

BAX® SYSTEM X5 - E. COLI O157:H7 ASSAY

KIT2022

Date of compilation: 2022-12-28

Bill of materials

| Name of substance | Identifier | Classification acc. to GHS | Pictograms | Page |
|--------------------------|------------|----------------------------|------------|---------|
| BAX® System Lysis Buffer | | | | 2 - 13 |
| BAX® System Protease | | | | 14 - 25 |
| BAX® System PCR Tablets | | | | 26 - 38 |

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

SECTION 1: Identification**1.1 Product identifier**

Trade name **BAX® System Lysis Buffer**
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
Website: <https://www.hygiena.com>

e-mail (competent person) 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

SECTION 2: Hazard(s) identification**2.1 Classification of the substance or mixture**

Classification acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)
This mixture does not meet the criteria for classification.

2.2 Label elements

Labelling acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)
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 7732-18-5 | ≥ 90 | | |
| Tris | CAS No 77-86-1 | 0.1 – < 1 | | |
| Tris HCl | CAS No 1185-53-1 | 0.1 – < 1 | | |
| Potassium Chloride | CAS No 7447-40-7 | 0.1 – < 1 | | |
| Reduced Triton X-100 | CAS No 92046-34-9 | < 0.1 | | |
| Magnesium Chloride Hexahydrate | CAS No 7791-18-6 | < 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: Fire-fighting measures**5.1 Extinguishing media**

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂)**5.3 Advice for firefighters**

In case of fire and/or explosion do not breathe fumes. Coordinate 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 vapors/dust/aerosols/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 the 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 ³ | 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) |

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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

Appearance

| | |
|----------------|-----------------------|
| Physical state | liquid |
| Color | not determined |
| Particle | not relevant (liquid) |
| Odor | characteristic |

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Other safety parameters

| | |
|---|---|
| pH (value) | not determined |
| Melting point/freezing point | not determined |
| Initial boiling point and boiling range | not determined |
| Flash point | not determined |
| Evaporation rate | Not determined |
| Flammability (solid, gas) | not relevant, (fluid) |
| Vapor pressure | not determined |
| Density | not determined |
| Vapor density | this information is not available |
| Relative density | Information on this property is not available |
| Solubility(ies) | not determined |

Partition coefficient

| | |
|-----------------------------|-----------------------------------|
| - n-octanol/water (log KOW) | this information is not available |
| Auto-ignition temperature | not determined |
| Viscosity | not determined |
| Explosive properties | none |
| Oxidizing properties | none |

9.2 Other information

| | |
|-----------------|---------|
| 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

Oxidizers

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 toxicological effects

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 acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

This mixture does not meet the criteria for classification.

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 sensitization

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.

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 | not subject to transport regulations |
| 14.2 UN proper shipping name | not relevant |
| 14.3 Transport hazard class(es) | not assigned |
| 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 Transport in bulk according to Annex II of MARPOL and the IBC Code | |
| The cargo is not intended to be carried in bulk. | |

Information for each of the UN Model Regulations

Transport of dangerous goods by road or rail (49 CFR US DOT) - Additional information

Not subject to transport 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 specific for the product in question

National regulations (United States)

Superfund Amendment and Reauthorization Act (SARA TITLE III)

- The List of Extremely Hazardous Substances and Their Threshold Planning Quantities (EPCRA Section 302, 304)

none of the ingredients are listed

- Specific Toxic Chemical Listings (EPCRA Section 313)

none of the ingredients are listed

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

- List of Hazardous Substances and Reportable Quantities (CERCLA section 102a) (40 CFR 302.4)

none of the ingredients are listed

Clean Air Act

none of the ingredients are listed

Right to Know Hazardous Substance List

- Hazardous Substance List (NJ-RTK)

none of the ingredients are listed

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California Environmental Protection Agency (Cal/EPA): Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1987

none of the ingredients are listed

Industry or sector specific available guidance(s)

