

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 07/26/2022

Reviewed on 07/26/2022

* 1 Identification

- **Product Identifier**
- **Trade Name:** XL Quad Zyme
- **Relevant identified uses of the substance or mixture and uses advised against:**
- **Product Description:** Quad Enzymatic Detergent
- **Application of the substance / the mixture:** For Medical Instruments & Endoscopes
- **Details of the Supplier of the Safety Data Sheet:**
- **Manufacturer/Supplier:**
RM Medical Designs, LLC
PO Box 5862
Spring Hill, FL 34611
P: 352-600-9380
- **Emergency telephone number:** 352-600-9380

2 Hazard(s) Identification

- **Classification of the substance or mixture:**



Health hazard

Sensitization - Respiratory 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



Skin Irritation 2

H315 Causes skin irritation.

Eye Irritation 2A

H319 Causes serious eye irritation.

- **Label elements:**
- **Hazard pictograms:**



- **Signal word:** Danger

- **Hazard-determining components of labeling:**

Subtilisin

- **Hazard statements:**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

- **Precautionary statements:**

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

P284 [In case of inadequate ventilation] wear respiratory protection.

P302+P352 If on skin: Wash with plenty of water.

P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).

P304+P341 If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P332+P313 If skin irritation occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P342+P311 If experiencing respiratory symptoms: Call a poison center/doctor.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Unknown acute toxicity:**

This value refers to knowledge of known, established toxicological or ecotoxicological values.

1.3 % of the mixture consists of component(s) of unknown toxicity.

· **Classification system:** NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

· **NFPA ratings (scale 0 - 4)**



Health = 2

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *2

Fire = 0

Physical Hazard = 0

· **Hazard(s) not otherwise classified (HNOC):** None known

3 Composition/Information on Ingredients

· **Non-hazardous components:**

| | | |
|-----------|---|--------|
| 7732-18-5 | Water, distilled water, deionized water | 60-90% |
|-----------|---|--------|

· **Chemical characterization: Substance**

· **Description:** Mixture of substances listed below with non-hazardous additions.

· **Dangerous Components:**

| | | |
|-------------------------------------|--|-------|
| CAS: 1300-72-7 | Sodium Xylene Sulfonate ⚠ Skin Irritation 2, H315; Eye Irritation 2A, H319; Specific Target Organ Toxicity - Single Exposure 3, H335 | 2-12% |
| | Proprietary Component ⚠ Skin Irritation 2, H315; Eye Irritation 2A, H319 | 2-12% |
| CAS: 9014-01-1 RTECS: CO 9550000 | Subtilisin ⚠ Sensitization - Respiratory 1, H334; ⚠ Eye Damage 1, H318; ⚠ Skin Irritation 2, H315; Specific Target Organ Toxicity - Single Exposure 3, H335 | 2-12% |
| CAS: 1303-96-4 RTECS: ED4588000 | Disodium tetraborate, decahydrate ⚠ Toxic to Reproduction 1B, H360 Specific concentration limit: Toxic to Reproduction 1B; H360: C ≥ 8.5 % | ≤2.5% |

· **Additional information:**

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

4 First-Aid Measures

· **Description of first aid measures**

· **General information:** If symptoms persist, call a physician.

· **After inhalation:**

If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

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Supply fresh air; consult doctor in case of complaints.

· **After skin contact:**

Wash skin with soap and water. Take off contaminated clothing and wash before reuse. If irritation develops and persists, get medical attention.

· **After eye contact:**

If easy to do so, remove contact lenses if worn.

Flush with water or eyewash saline for at least 15 minutes. Consult a physician.

· **After swallowing:**

Rinse mouth with water.

If swallowed and symptoms occur, consult a doctor.

· **Information for doctor**

· **Most important symptoms and effects, both acute and delayed:** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed:** Treat symptomatically.

5 Fire-Fighting Measures

· **Extinguishing media**

· **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.

· **For safety reasons unsuitable extinguishing agents:** No further relevant information.

· **Special hazards arising from the substance or mixture:** No further relevant information available.

· **Advice for firefighters**

· **Special protective equipment for firefighters:**

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures:**

Avoid contact with skin, eyes and clothing.

