SAFETY DATA SHEET

PROTEASE 2

SECTION 1. IDENTIFICATION

Product name: PROTEASE 2
Mat.-No./ Genisys-No.: 05266696001

Manufacturer or supplier’s details
Company name of supplier: Roche Diagnostics
Address: 9115 Hague Road
46250 Indianapolis IN
Telephone: 1-800-428-5074
Emergency telephone: CHEMTREC
In case of emergencies: 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use
Restrictions on use: For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS Label element
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture
Substance name: PROTEASE/ISH Protease 1 / 2 / 3

Hazardous ingredients

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: Do not leave the victim unattended.

If inhaled:
Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.
In case of skin contact: If on skin, rinse well with water.

In case of eye contact: Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.

If swallowed: Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.

Most important symptoms and effects, both acute and delayed: None known.

Notes to physician: The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during fire fighting: No information available.

Hazardous combustion products: No hazardous combustion products are known

Further information: Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Refer to protective measures listed in sections 7 and 8.

Environmental precautions: Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE
Advice on protection against fire and explosion: Normal measures for preventive fire protection.

Advice on safe handling: For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage: Electrical installations / working materials must comply with the technological safety standards.

Technical measures/Precautions: See label, package insert or internal guidelines

Materials to avoid: No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>US WEEL</td>
</tr>
</tbody>
</table>

Engineering measures: No data available

Personal protective equipment

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Eye protection: Safety glasses

Skin and body protection: Protective suit

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: colorless

Odor: none

Odor Threshold: No data available

pH: 7.4

Melting point/range: No data available
**SAFETY DATA SHEET**

**PROTEASE 2**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>12-16-2015</td>
<td>12-14-2015</td>
<td>08-12-2015</td>
</tr>
</tbody>
</table>

- **Boiling point/boiling range**: No data available
- **Flash point**: does not flash
- **Evaporation rate**: No data available
- **Upper explosion limit**: No data available
- **Lower explosion limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Relative density**: No data available
- **Density**: 1.044 g/cm³
- **Solubility(ies)**
  - **Water solubility**: completely miscible
  - **Solubility in other solvents**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Autoignition temperature**: No data available
- **Decomposition temperature**: Hazardous decomposition products formed under fire conditions.
- **Viscosity**
  - **Viscosity, dynamic**: No data available
  - **Viscosity, kinematic**: No data available

### SECTION 10. STABILITY AND REACTIVITY

- **Reactivity**: No dangerous reaction known under conditions of normal use.
- **Chemical stability**: No decomposition if stored and applied as directed.
- **Possibility of hazardous reactions**
  - Reacts with the following substances:
    - Oxidizing agents
    - Reducing agents
    - Stable under recommended storage conditions.
    - No hazards to be specially mentioned.
- **Conditions to avoid**: No data available
- **Incompatible materials**: No data available
- **Hazardous decomposition products**
  - Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke).
  - Gaseous hydrogen chloride (HCl).
SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

**Product:**
- Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

**Ingredients:**
- **Propylene glycol:**
  - Acute oral toxicity:
    - LD50 (Rat): 20,000 mg/kg
    - LD50 (Mouse): 20,300 mg/kg
  - Acute inhalation toxicity:
    - Acute toxicity estimate: > 30 mg/l
    Method: Expert judgment
  - Acute dermal toxicity:
    - LD50 (Rabbit): 20,800 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Ingredients:**
- **Propylene glycol:**
  Remarks: This information is not available.

**Serious eye damage/eye irritation**
Not classified based on available information.

**Ingredients:**
- **Propylene glycol:**
  Remarks: This information is not available.

**Respiratory or skin sensitization**
Skin sensitization: Not classified based on available information.
Respiratory sensitization: Not classified based on available information.

**Germ cell mutagenicity**
Not classified based on available information.

**Carcinogenicity**
Not classified based on available information.

**IARC**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

STOT-single exposure
Not classified based on available information.

Product:
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

Ingredients:
Propylene glycol:
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
Not classified based on available information.

Product:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Ingredients:
Propylene glycol:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity
Not classified based on available information.

Ingredients:
Propylene glycol:
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:
Ecotoxicology Assessment
Toxicity Data on Soil: Not expected to adsorb on soil.