NPCA-HMIS® III

Hazardous Materials Identification System. American Coatings Association.

| Category | Rating | Description |
|---------------------|--------|--|
| Chronic | / | none |
| Health | 0 | no significant risk to health |
| Flammability | 1 | material that must be preheated before ignition can occur |
| Physical hazard | 0 | material that is normally stable, even under fire conditions, and will not react with water, polymerize, decompose, condense, or self-react. Non-explosive |
| Personal protection | - | |

NFPA® 704

National Fire Protection Association: Standard System for the Identification of the Hazards of Materials for Emergency Response (United States).

| Category | Degree of hazard | Description |
|----------------|------------------|---|
| Flammability | 1 | material that must be preheated before ignition can occur |
| Health | 0 | material that, under emergency conditions, would offer no hazard beyond that of ordinary combustible material |
| Instability | 0 | material that is normally stable, even under fire conditions |
| Special hazard | | |

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 |

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| Country | Inventory | Status |
|---------|-----------|--------------------------------|
| 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.

SECTION 16: Other information, including date of preparation or last revision

Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|----------------|---|
| 49 CFR US DOT | 49 CFR U.S. Department of Transportation |
| CAS | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances) |
| DGR | Dangerous Goods Regulations (see IATA/DGR) |
| DNEL | Derived No-Effect Level |
| 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 |
| MARPOL | International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant") |
| NLP | No-Longer Polymer |
| NPCA-HMIS® III | National Paint and Coatings Association: Hazardous Materials Identification System - HMIS® III, Third Edition |
| OSHA | Occupational Safety and Health Administration (United States) |
| PBT | Persistent, Bioaccumulative and Toxic |

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| Abbr. | Descriptions of used abbreviations |
|-------|---|
| PNEC | Predicted No-Effect Concentration |
| RTECS | Registry of Toxic Effects of Chemical Substances (database of NIOSH with toxicological information) |
| vPvB | Very Persistent and very Bioaccumulative |

Key literature references and sources for data

OSHA Hazard Communication Standard (HCS), 29 CFR 1910.1200.

Transport of dangerous goods by road or rail (49 CFR US DOT). 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 Protease

Version number: 1.1

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SECTION 1: Identification**1.1 Product identifier**

Trade name **BAX® System Protease**
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
Website: <https://www.hygiena.com>

e-mail (competent person) 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

SECTION 2: Hazard(s) identification**2.1 Classification of the substance or mixture**

Classification acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)
This mixture does not meet the criteria for classification.

2.2 Label elements

Labelling acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)
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 7732-18-5 | 50 - < 75 | | |
| Glycerol | CAS No 56-81-5 | 25 - < 50 | | |
| Protease | CAS No 9036-06-0 | 0.1 - < 1 | | |
| Tris HCl | CAS No 1185-53-1 | 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: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media

Water jet

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5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Coordinate 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 vapors/dust/aerosols/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.

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.

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7.2 Conditions for safe storage, including any incompatibilities

Control of the 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/m ³] | STEL [ppm] | STEL [mg/m ³] | Ceiling-C [ppm] | Ceiling-C [mg/m ³] | Notation | Source |
| US | glycerine | 56-81-5 | REL | | | | | | | mist, appx-D | NIOSH REL |
| US | glycerol | 56-81-5 | PEL | | 15 | | | | | mist, i | 29 CFR 1910.1000 |
| US | glycerol | 56-81-5 | PEL | | 5 | | | | | mist, r | 29 CFR 1910.1000 |

Notation

| | |
|-----------|--|
| appx-D | see Appendix D - Substances with No Established RELs |
| Ceiling-C | ceiling value is a limit value above which exposure should not occur |
| i | inhalable fraction |
| mist | as mists |
| r | respirable fraction |
| STEL | 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) |
| TWA | 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 ³ | human, inhalatory | worker (industry) | chronic - local effects |
| Tris HCl | 1185-53-1 | DNEL | 152.8 mg/m ³ | 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 |
| Glycerol | 56-81-5 | PNEC | 1,000 mg/l | aquatic organisms | sewage treatment plant (STP) | short-term (single instance) |

