

# **BAX® SYSTEM - REAL TIME GENUS LISTERIA KIT**

## **KIT2019**

Date of compilation: 2022-04-08

### **Bill of materials**

| <b>Name of substance</b>       | <b>Identifier</b> | <b>Classification acc.<br/>to GHS</b> | <b>Pictograms</b> | <b>Page</b> |
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**BAX® LYSING AGENT 2 (1.1ML)**

Version number: 1.1

Date of compilation: 2022-03-28

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

|                             |                                    |
|-----------------------------|------------------------------------|
| Trade name                  | <b>BAX® LYSING AGENT 2 (1.1ML)</b> |
| Registration number (REACH) | not relevant (mixture)             |
| Product code(s)             | ASY2009                            |

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

|                          |                               |
|--------------------------|-------------------------------|
| Relevant identified uses | Laboratory and analytical use |
|--------------------------|-------------------------------|

**1.3 Details of the supplier of the safety data sheet**

Qualicon Diagnostics LLC  
941 Avenida Acaso  
Camarillo CA 93012  
United States

Telephone: 1-302-695-5300  
Telefax: 1-302-351-6454  
e-mail: [diagnostics.support@hygiena.com](mailto:diagnostics.support@hygiena.com)  
Website: <https://www.hygiena.com>

e-mail (competent person) [diagnostics.support@hygiena.com](mailto:diagnostics.support@hygiena.com)

**1.4 Emergency telephone number**

|                               |                                                                                                                   |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Emergency information service | 1-302-695-5300<br>This number is only available during the following<br>office hours: Mon-Fri 08:00 AM - 05:00 PM |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------|

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No 1272/2008 (CLP)  
This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

**2.2 Label elements**

Labelling according to Regulation (EC) No 1272/2008 (CLP)  
not required

**2.3 Other hazards**

of no significance

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

Not relevant (mixture)

**3.2 Mixtures**

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## Description of the mixture

| Name of substance  | Identifier           | Wt%       | Classification acc. to GHS | Pictograms |
|--------------------|----------------------|-----------|----------------------------|------------|
| Pyrogen Free Water | CAS No<br>7732-18-5  | ≥ 90      |                            |            |
| Mutanolysin        | CAS No<br>55466-22-3 | 0.1 – < 1 |                            |            |

For full text of abbreviations: see SECTION 16.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

## General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

## Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

## Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

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

Symptoms and effects are not known to date.

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

none

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

## Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO<sub>2</sub>)

## Unsuitable extinguishing media

Water jet

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**5.2 Special hazards arising from the substance or mixture****5.3 Advice for firefighters**

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

**6.2 Environmental precautions**

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

**6.3 Methods and material for containment and cleaning up**

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

**6.4 Reference to other sections**

Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

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

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

**7.2 Conditions for safe storage, including any incompatibilities**

Control of effects

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Protect against external exposure, such as  
frost

**7.3 Specific end use(s)**

See section 16 for a general overview.

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

This information is not available.

**8.2 Exposure controls**

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

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

|                                                          |                 |
|----------------------------------------------------------|-----------------|
| Physical state                                           | liquid          |
| Colour                                                   | not determined  |
| Odour                                                    | characteristic  |
| Melting point/freezing point                             | not determined  |
| Boiling point or initial boiling point and boiling range | not determined  |
| Flammability                                             | non-combustible |

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|                                 |                |
|---------------------------------|----------------|
| Lower and upper explosion limit | not determined |
| Flash point                     | not determined |
| Auto-ignition temperature       | not determined |
| Decomposition temperature       | not relevant   |
| pH (value)                      | not determined |
| Kinematic viscosity             | not determined |
| Solubility(ies)                 | not determined |

## Partition coefficient

|                                                   |                                   |
|---------------------------------------------------|-----------------------------------|
| Partition coefficient n-octanol/water (log value) | this information is not available |
|---------------------------------------------------|-----------------------------------|

|                 |                |
|-----------------|----------------|
| Vapour pressure | not determined |
|-----------------|----------------|

## Density and/or relative density

|                         |                                               |
|-------------------------|-----------------------------------------------|
| Density                 | not determined                                |
| Relative vapour density | information on this property is not available |

|                          |                       |
|--------------------------|-----------------------|
| Particle characteristics | not relevant (liquid) |
|--------------------------|-----------------------|

**9.2 Other information**

|                                                    |                                                             |
|----------------------------------------------------|-------------------------------------------------------------|
| Information with regard to physical hazard classes | hazard classes acc. to GHS (physical hazards): not relevant |
|----------------------------------------------------|-------------------------------------------------------------|

## Other safety characteristics

|                 |       |
|-----------------|-------|
| Solvent content | 100 % |
| Solid content   | 0 %   |

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**SECTION 10: Stability and reactivity****10.1 Reactivity**

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

**10.2 Chemical stability**

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

**10.3 Possibility of hazardous reactions**

No known hazardous reactions.

**10.4 Conditions to avoid**

There are no specific conditions known which have to be avoided.

**10.5 Incompatible materials**

There is no additional information.

**10.6 Hazardous decomposition products**

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Test data are not available for the complete mixture.

**Classification procedure**

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

**Classification according to GHS (1272/2008/EC, CLP)**

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

**Acute toxicity**

Shall not be classified as acutely toxic.

**Skin corrosion/irritation**

Shall not be classified as corrosive/irritant to skin.

**Serious eye damage/eye irritation**

Shall not be classified as seriously damaging to the eye or eye irritant.

**Respiratory or skin sensitisation**

Shall not be classified as a respiratory or skin sensitizer.

**Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

**Carcinogenicity**

Shall not be classified as carcinogenic.

**Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

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Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

**11.2 Information on other hazards**

There is no additional information.

**SECTION 12: Ecological information****12.1 Toxicity**

Shall not be classified as hazardous to the aquatic environment.

**12.2 Persistence and degradability**

Data are not available.

**12.3 Bioaccumulative potential**

Data are not available.

**12.4 Mobility in soil**

Data are not available.

**12.5 Results of PBT and vPvB assessment**

Data are not available.

**12.6 Endocrine disrupting properties**

None of the ingredients are listed.

**12.7 Other adverse effects**

Data are not available.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

**Remarks**

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.



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**SECTION 14: Transport information**

- 14.1 UN number or ID number** not subject to transport regulations
- 14.2 UN proper shipping name** not relevant
- 14.3 Transport hazard class(es)** none
- 14.4 Packing group** not assigned
- 14.5 Environmental hazards** non-environmentally hazardous acc. to the dangerous goods regulations
- 14.6 Special precautions for user**  
There is no additional information.
- 14.7 Maritime transport in bulk according to IMO instruments**  
The cargo is not intended to be carried in bulk.

**Information for each of the UN Model Regulations****International Maritime Dangerous Goods Code (IMDG) - Additional information**

Not subject to IMDG.