· **Environmental precautions:** Dilute with plenty of water.

· **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust).

Dispose of contaminated material as waste according to section 13.

Ensure adequate ventilation.

Dispose of the collected material according to regulations.

· **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.

· **PAC-1:**

| | | |
|------------|-----------------------------------|----------------------|
| 25322-69-4 | Polypropylene Glycol | 30 mg/m ³ |
| 1303-96-4 | Disodium tetraborate, decahydrate | 6 mg/m ³ |

· **PAC-2:**

| | | |
|------------|-----------------------------------|-----------------------|
| 25322-69-4 | Polypropylene Glycol | 330 mg/m ³ |
| 1303-96-4 | Disodium tetraborate, decahydrate | 190 mg/m ³ |

· **PAC-3:**

| | | |
|------------|-----------------------------------|-------------------------|
| 25322-69-4 | Polypropylene Glycol | 2,000 mg/m ³ |
| 1303-96-4 | Disodium tetraborate, decahydrate | 1,100 mg/m ³ |

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7 Handling and Storage

- **Handling**
- **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s):** No further relevant information available.

8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**
- **Components with occupational exposure limits:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

9014-01-1 Subtilisin

| | |
|-----|--|
| REL | Short-term value: 0.00006* mg/m ³ *60-min |
| TLV | Ceiling limit value: 0.00006 mg/m ³ as 100% crystalline active pure enzyme |

1303-96-4 Disodium tetraborate, decahydrate

| | |
|-----|---|
| REL | Long-term value: 5 mg/m ³ |
| TLV | Short-term value: 6* mg/m ³ Long-term value: 2* mg/m ³ *as inhalable fraction, A4 |

- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
- **Exposure controls:**
- **Personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

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 preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the

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application.

· **Penetration time of glove material:**

The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

· **Eye protection:**



Safety glasses

· **Limitation and supervision of exposure into the environment:** None

9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:

Liquid

Color:

Clear

· **Odor:**

Characteristic

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

Melting point/Melting range:

Not determined.

· **Flash point:**

None

· **Flammability (solid, gaseous):**

Not applicable.

· **Ignition temperature:**

Not applicable

· **Decomposition temperature:**

Not determined.

· **Auto igniting:**

Product is not self-igniting.

· **Danger of explosion:**

Product does not present an explosion hazard.

· **Explosion limits:**

Lower:

Not determined.

Upper:

Not determined.

· **Vapor pressure @ 20 °C (68 °F):**

≤23 hPa (≤17.3 mm Hg)

· **Density:**

Not determined.

· **Relative density:**

Not determined.

· **Vapor density:**

Not determined.

· **Evaporation rate:**

Not determined.

· **Solubility in / Miscibility with:**

Water:

Fully miscible.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic:

Not determined.

Kinematic:

Not determined.

· **Solvent content:**

Water:

75.0 %

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Trade Name: XL Quad Zyme**VOC content:** 0.00 %**Solids content:** 11.8 %· **Other information:** No further relevant information available.

10 Stability and Reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Product is stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Incompatible Materials
- **Incompatible materials:** Strong oxidizing agents.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects:**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

1300-72-7 Sodium Xylene Sulfonate

Oral LD50 >7,200 mg/kg (Rat)

Dermal LD50 >2,000 mg/kg (Rabbit)

9014-01-1 Subtilisin

Oral LD50 3,700 mg/kg (Rat)

- **Primary irritant effect:**
- **On the skin:** No irritating effect.
- **On the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through inhalation.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Harmful

- **Carcinogenic categories:**

- **IARC (International Agency for Research on Cancer):**

None of the ingredients are listed.

- **NTP (National Toxicology Program):**

None of the ingredients are listed.

- **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

12 Ecological Information

- **Toxicity:**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability:** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.