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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

Appearance

| | |
|----------------|-----------------------|
| Physical state | liquid |
| Color | not determined |
| Particle | not relevant (liquid) |
| Odor | characteristic |

Other safety parameters

| | |
|---|-----------------------|
| pH (value) | not determined |
| Melting point/freezing point | not determined |
| Initial boiling point and boiling range | not determined |
| Flash point | not determined |
| Evaporation rate | Not determined |
| Flammability (solid, gas) | not relevant, (fluid) |

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| | |
|------------------|---|
| Vapor pressure | not determined |
| Density | not determined |
| Vapor density | this information is not available |
| Relative density | Information on this property is not available |
| Solubility(ies) | not determined |

Partition coefficient

| | |
|-----------------------------|-----------------------------------|
| - n-octanol/water (log KOW) | this information is not available |
| Auto-ignition temperature | not determined |
| Viscosity | not determined |
| Explosive properties | none |
| Oxidizing properties | none |

9.2 Other information

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

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

Oxidizers

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.

BAX® System Protease

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Date of compilation: 2022-03-21

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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 acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

This mixture does not meet the criteria for classification.

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 sensitization

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.

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.

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Date of compilation: 2022-03-21

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.

SECTION 14: Transport information

| | | |
|------|--|---|
| 14.1 | UN number | not subject to transport regulations |
| 14.2 | UN proper shipping name | not relevant |
| 14.3 | Transport hazard class(es) | not assigned |
| 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 | Transport in bulk according to Annex II of MARPOL and the IBC Code | The cargo is not intended to be carried in bulk. |

Information for each of the UN Model Regulations

Transport of dangerous goods by road or rail (49 CFR US DOT) - Additional information

Not subject to transport 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.

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Version number: 1.1

Date of compilation: 2022-03-21

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

National regulations (United States)

Superfund Amendment and Reauthorization Act (SARA TITLE III)

- The List of Extremely Hazardous Substances and Their Threshold Planning Quantities (EPCRA Section 302, 304)

none of the ingredients are listed

- Specific Toxic Chemical Listings (EPCRA Section 313)

none of the ingredients are listed

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

- List of Hazardous Substances and Reportable Quantities (CERCLA section 102a) (40 CFR 302.4)

none of the ingredients are listed

Clean Air Act

none of the ingredients are listed

Right to Know Hazardous Substance List

- Hazardous Substance List (NJ-RTK)

| Name of substance | CAS No | Remarks | Classifications |
|-------------------|---------|---------|-----------------|
| Glycerol | 56-81-5 | | |

California Environmental Protection Agency (Cal/EPA): Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1987

none of the ingredients are listed

Industry or sector specific available guidance(s)

NPCA-HMIS® III

Hazardous Materials Identification System. American Coatings Association.

| Category | Rating | Description |
|---------------------|--------|--|
| Chronic | / | none |
| Health | 0 | no significant risk to health |
| Flammability | 1 | material that must be preheated before ignition can occur |
| Physical hazard | 0 | material that is normally stable, even under fire conditions, and will not react with water, polymerize, decompose, condense, or self-react. Non-explosive |
| Personal protection | - | |

NFPA® 704

National Fire Protection Association: Standard System for the Identification of the Hazards of Materials for Emergency Response (United States).