**International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information**

Not subject to ICAO-IATA.

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Relevant provisions of the European Union (EU)****Restrictions according to REACH, Annex XVII**

none of the ingredients are listed

**List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list**

none of the ingredients are listed

**Deco-Paint Directive**

|             |         |
|-------------|---------|
| VOC content | 1.452 % |
|-------------|---------|

**Industrial Emissions Directive (IED)**

|             |         |
|-------------|---------|
| VOC content | 1.452 % |
|-------------|---------|

**Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)**

none of the ingredients are listed

**Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)**

none of the ingredients are listed

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### Water Framework Directive (WFD)

none of the ingredients are listed

### Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

### National inventories

| Country | Inventory | Status                         |
|---------|-----------|--------------------------------|
| AU      | AICS      | not all ingredients are listed |
| CA      | DSL       | not all ingredients are listed |
| CN      | IECSC     | not all ingredients are listed |
| EU      | ECSI      | not all ingredients are listed |
| JP      | CSCL-ENCS | not all ingredients are listed |
| KR      | KECI      | not all ingredients are listed |
| MX      | INSQ      | not all ingredients are listed |
| NZ      | NZIoC     | not all ingredients are listed |
| PH      | PICCS     | not all ingredients are listed |
| TW      | TCSI      | all ingredients are listed     |
| US      | TSCA      | not all ingredients are listed |

#### Legend

|           |                                                                         |
|-----------|-------------------------------------------------------------------------|
| AICS      | Australian Inventory of Chemical Substances                             |
| CSCL-ENCS | List of Existing and New Chemical Substances (CSCL-ENCS)                |
| DSL       | Domestic Substances List (DSL)                                          |
| ECSI      | EC Substance Inventory (EINECS, ELINCS, NLP)                            |
| IECSC     | Inventory of Existing Chemical Substances Produced or Imported in China |
| INSQ      | National Inventory of Chemical Substances                               |
| KECI      | Korea Existing Chemicals Inventory                                      |
| NZIoC     | New Zealand Inventory of Chemicals                                      |
| PICCS     | Philippine Inventory of Chemicals and Chemical Substances (PICCS)       |
| TCSI      | Taiwan Chemical Substance Inventory                                     |
| TSCA      | Toxic Substance Control Act                                             |

## 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## SECTION 16: Other information

### Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations                                                                                                                            |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ADR   | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road) |
| CAS   | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)                                                        |
| CLP   | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures                                                            |
| DGR   | Dangerous Goods Regulations (see IATA/DGR)                                                                                                                    |

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| Abbr.    | Descriptions of used abbreviations                                                                                                                                                |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EC No    | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union) |
| EINECS   | European Inventory of Existing Commercial Chemical Substances                                                                                                                     |
| ELINCS   | European List of Notified Chemical Substances                                                                                                                                     |
| GHS      | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations                                                                         |
| IATA     | International Air Transport Association                                                                                                                                           |
| IATA/DGR | Dangerous Goods Regulations (DGR) for the air transport (IATA)                                                                                                                    |
| ICAO     | International Civil Aviation Organization                                                                                                                                         |
| IMDG     | International Maritime Dangerous Goods Code                                                                                                                                       |
| index No | The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008                                                          |
| NLP      | No-Longer Polymer                                                                                                                                                                 |
| PBT      | Persistent, Bioaccumulative and Toxic                                                                                                                                             |
| REACH    | Registration, Evaluation, Authorisation and Restriction of Chemicals                                                                                                              |
| RID      | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)           |
| SVHC     | Substance of Very High Concern                                                                                                                                                    |
| VOC      | Volatile Organic Compounds                                                                                                                                                        |
| vPvB     | Very Persistent and very Bioaccumulative                                                                                                                                          |

**Key literature references and sources for data**

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

**Classification procedure**

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

**Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

**BAX® System Lysis Buffer**

Version number: 1.1

Date of compilation: 2022-03-21

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

|                             |                                 |
|-----------------------------|---------------------------------|
| Trade name                  | <b>BAX® System Lysis Buffer</b> |
| Registration number (REACH) | not relevant (mixture)          |
| Product code(s)             | ASY2011                         |

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

|                          |                               |
|--------------------------|-------------------------------|
| Relevant identified uses | Laboratory and analytical use |
|--------------------------|-------------------------------|

**1.3 Details of the supplier of the safety data sheet**

Qualicon Diagnostics LLC  
941 Avenida Acaso  
Camarillo CA 93012  
United States

Telephone: 1-302-695-5300  
Telefax: 1-302-351-6454  
e-mail: [diagnostics.support@hygiena.com](mailto:diagnostics.support@hygiena.com)  
Website: <https://www.hygiena.com>

e-mail (competent person) [diagnostics.support@hygiena.com](mailto:diagnostics.support@hygiena.com)

**1.4 Emergency telephone number**

|                               |                                                                                                                   |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Emergency information service | 1-302-695-5300<br>This number is only available during the following<br>office hours: Mon-Fri 08:00 AM - 05:00 PM |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------|

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No 1272/2008 (CLP)  
This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

**2.2 Label elements**

Labelling according to Regulation (EC) No 1272/2008 (CLP)  
not required

**2.3 Other hazards**

of no significance

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

Not relevant (mixture)

**3.2 Mixtures**

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## Description of the mixture

| Name of substance                 | Identifier                                                                                  | Wt%       | Classification acc. to GHS | Pictograms |
|-----------------------------------|---------------------------------------------------------------------------------------------|-----------|----------------------------|------------|
| Pyrogen Free Water                | CAS No<br>7732-18-5                                                                         | ≥ 90      |                            |            |
| Tris                              | CAS No<br>77-86-1                                                                           | 0.1 – < 1 |                            |            |
| Tris HCl                          | CAS No<br>1185-53-1<br><br>EC No<br>214-684-5<br><br>REACH Reg. No<br>01-2120301688-54-xxxx | 0.1 – < 1 |                            |            |
| Potassium Chloride                | CAS No<br>7447-40-7                                                                         | 0.1 – < 1 |                            |            |
| Reduced Triton X-100              | CAS No<br>92046-34-9                                                                        | < 0.1     |                            |            |
| Magnesium Chloride<br>Hexahydrate | CAS No<br>7791-18-6<br><br>EC No<br>232-094-6                                               | < 0.1     |                            |            |

For full text of abbreviations: see SECTION 16.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

## General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

## Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

## Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

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

Symptoms and effects are not known to date.

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

none

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO<sub>2</sub>)

Unsuitable extinguishing media

Water jet

**5.2 Special hazards arising from the substance or mixture**

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)**5.3 Advice for firefighters**

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

**6.2 Environmental precautions**

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

**6.3 Methods and material for containment and cleaning up**

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

**6.4 Reference to other sections**

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

## BAX® System Lysis Buffer

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Date of compilation: 2022-03-21

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

#### 7.2 Conditions for safe storage, including any incompatibilities

Control of effects

Protect against external exposure, such as

frost

#### 7.3 Specific end use(s)

See section 16 for a general overview.

