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

1.1 Product identifier

Trade name: NOSOZYM 6 PLUS

1.2 Relevant identified uses of the substance or mixture and uses advised against
No further relevant information available.
Application of the substance / the mixture:
Multi enzymatic detergent for surgical instruments and endoscopes.

1.3 Details of the supplier of the safety data sheet
Manufacturer/Supplier:
MEDALKAN
Michalakopoulou 102, P.C. 11528, Athens, Greece
Tel.. 2107484847, Fax. 210 7772009
e-mail: contact@medalkan.gr
website: www.medalkan.com

1.4 Emergency telephone number:

European Emergency Tel.: 112

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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification according to Regulation EC No 1272/2008 CLP:
This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements
Labelling according to Regulation EC No 1272/2008 CLP: Void
Hazard pictograms: Void

Signal word: Void

Hazard statements: Void

Precautionary statements
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
Additional information:
EUH208 Contains Subtilisin. May produce an allergic reaction.

Regulation (EC) No 648/2004 on detergents / Labelling for contents	
anionic surfactants, non-ionic surfactants	<5%
preservation agents (2-BROMO-2-NITROPROPANE-1,3-DIOL), enzymes	

2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.

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vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture: consisting of the following components.

Ingredients according Regulation (EU) 2020/878:

CAS: 9014-01-1 EINECS: 232-752-2 Index number: 647-012-00-8 Reg.nr.: 01-2119480434-38-XXXX	Subtilisin Resp. Sens. 1, H334; Eye Dam. 1, H318; Aquatic Acute 1, H400; Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	≥0.1-<1%

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:
Take affected persons out into the fresh air.
In all cases call a doctor

After inhalation:
Keep patient calm, remove to fresh air.
Seek medical treatment in case of complaints.

After skin contact:
Immediately wash with water and soap and rinse thoroughly.
In case of skin irritation, consult a physician.

After eye contact:
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Remove contact lenses and continue rinsing for several minutes
Avoid strong water jet-risk of cornea damage, consult a doctor.

After swallowing:
Drink plenty of water and provide fresh air. Call for a doctor immediately.
Seek immediate medical advice.
Never give anything by mouth to an unconscious person.

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.

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.

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5.3 Advice for firefighters
Protective equipment:
Self contained breathing apparatus and full protective clothing must be worn in case of fire.
Additional information
Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:
Avoid contact with skin and eyes.
Avoid inhalation of vapors.
Ensure adequate ventilation.
6.1.1 For non-emergency personnel
Avoid contact with dripping or leaking material
Use personal protective equipment.
6.1.2 For emergency responders
Wear protective equipment. Keep unprotected persons away.
First-aid responders must wear protectice clothing, gloves, goggles and respiratory device with filter type A.
6.2 Environmental precautions: No special measures required.
6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust, silica gel).
Dispose contaminated material as waste according to item 13.
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
Avoid contact with skin, eyes and clothing.
Use in well ventilated areas.
Wash your hands and face in the break.
Wash contaminated clothing before reuse.
Avoid inhaling vapors.
Do not eat, drink or smoke during the usage of the product.
Information about fire - and explosion protection: No special measures required.
7.2 Conditions for safe storage, including any incompatibilities
Storage: Store in cool, dry conditions in well sealed receptacles.
Requirements to be met by storerooms and receptacles: Store in a cool location.
Information about storage in one common storage facility: Not required.
Further information about storage conditions:
Keep away from children
Protect from heat and direct sunlight.
7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:	
CAS: 57-55-6 Propane-1,2-diol	
WEL (Great Britain)	Long-term value: 474* 10** mg/m³, 150* ppm *total vapour and particulates **particulates
CAS: 9014-01-1 Subtilisin	
WEL (Great Britain)	Long-term value: 0.00004 mg/m³ Sen

DNELs
(CAS: 9014-01-1) Subtilisin
Workers:
Inhalation - Long term exposure, Local effects: 60 ng/m³
General Population:
Inhalation - Long term exposure, Local effects: 15 ng/m³
Oral - Long term exposure, Systemic effects: 2.86 mg/kg bw/d
Oral - Acute/Short term exposure, Systemic effects: 17.28 mg/kg bw/d
PNECs
(CAS: 9014-01-1) Subtilisin
Fresh water: 1.7 µg/L
Marine water: 0.17 µg/L
Intermittent releases: 0.9 µg/L
(STP) Sewage treatment plant: 65,000 µg/L
Soil: 568 µg/kg soil dw

8.2 Exposure controls

8.2.1. Appropriate engineering controls Provide adequate ventilation.

Individual protection measures, such as personal protective equipment
General protective and hygienic measures:
The usual precautionary measures are to be adhered to when handling chemicals.
Avoid contact with skin and eyes.
Wash hands before breaks and at the end of work.
Do not eat, drink or smoke while using the product.
Remove contaminated clothes and wash before reusing them.
Respiratory protection:

Use suitable respiratory protective device in case of insufficient ventilation.