Other organisms relevant to the environment: No data available

Ingredients:
Propylene glycol:
Toxicity to fish:
- LC0 (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l
  Exposure time: 24 h
- NOEC (Pimephales promelas (fathead minnow)): 52,930 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 34,400 mg/l
  Exposure time: 48 h

Toxicity to algae:
- EC50 (Chlorella pyrenoidosa): 92,000 mg/l

Toxicity to fish (Chronic toxicity):
- > 1 mg/l

Toxicity to bacteria:
- EC50 (Photobacterium phosphoreum): 26,800 mg/l
  Exposure time: 0.5 h

Ecotoxicology Assessment:
- Toxicity Data on Soil: Not expected to adsorb on soil.
- Other organisms relevant to the environment: No data available

Persistence and degradability

Ingredients:
- Propylene glycol

Biodegradability:
- Zahn-Wellens Test
  Result: Readily biodegradable.
  Biodegradation: 98 %
  Exposure time: 5 d
  Method: OECD Test Guideline 302

Bioaccumulative potential

Ingredients:
- Propylene glycol

Partition coefficient: n-octanol/water
- log Pow: -0.92

Mobility in soil:
No data available

Other adverse effects

Product:
- Ozone-Depletion Potential
  Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
  Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulation

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Component RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>1000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>26628-22-8</td>
<td>1000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 311/312 Hazards: No SARA Hazards

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B). This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61). This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F). The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

- Propylene glycol 57-55-6 49.98 %

Clean Water Act
The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

- Hydrochloric acid (theor. 100%) 7647-01-0 0.0755 %
- Sodium hydroxide 1310-73-2 0.0079 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

- Hydrochloric acid (theor. 100%) 7647-01-0 0.0755 %
- Sodium hydroxide 1310-73-2 0.0079 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.

US State Regulations

Massachusetts Right To Know
- Sodium azide 26628-22-8 0 - 0.1 %
- Hydrochloric acid (theor. 100%) 7647-01-0 0 - 0.1 %

Pennsylvania Right To Know
- Propylene glycol 57-55-6 30 - 50 %
- Water 7732-18-5 30 - 50 %
- Sodium azide 26628-22-8 0 - 0.1 %
- Hydrochloric acid (theor. 100%) 7647-01-0 0 - 0.1 %

New Jersey Right To Know
- Propylene glycol 57-55-6 30 - 50 %
- Water 7732-18-5 30 - 50 %

California Prop. 65
This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

- CH INV: On the inventory, or in compliance with the inventory
- TSCA: On TSCA Inventory
- DSL: This product contains the following components that are not on the Canadian DSL nor NDSL.
Subtilisin from Bacillus subtilis

AICS: On the inventory, or in compliance with the inventory
NZIoC: On the inventory, or in compliance with the inventory
ENCS: Not in compliance with the inventory
   Water Subtilisin from Bacillus subtilis
ISHL: On the inventory, or in compliance with the inventory
KECI: On the inventory, or in compliance with the inventory
PICCS: On the inventory, or in compliance with the inventory
IECSC: On the inventory, or in compliance with the inventory

TSCA list
No substances are subject to a Significant New Use Rule.
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

(Q)SAR - (Quantitative) Structure Activity Relationship; ASTM - American Society for the Testing of Materials; bw - Body weight; DIN - Standard of the German Institute for Standardisation; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative; DSL - Domestic Substances List (Canada); KECI - Korea Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); AICS - Australian Inventory of Chemical Substances; IECS - Inventory of Existing Chemical Substances in China; ENCS - Existing and New Chemical Substances (Japan); ISHL - Industrial Safety and Health Law (Japan); PICCS - Philippines Inventory of Chemicals and Chemical Substances; NZIoC - New Zealand Inventory of Chemicals; TCSI - Taiwan Chemical Substance Inventory; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; DOT - Department of Transportation; EHS - Extremely Hazardous Substance; HMIS - Hazardous Materials Identification System; MSHA - Mine Safety and Health Administration; NFPA - National Fire Protection Association; RCRA - Resource Conservation and Recovery Act;
Further information

NFPA:

- Flammability: 0
- Health: 0
- Instability: 0

Special hazard.

HMIS III:

- HEALTH: 0
- FLAMMABILITY: 0
- PHYSICAL HAZARD: 0

0 = not significant, 1 = Slight, 2 = Moderate, 3 = High, 4 = Extreme, * = Chronic

Revision Date: 12-16-2015

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The 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, unless specified in the text.

US / Z8