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

This information is not available.

Relevant DNELs of components of the mixture

| Name of substance | CAS No    | Endpoint | Threshold level         | Protection goal, route of exposure | Used in           | Exposure time              |
|-------------------|-----------|----------|-------------------------|------------------------------------|-------------------|----------------------------|
| Tris HCl          | 1185-53-1 | DNEL     | 152.8 mg/m <sup>3</sup> | human, inhalatory                  | worker (industry) | chronic - systemic effects |
| Tris HCl          | 1185-53-1 | DNEL     | 216.6 mg/kg bw/day      | human, dermal                      | worker (industry) | chronic - systemic effects |

Relevant PNECs of components of the mixture

| Name of substance              | CAS No    | Endpoint | Threshold level | Organism          | Environmental compartment    | Exposure time                |
|--------------------------------|-----------|----------|-----------------|-------------------|------------------------------|------------------------------|
| Magnesium Chloride Hexahydrate | 7791-18-6 | PNEC     | 3.21 mg/l       | aquatic organisms | freshwater                   | short-term (single instance) |
| Magnesium Chloride Hexahydrate | 7791-18-6 | PNEC     | 0.32 mg/l       | aquatic organisms | marine water                 | short-term (single instance) |
| Magnesium Chloride Hexahydrate | 7791-18-6 | PNEC     | 90 mg/l         | aquatic organisms | sewage treatment plant (STP) | short-term (single instance) |
| Magnesium Chloride Hexahydrate | 7791-18-6 | PNEC     | 288.9 mg/kg     | aquatic organisms | freshwater sediment          | short-term (single instance) |
| Magnesium Chloride Hexahydrate | 7791-18-6 | PNEC     | 28.89 mg/kg     | aquatic organisms | marine sediment              | short-term (single instance) |

## BAX® System Lysis Buffer

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| Relevant PNECs of components of the mixture |           |          |                 |                       |                           |                              |
|---------------------------------------------|-----------|----------|-----------------|-----------------------|---------------------------|------------------------------|
| Name of substance                           | CAS No    | Endpoint | Threshold level | Organism              | Environmental compartment | Exposure time                |
| Magnesium Chloride Hexahydrate              | 7791-18-6 | PNEC     | 662.8 mg/kg     | terrestrial organisms | soil                      | short-term (single instance) |

### 8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

|                                                          |                                                           |
|----------------------------------------------------------|-----------------------------------------------------------|
| Physical state                                           | liquid                                                    |
| Colour                                                   | not determined                                            |
| Odour                                                    | characteristic                                            |
| Melting point/freezing point                             | not determined                                            |
| Boiling point or initial boiling point and boiling range | not determined                                            |
| Flammability                                             | this material is combustible, but will not ignite readily |
| Lower and upper explosion limit                          | not determined                                            |



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|                           |                |
|---------------------------|----------------|
| Flash point               | not determined |
| Auto-ignition temperature | not determined |
| Decomposition temperature | not relevant   |
| pH (value)                | not determined |
| Kinematic viscosity       | not determined |
| Solubility(ies)           | not determined |

## Partition coefficient

|                                                   |                                   |
|---------------------------------------------------|-----------------------------------|
| Partition coefficient n-octanol/water (log value) | this information is not available |
|---------------------------------------------------|-----------------------------------|

|                 |                |
|-----------------|----------------|
| Vapour pressure | not determined |
|-----------------|----------------|

## Density and/or relative density

|                         |                                               |
|-------------------------|-----------------------------------------------|
| Density                 | not determined                                |
| Relative vapour density | information on this property is not available |

|                          |                       |
|--------------------------|-----------------------|
| Particle characteristics | not relevant (liquid) |
|--------------------------|-----------------------|

**9.2 Other information**

|                                                    |                                                             |
|----------------------------------------------------|-------------------------------------------------------------|
| Information with regard to physical hazard classes | hazard classes acc. to GHS (physical hazards): not relevant |
|----------------------------------------------------|-------------------------------------------------------------|

## Other safety characteristics

|                 |         |
|-----------------|---------|
| Solvent content | 99.65 % |
| Solid content   | 0.346 % |

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**SECTION 10: Stability and reactivity****10.1 Reactivity**

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

**10.2 Chemical stability**

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

**10.3 Possibility of hazardous reactions**

No known hazardous reactions.

**10.4 Conditions to avoid**

There are no specific conditions known which have to be avoided.

**10.5 Incompatible materials**

Oxidisers

**10.6 Hazardous decomposition products**

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Test data are not available for the complete mixture.

**Classification procedure**

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

**Classification according to GHS (1272/2008/EC, CLP)**

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

**Acute toxicity**

Shall not be classified as acutely toxic.

**Skin corrosion/irritation**

Shall not be classified as corrosive/irritant to skin.

**Serious eye damage/eye irritation**

Shall not be classified as seriously damaging to the eye or eye irritant.

**Respiratory or skin sensitisation**

Shall not be classified as a respiratory or skin sensitizer.

**Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

**Carcinogenicity**

Shall not be classified as carcinogenic.

**Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

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Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

**11.2 Information on other hazards**

There is no additional information.

**SECTION 12: Ecological information****12.1 Toxicity**

Shall not be classified as hazardous to the aquatic environment.

**12.2 Persistence and degradability**

Data are not available.

**12.3 Bioaccumulative potential**

Data are not available.

**12.4 Mobility in soil**

Data are not available.

**12.5 Results of PBT and vPvB assessment**

Data are not available.

**12.6 Endocrine disrupting properties**

None of the ingredients are listed.

**12.7 Other adverse effects**

Data are not available.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packages

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

**Remarks**

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

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**SECTION 14: Transport information**

- 14.1 UN number or ID number** not subject to transport regulations
- 14.2 UN proper shipping name** not relevant
- 14.3 Transport hazard class(es)** none
- 14.4 Packing group** not assigned
- 14.5 Environmental hazards** non-environmentally hazardous acc. to the dangerous goods regulations
- 14.6 Special precautions for user**  
There is no additional information.
- 14.7 Maritime transport in bulk according to IMO instruments**  
The cargo is not intended to be carried in bulk.

**Information for each of the UN Model Regulations****International Maritime Dangerous Goods Code (IMDG) - Additional information**

Not subject to IMDG.

**International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information**

Not subject to ICAO-IATA.