Hand protection

Wear suitable gloves (EN 374)

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Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Material of gloves

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. As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The determined penetration times according to EN 16523-1:2015 are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

Eye/face protection

Goggles recommended during refilling

Body protection:

Protective work clothing

*
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state	Liquid
Colour:	transparent/yellowish
Odour:	Characteristic
Odour threshold:	Not determined
Melting point/freezing point:	Not determined
Boiling point or initial boiling point and boiling range	Not determined
Flammability	Not applicable
Lower and upper explosion limit	
Lower:	Not determined
Upper:	Not determined
Flash point:	Not Flammable
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
pH at 20 °C	6-8
Viscosity:	
Kinematic viscosity	Not determined
Dynamic:	Not determined

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Solubility	
water:	Not determined
Partition coefficient n-octanol/water (log value)	Not determined
Vapour pressure:	Not determined
Density and/or relative density	
Density:	Not determined
Relative density	Not determined
Vapour density	Not determined

9.2 Other information

Appearance:	
Form:	Liquid
Important information on protection of health and environment, and on safety.	
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Cloud point / clarification point:	
Oxidising properties	Not oxidising
Evaporation rate	Not determined

Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

SECTION 10: Stability and reactivity

10.1 Reactivity Stable under normal conditions
10.2 Chemical stability Material is stable under normal conditions.
Thermal decomposition / conditions to be avoided
No decomposition if used and stored according to specifications.
Stable at environment temperature.

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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 hazard classes as defined in Regulation (EC) No 1272/2008
Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:		
CAS: 9014-01-1 Subtilisin		
Oral	LD50	1.728 mg/kg (rat)

Skin corrosion/irritation Based on available data, the classification criteria are not met.
Serious eye damage/irritation
Potentially irritant
Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
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.
Additional toxicological information:
Repeated dose toxicity Based on available data, the classification criteria are not met.
11.2 Information on other hazards

Endocrine disrupting properties
None of the ingredients is listed.

*
SECTION 12: Ecological information

12.1 Toxicity
Aquatic toxicity:
(CAS: 9014-01-1) Subtilisin
Acute fish:
The 96-hour LC50 for Subtilisin, batch PXI48489 (measured) was 15.6 mg enzyme concentrate dry matter/L (equivalent to 8.2 mg active enzyme protein/L) . ≤10% mortality based on measured 10.9 mg enzyme concentrate dry matter/L (equivalent to 5.7 mg active enzyme protein/L). Conducted under semi-static (daily renewal) exposure conditions.
Long-term fish:
The EC50 value of Subtilisin, batch PPA25057, measure on mortality was estimated to be 0.74 mg enzyme concentrate dry matter/L (equivalent to 0.21 mg active enzyme protein/L). The EC10 value was 0.06 mg enzyme concentrate dry matter/L (equivalent to 0.017 mg active enzyme protein/L). NOEC on hatching success in fathead minnows is ≥1.49 mg enzyme concentrate dry matter/L. Mortality, body length and weight and time to 95% hatch appear to be the most sensitive parameters in this early life stage test of the fathead minnow, with the NOEC for Subtilisin, batch PPA 25057 being 0.15 mg enzyme concentrate dry matter/L (measured as/equivalent to 0.426 mg active enzyme protein/L). Conducted under continuous flow conditions.

