NOVAPLUS®

SAFETY DATA SHEET

NOVAPLUS EXPRESS Multi-Enzymatic Cleaner Low Foam Concentrate

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

1.1. Product identifier

Product name NOVAPLUS EXPRESS Multi-Enzymatic Cleaner Low Foam Concentrate

Product No. NPC155

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

Identified uses Soaking, manual and automated cleaning of surgical instruments and medical devices

1.3. Details of the supplier of the safety data sheet

Supplier Case Medical Inc.

19 Empire Blvd. South Hackensack NJ

07606 USA

Tel: 201-313-1999 Fax: 201-373-9090

Contact Person SDS Contact: DCM Compliance, info@dcmcompliance.com

1.4. Emergency telephone number

201-313-1999

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical and Chemical

Hazards

Human health Environment

Eye Dam. 1 - H318; Resp. Sens. 1 - H334; Skin Sens. 1 - H317

Not classified.

Not classified.

Classification (1999/45/EEC) R42/43. Xi;R41.

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

Human health

The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals in contact with skin. Risk of serious damage to eyes.

Environment

The product is not expected to be hazardous to the environment.

2.2. Label elements

Contains 1,2-BENZISOTHIAZOL-3(2H)-ONE

SUBTILISIN

Label In Accordance With (EC) No. 1272/2008





Signal Word Danger

Hazard Statements

H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary Statements

P280 Wear protective gloves/protective clothing/eye protection/face

protection.

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue

rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

Supplementary Precautionary Statements

P285 In case of inadequate ventilation wear respiratory protection.

P261 Avoid breathing vapour/spray.

P304+341 IF INHALED: If breathing is difficult, remove victim to fresh air

and keep at rest in a position comfortable for breathing.

P501 Dispose of contents/container to ...

2.3. Other hazards

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

| 1,2-BENZISOTHIAZOL-3(2H)-0 | ONE | | < 1% |
|---|-------------------|---|------|
| CAS-No.: 2634-33-5 | EC No.: 220-120-9 | | |
| Classification (EC 1272/2008) Acute Tox. 4 - H302 Skin Irrit. 2 - H315 Eye Dam. 1 - H318 Skin Sens. 1 - H317 Aquatic Acute 1 - H400 | | Classification (67/548/EEC) Xn;R22 R43 Xi;R38,R41 N;R50 | |
| AMYLASE, alpha | | | < 1% |

| AMYLASE, alpha | | | < 1% |
|---|----------------------|--|--------|
| CAS-No.: 9000-90-2 | EC No.: 232-565-6 | | |
| Classification (EC 1272/2008) Resp. Sens. 1 - H334 | | Classification (67/548/EEC) R42 | |
| Poly(oxy-1,2-ethanediyl), a-(2- | ethylhexyl)-w-hydrox | y-) | 10-20% |
| CAS-No.: 26468-86-0 | EC No.: | | |
| Classification (EC 1272/2008) Eye Dam. 1 - H318 | | Classification (67/548/EEC) Xi;R41. | |

| PROPYLENE GLYCOL | | | 10-20% |
|--|-------------------|--|--------|
| | | | |
| CAS-No.: 57-55-6 | EC No.: 200-338-0 | | |
| | | | |
| Classification (EC 1272/2008) Not classified. | | Classification (67/548/EEC) Not classified. | |

| SODIUM HYDROXIDE | | | < 1% |
|--|-------------------|--|-------|
| CAS-No.: 1310-73-2 | EC No.: 215-185-5 | | |
| Classification (EC 1272/2008) Skin Corr. 1A - H314 | | Classification (67/548/EEC) C;R35. | |
| SODIUM XYLENE SULPHONA | TE 40% | | 1-10% |
| CAS-No.: 1300-72-7 | EC No.: 215-090-9 | | |
| Classification (EC 1272/2008) Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 STOT SE 3 - H335 | | Classification (67/548/EEC) Xi;R36/37/38. | |

| SUBTILISIN | | | 1-10% |
|---|-------------------|-----------------------------|-------|
| CAS-No.: 9014-01-1 | EC No.: 232-752-2 | | |
| Classification (EC 1272/2008) | | Classification (67/548/EEC) | |
| Skin Irrit. 2 - H315 Eye Dam. 1 - H318 | | R42 Xi;R37/38,R41 | |
| Resp. Sens. 1 - H334 STOT SE 3 - H335 | | | |

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

Composition Comments

The data shown are in accordance with the latest EC Directives.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General information

General first aid, rest, warmth and fresh air. Do not give victim anything to drink if they are unconscious. Get medical attention if any discomfort continues.

Inhalation

Place unconscious person on the side in the recovery position and ensure breathing can take place. If respiratory problems, artificial respiration/oxygen. Get medical attention if any discomfort continues.

Ingestion

Immediately rinse mouth and drink plenty of water or milk. Keep person under observation. Do not induce vomiting. If vomiting occurs, keep head low. Transport immediately to hospital and bring along these instructions.

Skin contact

Immediately remove contaminated clothing. Wash off promptly and flush contaminated skin with water. Promptly remove clothing if soaked through and flush skin with water.

Eye contact

Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Get medical attention promptly if symptoms occur after washing.

4.2. Most important symptoms and effects, both acute and delayed

Inhalation.

Irritation of nose, throat and airway.