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Relevant provisions of the European Union (EU)****Restrictions according to REACH, Annex XVII**

none of the ingredients are listed

**List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list**

none of the ingredients are listed

**Deco-Paint Directive**

|             |         |
|-------------|---------|
| VOC content | 99.94 % |
|-------------|---------|

**Industrial Emissions Directive (IED)**

|             |         |
|-------------|---------|
| VOC content | 99.65 % |
|-------------|---------|

**Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)**

none of the ingredients are listed

**Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)**

none of the ingredients are listed

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### Water Framework Directive (WFD)

none of the ingredients are listed

### Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

### National inventories

| Country | Inventory  | Status                         |
|---------|------------|--------------------------------|
| AU      | AICS       | not all ingredients are listed |
| CA      | DSL        | not all ingredients are listed |
| CN      | IECSC      | not all ingredients are listed |
| EU      | ECSI       | not all ingredients are listed |
| EU      | REACH Reg. | not all ingredients are listed |
| JP      | CSCL-ENCS  | not all ingredients are listed |
| KR      | KECI       | not all ingredients are listed |
| MX      | INSQ       | not all ingredients are listed |
| NZ      | NZIoC      | not all ingredients are listed |
| PH      | PICCS      | not all ingredients are listed |
| TR      | CICR       | not all ingredients are listed |
| TW      | TCSI       | all ingredients are listed     |
| US      | TSCA       | not all ingredients are listed |

#### Legend

|            |                                                                         |
|------------|-------------------------------------------------------------------------|
| AICS       | Australian Inventory of Chemical Substances                             |
| CICR       | Chemical Inventory and Control Regulation                               |
| CSCL-ENCS  | List of Existing and New Chemical Substances (CSCL-ENCS)                |
| DSL        | Domestic Substances List (DSL)                                          |
| ECSI       | EC Substance Inventory (EINECS, ELINCS, NLP)                            |
| IECSC      | Inventory of Existing Chemical Substances Produced or Imported in China |
| INSQ       | National Inventory of Chemical Substances                               |
| KECI       | Korea Existing Chemicals Inventory                                      |
| NZIoC      | New Zealand Inventory of Chemicals                                      |
| PICCS      | Philippine Inventory of Chemicals and Chemical Substances (PICCS)       |
| REACH Reg. | REACH registered substances                                             |
| TCSI       | Taiwan Chemical Substance Inventory                                     |
| TSCA       | Toxic Substance Control Act                                             |

## 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

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### SECTION 16: Other information

#### Abbreviations and acronyms

| Abbr.    | Descriptions of used abbreviations                                                                                                                                                |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ADR      | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)                     |
| CAS      | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)                                                                            |
| CLP      | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures                                                                                |
| DGR      | Dangerous Goods Regulations (see IATA/DGR)                                                                                                                                        |
| DNEL     | Derived No-Effect Level                                                                                                                                                           |
| EC No    | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union) |
| EINECS   | European Inventory of Existing Commercial Chemical Substances                                                                                                                     |
| ELINCS   | European List of Notified Chemical Substances                                                                                                                                     |
| GHS      | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations                                                                         |
| IATA     | International Air Transport Association                                                                                                                                           |
| IATA/DGR | Dangerous Goods Regulations (DGR) for the air transport (IATA)                                                                                                                    |
| ICAO     | International Civil Aviation Organization                                                                                                                                         |
| IMDG     | International Maritime Dangerous Goods Code                                                                                                                                       |
| index No | The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008                                                          |
| NLP      | No-Longer Polymer                                                                                                                                                                 |
| PBT      | Persistent, Bioaccumulative and Toxic                                                                                                                                             |
| PNEC     | Predicted No-Effect Concentration                                                                                                                                                 |
| REACH    | Registration, Evaluation, Authorisation and Restriction of Chemicals                                                                                                              |
| RID      | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)           |
| SVHC     | Substance of Very High Concern                                                                                                                                                    |
| VOC      | Volatile Organic Compounds                                                                                                                                                        |
| vPvB     | Very Persistent and very Bioaccumulative                                                                                                                                          |

#### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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**Classification procedure**

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

**Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

|                             |                             |
|-----------------------------|-----------------------------|
| Trade name                  | <b>BAX® System Protease</b> |
| Registration number (REACH) | not relevant (mixture)      |
| Product code(s)             | ASY2012                     |

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

|                          |                               |
|--------------------------|-------------------------------|
| Relevant identified uses | Laboratory and analytical use |
|--------------------------|-------------------------------|

**1.3 Details of the supplier of the safety data sheet**

Qualicon Diagnostics LLC  
941 Avenida Acaso  
Camarillo CA 93012  
United States

Telephone: 1-302-695-5300  
Telefax: 1-302-351-6454  
e-mail: [diagnostics.support@hygiena.com](mailto:diagnostics.support@hygiena.com)  
Website: <https://www.hygiena.com>

|                           |                                                                                      |
|---------------------------|--------------------------------------------------------------------------------------|
| e-mail (competent person) | <a href="mailto:diagnostics.support@hygiena.com">diagnostics.support@hygiena.com</a> |
|---------------------------|--------------------------------------------------------------------------------------|

**1.4 Emergency telephone number**

|                               |                                                                                                                   |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Emergency information service | 1-302-695-5300<br>This number is only available during the following<br>office hours: Mon-Fri 08:00 AM - 05:00 PM |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------|

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No 1272/2008 (CLP)  
This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

**2.2 Label elements**

Labelling according to Regulation (EC) No 1272/2008 (CLP)  
not required

**2.3 Other hazards**

of no significance

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

Not relevant (mixture)

**3.2 Mixtures**



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## Description of the mixture

| Name of substance  | Identifier                                                                                  | Wt%       | Classification acc. to GHS | Pictograms |
|--------------------|---------------------------------------------------------------------------------------------|-----------|----------------------------|------------|
| Pyrogen Free Water | CAS No<br>7732-18-5                                                                         | 50 – < 75 |                            |            |
| Glycerol           | CAS No<br>56-81-5<br><br>EC No<br>200-289-5<br><br>REACH Reg. No<br>01-2119471987-18-xxxx   | 25 – < 50 |                            |            |
| Protease           | CAS No<br>9036-06-0                                                                         | 0.1 – < 1 |                            |            |
| Tris HCl           | CAS No<br>1185-53-1<br><br>EC No<br>214-684-5<br><br>REACH Reg. No<br>01-2120301688-54-xxxx | 0.1 – < 1 |                            |            |

For full text of abbreviations: see SECTION 16.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

## General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

## Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

## Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

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

Symptoms and effects are not known to date.

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

none

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO<sub>2</sub>)

Unsuitable extinguishing media

Water jet

**5.2 Special hazards arising from the substance or mixture**

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)**5.3 Advice for firefighters**

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

**6.2 Environmental precautions**

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

**6.3 Methods and material for containment and cleaning up**

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

**6.4 Reference to other sections**

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

#### 7.2 Conditions for safe storage, including any incompatibilities

Control of effects

Protect against external exposure, such as

frost

#### 7.3 Specific end use(s)

See section 16 for a general overview.

