of the population tested exhibits a response.
- IMDG: International maritime dangerous goods code
- IMO: International Maritime Organisation
- INDEX NUMBER: Identification number as mentioned in the CLP regulation Annex VI,
- LC50: Lethal concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational exposure level
- PBT: Persistent, bioaccumulative and toxic according to REACH regulation.
- PEC: Predicted environmental concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold limit value
- TLV CEILING: Concentration that should not be exceeded at any time during occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic compound
- vPvB: Very persistent and very bioaccumulative according to the REACH regulation
- WGK: Water hazard class (Germany).

GENERAL BIBLIOGRAPHY:

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I ATP. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II ATP. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III ATP. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV ATP. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V ATP. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI ATP. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII ATP. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII ATP. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- SDS template database for chemical substances - Italian Ministry of Health and National Institute of Health

Note for users:

The information contained in the present sheet is based on our own knowledge on the date of the last version. Users must determine the suitability and thoroughness of the information provided for its particular purpose.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. We accept no liability resulting from the improper use.

Provide appropriate training to personnel who use chemical products.