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The EC10 and LOEC of Subtilisin, batch PBI48037 for larval mortality was 0.047 mg enzyme concentrate dry matter/L (equivalent to 0.024 mg active enzyme protein/L). The NOEC for larval mortality was estimated to be 0.12 mg enzyme concentrate dry matter/L. The lowest observed effect level (LOEC) for larval mortality of the test substance was nominally 0.37 mg enzyme concentrate dry matter/L, which was estimated to be 0.047 mg enzyme concentrate dry matter/L (measured). LC50 ≥0.092 mg enzyme concentrate dry matter/L (highest concentration). Performed under flow-through conditions.
Acute invertebrates:
The geometrical mean of the EC50 values was 2.56 mg enzyme concentrate dry matter/L and the geometrical mean of the four values in active enzyme protein was 0.331 mg aep/L.
The 48-hour EC50 of Subtilisin, batch PXI48489 for the immobilisation of Daphnia magna was 0.327 mg enzyme concentrate dry matter/L (corresponding to 0.172 mg active enzyme protein/L). The 'no-observed effect concentration' NOEC was 0.071 mg enzyme concentrate dry matter/L. Media was renewed after 24 hours.
(Reliability: 2) The nominal 48-hour EC50 of the Subtilisin, batch PPA3980 for the immobilisation of Daphnia magna was 0.90 mg enzyme concentrate dry matter/L, equivalent to 0.092 mg/L. NOEC at 48 h was 0.55 mg enzyme concentrate dry matter/L.
(Reliability: 2) The nominal 48-hour EC50 of Subtilisin, batch PPA3352 for the immobilisation of Daphnia magna was nominal 2.4 mg enzyme concentrate dry matter/L (equivalent to to 0.062 mg active enzyme protein/L). NOEC at 24 and 48 hours was 1.7 mg enzyme concentrate dry matter/L.
(Reliability: 2) The nominal 48-hour EC50 of the Subtilisin, batch PPA4046 for the immobilisation of Daphnia magna was 60.4 mg enzyme concentrate dry matter/L, corresponding to 12.4 mg active enzyme protein/L. NOEC at 24 and 48h: 30.2 mg enzyme concentrate dry matter/L.
Long-term invertebrates:
The long-term effect of Subtilisin on invertebrates was based on the flow-through test, since it was the most reliable study.
(Reliability:2) The time integrated mean value of 7% for Subtilisin, batch PBI48037 was used for the calculation of NOEC. The data processing showed that 21-day NOEC was 0.0016 mg enzyme concentrate dry matter/L. The 21-d EC10 was estimated to be between 0.0016 mg/L and 0.0053 mg enzyme concentrate dry matter/L, corresponding to values 0.79 and 2.7 µg active enzyme protein/L. The 21-day EC50 was estimated to be between 0.022 mg enzyme concentrate dry matter/L and 0.11 mg enzyme concentrate dry matter/L. Media renewal every second day.
The 21-day EC50 (reproduction) of Savinase, batch PPA25057 could not be calculated due to low levels of inhibition. 21-d NOEC (reproduction) was 1.14 mg enzyme concentrate dry matter/L (equivalent to 0.324 mg active enzyme protein/L).

12.2 Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.
Subtilisin has been tested for ready biodegradation in the modified sturm test (OECD 301B) where it was found to be readily biodegradable.

12.3 Bioaccumulative potential

Subtilisin will not bioaccumulate, because it is highly water soluble, has a low logPow(<-1.3) and is ready biodegradable.

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

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12.6 Endocrine disrupting properties
The product does not contain substances with endocrine disrupting properties.
12.7 Other adverse effects No further relevant information available.

*
SECTION 13: Disposal considerations

13.1 Waste treatment methods
Recommendation

Dispose according to National Regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Contact manufacturer for recycling information.

Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN number or ID number
ADR, ADN, IMDG, IATA Void
14.2 UN proper shipping name
ADR, ADN, IMDG, IATA Void
14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA
Class Void
14.4 Packing group
ADR, IMDG, IATA Void
14.5 Environmental hazards: Not applicable.
14.6 Special precautions for user Not applicable.
14.7 Maritime transport in bulk according to IMO instruments Not applicable.
UN "Model Regulation": Void

*
SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH Regulation 1907/2006/EC
Regulation (EU) 2020/878
CLP Regulation 1272/2008/EC
Regulation (EC) No.648/2004 on detergents, as amended.
Directive 98/24/EC on the protection of health and safety of workers from the risks related to chemicals agents at work.

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Council Directive 94/33/EC on the protection of young people at work, as ammended.
Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding, as ammended
REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 65

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II
None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))
None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS
None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors
None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors
None of the ingredients is listed.

National regulations:

Other regulations, limitations and prohibitive regulations

Substances of very high concern (SVHC) according to REACH, Article 57
It doesn't contain substances of very high concern (SVHC).

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
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
Training hints
Suitable training on safety in handling, storing and converting the product should be given to the employees based on all the existing information.

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Version number of previous version: 2

Abbreviations and acronyms:

ADR: Accord relatif au transport international 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)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Resp. Sens. 1: Respiratory sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

*** Data compared to the previous version altered.**