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)

| Country | Name of agent | CAS No  | Identifier | TWA [ppm] | TWA [mg/m³] | STEL [ppm] | STEL [mg/m³] | Ceiling-C [ppm] | Ceiling-C [mg/m³] | Notation | Source    |
|---------|---------------|---------|------------|-----------|-------------|------------|--------------|-----------------|-------------------|----------|-----------|
| GB      | glycerol      | 56-81-5 | WEL        |           | 10          |            |              |                 |                   | mist     | EH40/2005 |

Notation

Ceiling-C

mist

STEL

TWA

ceiling value is a limit value above which exposure should not occur as mists

short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

Relevant DNELs of components of the mixture

| Name of substance | CAS No    | Endpoint | Threshold level    | Protection goal, route of exposure | Used in           | Exposure time              |
|-------------------|-----------|----------|--------------------|------------------------------------|-------------------|----------------------------|
| Glycerol          | 56-81-5   | DNEL     | 220 mg/m³          | human, inhalatory                  | worker (industry) | chronic - local effects    |
| Tris HCl          | 1185-53-1 | DNEL     | 152.8 mg/m³        | human, inhalatory                  | worker (industry) | chronic - systemic effects |
| Tris HCl          | 1185-53-1 | DNEL     | 216.6 mg/kg bw/day | human, dermal                      | worker (industry) | chronic - systemic effects |

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| Relevant PNECs of components of the mixture |         |          |                 |                   |                              |                              |
|---------------------------------------------|---------|----------|-----------------|-------------------|------------------------------|------------------------------|
| Name of substance                           | CAS No  | Endpoint | Threshold level | Organism          | Environmental compartment    | Exposure time                |
| Glycerol                                    | 56-81-5 | PNEC     | 1,000 mg/l      | aquatic organisms | sewage treatment plant (STP) | short-term (single instance) |

### 8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

|                                                          |                                                           |
|----------------------------------------------------------|-----------------------------------------------------------|
| Physical state                                           | liquid                                                    |
| Colour                                                   | not determined                                            |
| Odour                                                    | characteristic                                            |
| Melting point/freezing point                             | not determined                                            |
| Boiling point or initial boiling point and boiling range | not determined                                            |
| Flammability                                             | this material is combustible, but will not ignite readily |
| Lower and upper explosion limit                          | not determined                                            |

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|                           |                |
|---------------------------|----------------|
| Flash point               | not determined |
| Auto-ignition temperature | not determined |
| Decomposition temperature | not relevant   |
| pH (value)                | not determined |
| Kinematic viscosity       | not determined |
| Solubility(ies)           | not determined |

## Partition coefficient

|                                                   |                                   |
|---------------------------------------------------|-----------------------------------|
| Partition coefficient n-octanol/water (log value) | this information is not available |
|---------------------------------------------------|-----------------------------------|

|                 |                |
|-----------------|----------------|
| Vapour pressure | not determined |
|-----------------|----------------|

## Density and/or relative density

|                         |                                               |
|-------------------------|-----------------------------------------------|
| Density                 | not determined                                |
| Relative vapour density | information on this property is not available |

|                          |                       |
|--------------------------|-----------------------|
| Particle characteristics | not relevant (liquid) |
|--------------------------|-----------------------|

**9.2 Other information**

|                                                    |                                                             |
|----------------------------------------------------|-------------------------------------------------------------|
| Information with regard to physical hazard classes | hazard classes acc. to GHS (physical hazards): not relevant |
|----------------------------------------------------|-------------------------------------------------------------|

## Other safety characteristics

|                 |          |
|-----------------|----------|
| Solvent content | 99.34 %  |
| Solid content   | 0.6562 % |

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### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

#### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### 10.5 Incompatible materials

Oxidisers

#### 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

### SECTION 11: Toxicological information

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

##### Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

##### Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

##### Acute toxicity

Shall not be classified as acutely toxic.

##### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

##### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

##### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

##### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

##### Carcinogenicity

Shall not be classified as carcinogenic.

##### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

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Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

### 11.2 Information on other hazards

There is no additional information.

## SECTION 12: Ecological information

### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

### 12.2 Persistence and degradability

Data are not available.

### 12.3 Bioaccumulative potential

Data are not available.

### 12.4 Mobility in soil

Data are not available.

### 12.5 Results of PBT and vPvB assessment

Data are not available.

### 12.6 Endocrine disrupting properties

None of the ingredients are listed.

### 12.7 Other adverse effects

Data are not available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

**BAX® System Protease**

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**SECTION 14: Transport information**

- 14.1 UN number or ID number** not subject to transport regulations
- 14.2 UN proper shipping name** not relevant
- 14.3 Transport hazard class(es)** none
- 14.4 Packing group** not assigned
- 14.5 Environmental hazards** non-environmentally hazardous acc. to the dangerous goods regulations
- 14.6 Special precautions for user**  
There is no additional information.
- 14.7 Maritime transport in bulk according to IMO instruments**  
The cargo is not intended to be carried in bulk.

**Information for each of the UN Model Regulations****International Maritime Dangerous Goods Code (IMDG) - Additional information**

Not subject to IMDG.

**International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information**

Not subject to ICAO-IATA.

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Relevant provisions of the European Union (EU)****Restrictions according to REACH, Annex XVII**

none of the ingredients are listed

**List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list**

none of the ingredients are listed

**Deco-Paint Directive**

|             |       |
|-------------|-------|
| VOC content | 100 % |
|-------------|-------|

**Industrial Emissions Directive (IED)**

|             |         |
|-------------|---------|
| VOC content | 99.34 % |
|-------------|---------|

**Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)**

none of the ingredients are listed

**Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)**

none of the ingredients are listed



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Date of compilation: 2022-03-21

### Water Framework Directive (WFD)

none of the ingredients are listed

### Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

### National inventories

| Country | Inventory  | Status                         |
|---------|------------|--------------------------------|
| AU      | AICS       | not all ingredients are listed |
| CA      | DSL        | not all ingredients are listed |
| CN      | IECSC      | all ingredients are listed     |
| EU      | ECSI       | all ingredients are listed     |
| EU      | REACH Reg. | not all ingredients are listed |
| JP      | CSCL-ENCS  | not all ingredients are listed |
| KR      | KECI       | not all ingredients are listed |
| MX      | INSQ       | not all ingredients are listed |
| NZ      | NZIoC      | all ingredients are listed     |
| PH      | PICCS      | not all ingredients are listed |
| TR      | CICR       | not all ingredients are listed |
| TW      | TCSI       | all ingredients are listed     |
| US      | TSCA       | not all ingredients are listed |