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- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **Results of PBT and vPvB assessment:**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

13 Disposal Considerations

- **Waste treatment methods**
- **Recommendation:**
Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packaging**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport Information

- **UN-Number:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR/ADN, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
No further relevant information available.
- **SARA (Superfund Amendments and Reauthorization):**

| |
|--|
| Section 355 (extremely hazardous substances): |
| None of the ingredients are listed. |

| |
|--|
| Section 313 (Specific toxic chemical listings): |
| None of the ingredients are listed. |

| | | |
|---|---|--------|
| TSCA (Toxic Substances Control Act): | | |
| 7732-18-5 | Water, distilled water, deionized water | ACTIVE |
| 1300-72-7 | Sodium Xylene Sulfonate | ACTIVE |
| 9014-01-1 | Subtilisin | ACTIVE |
| 25322-69-4 | Polypropylene Glycol | ACTIVE |
| 9001-62-1 | Lipase, triacylglycerol | ACTIVE |
| 1303-96-4 | Disodium tetraborate, decahydrate | ACTIVE |

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| | | |
|--|-----------------------------------|----------|
| 9012-54-8 | Cellulase | ACTIVE |
| 9000-90-2 | Amylase, alpha- | ACTIVE |
| · Hazardous Air Pollutants | | |
| None of the ingredients are listed. | | |
| · California Proposition 65: | | |
| · Chemicals known to cause cancer: | | |
| None of the ingredients are listed. | | |
| · Chemicals known to cause reproductive toxicity for females: | | |
| None of the ingredients are listed. | | |
| · Chemicals known to cause reproductive toxicity for males: | | |
| None of the ingredients are listed. | | |
| · Chemicals known to cause developmental toxicity: | | |
| None of the ingredients are listed. | | |
| · New Jersey Right-to-Know List: | | |
| None of the ingredients are listed. | | |
| · New Jersey Special Hazardous Substance List: | | |
| None of the ingredients are listed. | | |
| · Pennsylvania Right-to-Know List: | | |
| 1303-96-4 | Disodium tetraborate, decahydrate | |
| · Pennsylvania Special Hazardous Substance List: | | |
| None of the ingredients are listed. | | |
| · Carcinogenic categories: | | |
| · EPA (Environmental Protection Agency): | | |
| 1303-96-4 | Disodium tetraborate, decahydrate | I (oral) |
| · TLV (Threshold Limit Value established by ACGIH): | | |
| 1303-96-4 | Disodium tetraborate, decahydrate | A4 |
| · NIOSH-Ca (National Institute for Occupational Safety and Health): | | |
| None of the ingredients are listed. | | |

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:**· **Signal word:** Danger· **Hazard-determining components of labeling:**

Subtilisin

· **Hazard statements:**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

· **Precautionary statements:**

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

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| | |
|----------------|--|
| P264 | Wash thoroughly after handling. |
| P280 | Wear protective gloves / eye protection / face protection. |
| P284 | [In case of inadequate ventilation] wear respiratory protection. |
| P302+P352 | If on skin: Wash with plenty of water. |
| P321 | Specific treatment (see supplementary first aid instructions on this Safety Data Sheet). |
| P304+P341 | If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. |
| P305+P351+P338 | If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |
| P337+P313 | If eye irritation persists: Get medical advice/attention. |
| P342+P311 | If experiencing respiratory symptoms: Call a poison center/doctor. |
| P501 | Dispose of contents/container in accordance with local/regional/national/international regulations. |

• **National regulations:**

The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.

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

16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

• **Contact:**

• **Date of last revision/ revision number:** 07/26/2022 / 2

• **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
 ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 IMDG: International Maritime Code for Dangerous Goods
 DOT: US Department of Transportation
 IATA: International Air Transport Association
 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)
 NFPA: National Fire Protection Association (USA)
 HMIS: Hazardous Materials Identification System (USA)
 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
 NIOSH: National Institute for Occupational Safety and Health
 OSHA: Occupational Safety & Health Administration
 TLV: Threshold Limit Value
 PEL: Permissible Exposure Limit
 REL: Recommended Exposure Limit
 Skin Irritation 2: Skin corrosion/irritation – Category 2
 Eye Damage 1: Serious eye damage/eye irritation – Category 1
 Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
 Sensitization - Respiratory 1: Respiratory sensitisation – Category 1
 Toxic to Reproduction 1B: Reproductive toxicity – Category 1B
 Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

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

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