Skin contact

May cause skin irritation/eczema.

Eye contact

May cause severe irritation to eyes.

4.3. Indication of any immediate medical attention and special treatment needed

Treat Symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media

This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials. Use: Water spray. Dry chemicals. Foam.

5.2. Special hazards arising from the substance or mixture

Unusual Fire & Explosion Hazards

No unusual fire or explosion hazards noted.

5.3. Advice for firefighters

Special Fire Fighting Procedures

Do not enter confined fire-spaces without protective clothing and self-contained air supply

Protective equipment for fire-fighters

Self contained breathing apparatus and full protective clothing must be worn in case of fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Do not discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Absorb in vermiculite, dry sand or earth and place into containers. Wash thoroughly after dealing with a spillage.

6.4. Reference to other sections

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid spilling, skin and eye contact. Ventilate well, avoid breathing vapours. Use approved respirator if air contamination is above accepted level.

7.2. Conditions for safe storage, including any incompatibilities

If pH exposure is below 2.5 or above 9.5 products efficacy may be lost. If temperature exceeds 77°F (25°C)product efficacy may be lost. Follow GMP. Keep containers closed when not in use. Wash thoroughly after handling.

7.3. Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

| Name | STD | TWA | - 8 Hrs | STEL | - 15 Min | Notes |
|------------------|-----|---------|-----------|------|----------|-------|
| PROPYLENE GLYCOL | | 150 ppm | 470 mg/m3 | | | |
| SODIUM HYDROXIDE | WEL | | | | mg/m3 | |

WEL = Workplace Exposure Limit.

Ingredient Comments

Ireland, Occupational Exposure Limits 2010

8.2. Exposure controls

Protective equipment





Process conditions

Provide eyewash station.

Engineering measures

Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. All handling to take place in well-ventilated area.

Respiratory equipment

Wear mask supplied with: Gas cartridge suitable for organic substances.

Hand protection

Use suitable protective gloves if risk of skin contact. Protective gloves complying with EN 374.

Eve protection

If risk of splashing, wear safety goggles or face shield. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Other Protection

Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene measures

DO NOT SMOKE IN WORK AREA! Wash hands at the end of each work shift and before eating, smoking and using the toilet. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When using do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance Liquid
Colour Amber.

Odour Characteristic.
Solubility Soluble in water.

Initial boiling point and boiling

>100 °C

range

Relative density 1.04 ± 0.005 pH-Value, Conc. Solution 7 ± 0.5

9.2. Other information

Not known.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No specific reactivity hazards associated with this product.

10.2. Chemical stability

No particular stability concerns.

10.3. Possibility of hazardous reactions

Hazardous Polymerisation

Will not polymerise.

10.4. Conditions to avoid

10.5. Incompatible materials

Materials To Avoid

Strong acid s/oxidizers. Do not mix with chlorinated detergents (bleach).

10.6. Hazardous decomposition products

Burning may produce oxides of carbon and other substances.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Ingestion

Ingestion may causes irritation of mouth, throat and stomach with possible nausea

Skin contact

Prolonged or repeated contact with skin may cause irritation.

Eve contact

Risk of serious damage to eyes.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

The product is not expected to be hazardous to the environment.

12.1. Toxicity

12.2. Persistence and degradability

Degradability

There are no data on the degradability of this product.

12.3. Bioaccumulative potential

Bioaccumulative potential

The product does not contain any substances expected to be bioaccumulating.

12.4. Mobility in soil

Mobility:

The product is soluble in water.

12.5. Results of PBT and vPvB assessment

12.6. Other adverse effects

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

General information

Waste to be treated as controlled waste. Disposal to licensed waste disposal site in accordance with local Waste Disposal Authority.

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements. Absorb in vermiculite or dry sand and dispose of at a licenced hazardous waste collection point.

SECTION 14: TRANSPORT INFORMATION

General

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Transport Labels

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally Hazardous Substance/Marine Pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

EU Legislation

The UN Globally Harmonised System (GHS) Safety Data Sheet format (Annex IV) is implemented as Annex II of REACH EU No 453/2010 of 20th May 2010 amending regulation (EC) No 1907/2006

National Regulations

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2002. No. 1689. Workplace Exposure Limits 2005 (EH40)

15.2. Chemical Safety Assessment

SECTION 16: OTHER INFORMATION

Revision Date Apr' 19, 2012

Revision C

Risk Phrases In Full

R35 Causes severe burns. R22 Harmful if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

R37/38 Irritating to respiratory system and skin.

R38 Irritating to skin.

R42/43 May cause sensitisation by inhalation and skin contact.

R42 May cause sensitisation by inhalation.
R43 May cause sensitisation by skin contact.

NC Not classified.

R41 Risk of serious damage to eyes.
R50 Very toxic to aquatic organisms.

Hazard Statements In Full

H318 Causes serious eye damage. H319 Causes serious eye irritation.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation. H302 Harmful if swallowed.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction. H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

HIMS Rating

| HIIVIS Rating | | | | | |
|------------------------|---|--------------------------|--|--|--|
| Health | 1 | 0- least | | | |
| Flammability | 0 | 1- slight 2- moderate | | | |
| Reactivity | 0 | 3- high | | | |
| Personal Protection | В | 4- extreme | | | |

Disclaimer

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.