#### Legend

|            |                                                                         |
|------------|-------------------------------------------------------------------------|
| AICS       | Australian Inventory of Chemical Substances                             |
| CICR       | Chemical Inventory and Control Regulation                               |
| CSCL-ENCS  | List of Existing and New Chemical Substances (CSCL-ENCS)                |
| DSL        | Domestic Substances List (DSL)                                          |
| ECSI       | EC Substance Inventory (EINECS, ELINCS, NLP)                            |
| IECSC      | Inventory of Existing Chemical Substances Produced or Imported in China |
| INSQ       | National Inventory of Chemical Substances                               |
| KECI       | Korea Existing Chemicals Inventory                                      |
| NZIoC      | New Zealand Inventory of Chemicals                                      |
| PICCS      | Philippine Inventory of Chemicals and Chemical Substances (PICCS)       |
| REACH Reg. | REACH registered substances                                             |
| TCSI       | Taiwan Chemical Substance Inventory                                     |
| TSCA       | Toxic Substance Control Act                                             |

## 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## BAX® System Protease

Version number: 1.1

Date of compilation: 2022-03-21

### SECTION 16: Other information

#### Abbreviations and acronyms

| Abbr.     | Descriptions of used abbreviations                                                                                                                                                    |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ADR       | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)                         |
| CAS       | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)                                                                                |
| Ceiling-C | Ceiling value                                                                                                                                                                         |
| CLP       | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures                                                                                    |
| DGR       | Dangerous Goods Regulations (see IATA/DGR)                                                                                                                                            |
| DNEL      | Derived No-Effect Level                                                                                                                                                               |
| EC No     | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)     |
| EH40/2005 | EH40/2005 Workplace exposure limits ( <a href="http://www.nationalarchives.gov.uk/doc/open-government-licence/">http://www.nationalarchives.gov.uk/doc/open-government-licence/</a> ) |
| EINECS    | European Inventory of Existing Commercial Chemical Substances                                                                                                                         |
| ELINCS    | European List of Notified Chemical Substances                                                                                                                                         |
| GHS       | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations                                                                             |
| IATA      | International Air Transport Association                                                                                                                                               |
| IATA/DGR  | Dangerous Goods Regulations (DGR) for the air transport (IATA)                                                                                                                        |
| ICAO      | International Civil Aviation Organization                                                                                                                                             |
| IMDG      | International Maritime Dangerous Goods Code                                                                                                                                           |
| index No  | The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008                                                              |
| NLP       | No-Longer Polymer                                                                                                                                                                     |
| PBT       | Persistent, Bioaccumulative and Toxic                                                                                                                                                 |
| PNEC      | Predicted No-Effect Concentration                                                                                                                                                     |
| ppm       | Parts per million                                                                                                                                                                     |
| REACH     | Registration, Evaluation, Authorisation and Restriction of Chemicals                                                                                                                  |
| RID       | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)               |
| STEL      | Short-term exposure limit                                                                                                                                                             |
| SVHC      | Substance of Very High Concern                                                                                                                                                        |
| TWA       | Time-weighted average                                                                                                                                                                 |
| VOC       | Volatile Organic Compounds                                                                                                                                                            |
| vPvB      | Very Persistent and very Bioaccumulative                                                                                                                                              |
| WEL       | Workplace exposure limit                                                                                                                                                              |

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**Key literature references and sources for data**

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

**Classification procedure**

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

**Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

## BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

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

#### 1.1 Product identifier

Trade name

**BAX® System PCR Tablets**

Registration number (REACH)

not relevant (mixture)

Product code(s)

BAX® Sample Tablet, RT Campylobacter ASY2045 (D12748287), E.coli O157:H7 MP ASY2046 (D12415443), Cronobacter sakazakii ASY2047 (D12415480), Genus Listeria ASY2048 (D12498137), Listeria mono ASY2049 (D12498110), Salmonella ASY2050 (D12415473), Yeast and Mold ASY2051 (D12522072), Genus Listeria 24E ASY2052 (D14208527), Listeria mono 24E ASY2053 (D13623810), RT L.mono ASY2055 (D15134243), RT Shigella ASY2056 (D14816161), RT E.coli O157:H7 ASY2057 (D14227174), Salmonella 2 ASY2058 (D14368493), RT Vibrio ASY2059 (D13915754), RT Genus Listeria ASY2060 (D15130514), RT Staphylococcus aureus ASY2061 (D12762673), RT STEC panel 1 O26, O111, O121 ASY2062 (D14643070), RT STEC panel 2 O45, O103, O145 ASY2063 (D14643086), RT STEC screening stx eae ASY2064 (D14643068), X5 Ecoli O157:H7 ASY2066 (D15407254), X5 L.mono PACKAGE TABLETS - RT SHIGELLA 48 ASY2067 (D15407244), X5 Genus Listeria ASY2068 (D154072390), X5 Salmonella ASY2069 (D15407227)

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

Relevant identified uses

Laboratory and analytical use

#### 1.3 Details of the supplier of the safety data sheet

Qualicon Diagnostics LLC  
941 Avenida Acaso  
Camarillo CA 93012  
United States

Telephone: 1-302-695-5300  
Telefax: 1-302-351-6454  
e-mail: [diagnostics.support@hygiena.com](mailto:diagnostics.support@hygiena.com)  
Website: <https://www.hygiena.com>

e-mail (competent person)

[diagnostics.support@hygiena.com](mailto:diagnostics.support@hygiena.com)

#### 1.4 Emergency telephone number

Emergency information service

1-302-695-5300  
This number is only available during the following office hours: Mon-Fri 08:00 AM - 05:00 PM

## BAX® System PCR Tablets

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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 mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

#### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

not required

#### 2.3 Other hazards

of no significance

### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Not relevant (mixture)

#### 3.2 Mixtures

Description of the mixture

| Name of substance              | Identifier                                                                                  | Wt%       | Classification acc. to GHS | Pictograms |
|--------------------------------|---------------------------------------------------------------------------------------------|-----------|----------------------------|------------|
| Carbohydrate Excipient         | CAS No<br>64044-51-5                                                                        | ≥ 90      |                            |            |
| Tris                           | CAS No<br>77-86-1                                                                           | 1 – < 5   |                            |            |
| Potassium Chloride             | CAS No<br>7447-40-7                                                                         | 0.1 – < 1 |                            |            |
| Sodium Chloride                | CAS No<br>7647-14-5                                                                         | 0.1 – < 1 |                            |            |
| Magnesium Chloride (Anhydrous) | CAS No<br>7786-30-3<br><br>EC No<br>232-094-6<br><br>REACH Reg. No<br>01-2119485597-19-xxxx | 0.1 – < 1 |                            |            |
| SYBR Green Fluorophor          | CAS No<br>163795-75-3                                                                       | 0.1 – < 1 |                            |            |
| Glycerol                       | CAS No<br>56-81-5<br><br>EC No<br>200-289-5<br><br>REACH Reg. No<br>01-2119471987-18-xxxx   | < 0.1     |                            |            |
| Protein Excipient              | CAS No<br>9000-71-9                                                                         | < 0.1     |                            |            |

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| Name of substance         | Identifier           | Wt%   | Classification acc. to GHS | Pictograms |
|---------------------------|----------------------|-------|----------------------------|------------|
| DNA various sizes         | CAS No<br>99675-55-5 | < 0.1 |                            |            |
| dNTP multiple nucleotides |                      | < 0.1 |                            |            |
| Fluorophor Dye I          | CAS No<br>23491-45-4 | < 0.1 |                            |            |
| AmpliTAQ                  |                      | < 0.1 |                            |            |
| Surfactamps               |                      | < 0.1 |                            |            |

For full text of abbreviations: see SECTION 16.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

## General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

## Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

## Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

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

Symptoms and effects are not known to date.

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

none

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media

Water, Foam, ABC-powder

Unsuitable extinguishing media

Water jet

**5.2 Special hazards arising from the substance or mixture**

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

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**5.3 Advice for firefighters**

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

**6.2 Environmental precautions**

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

**6.3 Methods and material for containment and cleaning up**

Advice on how to contain a spill

Covering of drains, Take up mechanically

Advice on how to clean up a spill

Take up mechanically.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

**6.4 Reference to other sections**

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

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

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas. Ground/bond container and receiving equipment.

- Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

**7.2 Conditions for safe storage, including any incompatibilities**

Managing of associated risks

- Explosive atmospheres

Removal of dust deposits.

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### 7.3 Specific end use(s)

See section 16 for a general overview.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational exposure limit values (Workplace Exposure Limits)

| Country | Name of agent | CAS No  | Identifier | TWA [ppm] | TWA [mg/m <sup>3</sup> ] | STEL [ppm] | STEL [mg/m <sup>3</sup> ] | Ceiling-C [ppm] | Ceiling-C [mg/m <sup>3</sup> ] | Notation | Source    |
|---------|---------------|---------|------------|-----------|--------------------------|------------|---------------------------|-----------------|--------------------------------|----------|-----------|
| GB      | glycerol      | 56-81-5 | WEL        |           | 10                       |            |                           |                 |                                | mist     | EH40/2005 |

#### Notation

Ceiling-C

mist

STEL

TWA

ceiling value is a limit value above which exposure should not occur

as mists

short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

#### Relevant DNELs of components of the mixture

| Name of substance | CAS No  | Endpoint | Threshold level       | Protection goal, route of exposure | Used in           | Exposure time           |
|-------------------|---------|----------|-----------------------|------------------------------------|-------------------|-------------------------|
| Glycerol          | 56-81-5 | DNEL     | 220 mg/m <sup>3</sup> | human, inhalatory                  | worker (industry) | chronic - local effects |

#### Relevant PNECs of components of the mixture

| Name of substance              | CAS No    | Endpoint | Threshold level | Organism              | Environmental compartment    | Exposure time                |
|--------------------------------|-----------|----------|-----------------|-----------------------|------------------------------|------------------------------|
| Magnesium Chloride (Anhydrous) | 7786-30-3 | PNEC     | 3.21 mg/l       | aquatic organisms     | freshwater                   | short-term (single instance) |
| Magnesium Chloride (Anhydrous) | 7786-30-3 | PNEC     | 0.32 mg/l       | aquatic organisms     | marine water                 | short-term (single instance) |
| Magnesium Chloride (Anhydrous) | 7786-30-3 | PNEC     | 90 mg/l         | aquatic organisms     | sewage treatment plant (STP) | short-term (single instance) |
| Magnesium Chloride (Anhydrous) | 7786-30-3 | PNEC     | 288.9 mg/kg     | aquatic organisms     | freshwater sediment          | short-term (single instance) |
| Magnesium Chloride (Anhydrous) | 7786-30-3 | PNEC     | 28.89 mg/kg     | aquatic organisms     | marine sediment              | short-term (single instance) |
| Magnesium Chloride (Anhydrous) | 7786-30-3 | PNEC     | 662.8 mg/kg     | terrestrial organisms | soil                         | short-term (single instance) |
| Glycerol                       | 56-81-5   | PNEC     | 1,000 mg/l      | aquatic organisms     | sewage treatment plant (STP) | short-term (single instance) |

### 8.2 Exposure controls

Appropriate engineering controls

General ventilation.



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**Individual protection measures (personal protective equipment)****Eye/face protection**

Wear eye/face protection.

**Skin protection****- Hand protection**

Wear protective gloves.

**- Other protection measures**

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

**Respiratory protection**

In case of inadequate ventilation wear respiratory protection.

**Environmental exposure controls**

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

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

|                                                          |                                                           |
|----------------------------------------------------------|-----------------------------------------------------------|
| Physical state                                           | solid                                                     |
| Colour                                                   | white                                                     |
| Odour                                                    | characteristic                                            |
| Melting point/freezing point                             | not determined                                            |
| Boiling point or initial boiling point and boiling range | not determined                                            |
| Flammability                                             | this material is combustible, but will not ignite readily |
| Lower and upper explosion limit                          | not determined                                            |
| Flash point                                              | not applicable                                            |
| Auto-ignition temperature                                | not determined                                            |
| Decomposition temperature                                | not relevant                                              |
| pH (value)                                               | not applicable                                            |
| Kinematic viscosity                                      | not relevant                                              |
| Solubility(ies)                                          | not determined                                            |

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**Partition coefficient**

|                                                   |                                   |
|---------------------------------------------------|-----------------------------------|
| Partition coefficient n-octanol/water (log value) | this information is not available |
|---------------------------------------------------|-----------------------------------|

|                 |                |
|-----------------|----------------|
| Vapour pressure | not determined |
|-----------------|----------------|

**Density and/or relative density**

|                         |                                               |
|-------------------------|-----------------------------------------------|
| Density                 | not determined                                |
| Relative vapour density | information on this property is not available |

|                          |                   |
|--------------------------|-------------------|
| Particle characteristics | no data available |
|--------------------------|-------------------|

**9.2 Other information**

|                                                    |                                                             |
|----------------------------------------------------|-------------------------------------------------------------|
| Information with regard to physical hazard classes | hazard classes acc. to GHS (physical hazards): not relevant |
|----------------------------------------------------|-------------------------------------------------------------|

**Other safety characteristics**

|                 |        |
|-----------------|--------|
| Solvent content | 99.8 % |
| Solid content   | 0.2 %  |

**SECTION 10: Stability and reactivity****10.1 Reactivity**

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

**10.2 Chemical stability**

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

**10.3 Possibility of hazardous reactions**

No known hazardous reactions.

**10.4 Conditions to avoid**

There are no specific conditions known which have to be avoided.

**Hints to prevent fire or explosion**

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

**10.5 Incompatible materials**

Oxidisers

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**10.6 Hazardous decomposition products**

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Test data are not available for the complete mixture.

**Classification procedure**

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

**Classification according to GHS (1272/2008/EC, CLP)**

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

**Acute toxicity**

Shall not be classified as acutely toxic.

**Skin corrosion/irritation**

Shall not be classified as corrosive/irritant to skin.

**Serious eye damage/eye irritation**

Shall not be classified as seriously damaging to the eye or eye irritant.

**Respiratory or skin sensitisation**

Shall not be classified as a respiratory or skin sensitizer.

**Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

**Carcinogenicity**

Shall not be classified as carcinogenic.

**Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

**Specific target organ toxicity - single exposure**

Shall not be classified as a specific target organ toxicant (single exposure).

**Specific target organ toxicity - repeated exposure**

Shall not be classified as a specific target organ toxicant (repeated exposure).

**Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

**11.2 Information on other hazards**

There is no additional information.

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**SECTION 12: Ecological information****12.1 Toxicity**

Shall not be classified as hazardous to the aquatic environment.

**12.2 Persistence and degradability**

Data are not available.

**12.3 Bioaccumulative potential**

Data are not available.

**12.4 Mobility in soil**

Data are not available.

**12.5 Results of PBT and vPvB assessment**

Data are not available.

**12.6 Endocrine disrupting properties**

None of the ingredients are listed.

**12.7 Other adverse effects**

Data are not available.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

**Remarks**

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

**SECTION 14: Transport information****14.1 UN number or ID number**

not subject to transport regulations

**14.2 UN proper shipping name**

not relevant

**14.3 Transport hazard class(es)**

none

**14.4 Packing group**

not assigned

**14.5 Environmental hazards**

non-environmentally hazardous acc. to the dangerous goods regulations

**14.6 Special precautions for user**

There is no additional information.

**14.7 Maritime transport in bulk according to IMO instruments**

The cargo is not intended to be carried in bulk.

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### Information for each of the UN Model Regulations

#### International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

#### International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Not subject to ICAO-IATA.

## SECTION 15: Regulatory information

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

#### Relevant provisions of the European Union (EU)

##### Restrictions according to REACH, Annex XVII

none of the ingredients are listed

##### List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

none of the ingredients are listed

##### Deco-Paint Directive

|             |        |
|-------------|--------|
| VOC content | 99.6 % |
|-------------|--------|

##### Industrial Emissions Directive (IED)

|             |        |
|-------------|--------|
| VOC content | 99.6 % |
|-------------|--------|

##### Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

##### Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

##### Water Framework Directive (WFD)

| List of pollutants (WFD)       |        |           |         |
|--------------------------------|--------|-----------|---------|
| Name of substance              | CAS No | Listed in | Remarks |
| Magnesium Chloride (Anhydrous) |        | a)        |         |

#### Legend

A) Indicative list of the main pollutants

##### Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

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### National inventories

| Country | Inventory  | Status                         |
|---------|------------|--------------------------------|
| AU      | AICS       | not all ingredients are listed |
| CA      | DSL        | not all ingredients are listed |
| CN      | IECSC      | not all ingredients are listed |
| EU      | ECSI       | not all ingredients are listed |
| EU      | REACH Reg. | not all ingredients are listed |
| JP      | CSCL-ENCS  | not all ingredients are listed |
| KR      | KECI       | not all ingredients are listed |
| MX      | INSQ       | not all ingredients are listed |
| NZ      | NZIoC      | not all ingredients are listed |
| PH      | PICCS      | not all ingredients are listed |
| TR      | CICR       | not all ingredients are listed |
| TW      | TCSI       | not all ingredients are listed |
| US      | TSCA       | not all ingredients are listed |

#### Legend

|            |                                                                         |
|------------|-------------------------------------------------------------------------|
| AICS       | Australian Inventory of Chemical Substances                             |
| CICR       | Chemical Inventory and Control Regulation                               |
| CSCL-ENCS  | List of Existing and New Chemical Substances (CSCL-ENCS)                |
| DSL        | Domestic Substances List (DSL)                                          |
| ECSI       | EC Substance Inventory (EINECS, ELINCS, NLP)                            |
| IECSC      | Inventory of Existing Chemical Substances Produced or Imported in China |
| INSQ       | National Inventory of Chemical Substances                               |
| KECI       | Korea Existing Chemicals Inventory                                      |
| NZIoC      | New Zealand Inventory of Chemicals                                      |
| PICCS      | Philippine Inventory of Chemicals and Chemical Substances (PICCS)       |
| REACH Reg. | REACH registered substances                                             |
| TCSI       | Taiwan Chemical Substance Inventory                                     |
| TSCA       | Toxic Substance Control Act                                             |

### 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## SECTION 16: Other information

### Abbreviations and acronyms

| Abbr.     | Descriptions of used abbreviations                                                                                                                            |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ADR       | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road) |
| CAS       | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)                                                        |
| Ceiling-C | Ceiling value                                                                                                                                                 |
| CLP       | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures                                                            |
| DGR       | Dangerous Goods Regulations (see IATA/DGR)                                                                                                                    |

## BAX® System PCR Tablets

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| Abbr.     | Descriptions of used abbreviations                                                                                                                                                    |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DNEL      | Derived No-Effect Level                                                                                                                                                               |
| EC No     | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)     |
| EH40/2005 | EH40/2005 Workplace exposure limits ( <a href="http://www.nationalarchives.gov.uk/doc/open-government-licence/">http://www.nationalarchives.gov.uk/doc/open-government-licence/</a> ) |
| EINECS    | European Inventory of Existing Commercial Chemical Substances                                                                                                                         |
| ELINCS    | European List of Notified Chemical Substances                                                                                                                                         |
| GHS       | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations                                                                             |
| IATA      | International Air Transport Association                                                                                                                                               |
| IATA/DGR  | Dangerous Goods Regulations (DGR) for the air transport (IATA)                                                                                                                        |
| ICAO      | International Civil Aviation Organization                                                                                                                                             |
| IMDG      | International Maritime Dangerous Goods Code                                                                                                                                           |
| index No  | The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008                                                              |
| NLP       | No-Longer Polymer                                                                                                                                                                     |
| PBT       | Persistent, Bioaccumulative and Toxic                                                                                                                                                 |
| PNEC      | Predicted No-Effect Concentration                                                                                                                                                     |
| ppm       | Parts per million                                                                                                                                                                     |
| REACH     | Registration, Evaluation, Authorisation and Restriction of Chemicals                                                                                                                  |
| RID       | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)               |
| STEL      | Short-term exposure limit                                                                                                                                                             |
| SVHC      | Substance of Very High Concern                                                                                                                                                        |
| TWA       | Time-weighted average                                                                                                                                                                 |
| VOC       | Volatile Organic Compounds                                                                                                                                                            |
| vPvB      | Very Persistent and very Bioaccumulative                                                                                                                                              |
| WEL       | Workplace exposure limit                                                                                                                                                              |

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

## **BAX® System PCR Tablets**

Version number: 1.0

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### **Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.