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Version number: 1.1

Date of compilation: 2022-03-21

| Category | Degree of hazard | Description |
|----------------|------------------|---|
| Flammability | 1 | material that must be preheated before ignition can occur |
| Health | 0 | material that, under emergency conditions, would offer no hazard beyond that of ordinary combustible material |
| Instability | 0 | material that is normally stable, even under fire conditions |
| Special hazard | | |

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, including date of preparation or last revision

Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|------------------|---|
| 29 CFR 1910.1000 | 29 CFR 1910.1000, Tables Z-1, Z-2, Z-3 - Occupational Safety and Health Standards: Toxic and Hazardous Substances (permissible exposure limits) |
| 49 CFR US DOT | 49 CFR U.S. Department of Transportation |
| CAS | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances) |
| Ceiling-C | Ceiling value |
| DGR | Dangerous Goods Regulations (see IATA/DGR) |
| DNEL | Derived No-Effect Level |
| 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 |
| MARPOL | International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant") |
| NIOSH REL | National Institute for Occupational Safety and Health (NIOSH): Recommended Exposure Limits (RELs) |
| NLP | No-Longer Polymer |
| NPCA-HMIS® III | National Paint and Coatings Association: Hazardous Materials Identification System - HMIS® III, Third Edition |
| OSHA | Occupational Safety and Health Administration (United States) |
| PBT | Persistent, Bioaccumulative and Toxic |
| PEL | Permissible exposure limit |
| PNEC | Predicted No-Effect Concentration |
| ppm | Parts per million |
| RTECS | Registry of Toxic Effects of Chemical Substances (database of NIOSH with toxicological information) |
| STEL | Short-term exposure limit |
| TWA | Time-weighted average |
| vPvB | Very Persistent and very Bioaccumulative |

Key literature references and sources for data

OSHA Hazard Communication Standard (HCS), 29 CFR 1910.1200.

Transport of dangerous goods by road or rail (49 CFR US DOT). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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Date of compilation: 2022-03-21

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

1.1 Product identifier

Trade name

BAX® System PCR Tablets

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
Website: <https://www.hygiena.com>

e-mail (competent person)

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

Version number: 1.0

Date of compilation: 2022-03-21

SECTION 2: Hazard(s) identification

2.1 Classification of the substance or mixture

Classification acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

This mixture does not meet the criteria for classification.

2.2 Label elements

Labelling acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

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 64044-51-5 | ≥ 90 | | |
| Tris | CAS No 77-86-1 | 3 – < 5 | | |
| Potassium Chloride | CAS No 7447-40-7 | 0.1 – < 1 | | |
| Sodium Chloride | CAS No 7647-14-5 | 0.1 – < 1 | | |
| Magnesium Chloride (Anhydrous) | CAS No 7786-30-3 | 0.1 – < 1 | | |
| SYBR Green Fluorophor | CAS No 163795-75-3 | 0.1 – < 1 | | |
| Glycerol | CAS No 56-81-5 | < 0.1 | | |
| Protein Excipient | CAS No 9000-71-9 | < 0.1 | | |
| DNA various sizes | CAS No 99675-55-5 | < 0.1 | | |
| dNTP multiple nucleotides | | < 0.1 | | |
| Fluorophor Dye I | CAS No 23491-45-4 | < 0.1 | | |
| AmpliTAQ | | < 0.1 | | |
| Surfactamps | | < 0.1 | | |

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Date of compilation: 2022-03-21

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: Fire-fighting 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 (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Coordinate 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.

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Version number: 1.0

Date of compilation: 2022-03-21

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 vapors/dust/aerosols/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.

7.3 Specific end use(s)

See section 16 for a general overview.

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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 ³] | STEL [ppm] | STEL [mg/m ³] | Ceiling-C [ppm] | Ceiling-C [mg/m ³] | Notation | Source |
| US | glycerine | 56-81-5 | REL | | | | | | | mist, appx-D | NIOSH REL |
| US | glycerol | 56-81-5 | PEL | | 15 | | | | | mist, i | 29 CFR 1910.1000 |
| US | glycerol | 56-81-5 | PEL | | 5 | | | | | mist, r | 29 CFR 1910.1000 |

Notation

appx-D

Ceiling-C

i

mist

r

STEL

TWA

see Appendix D - Substances with No Established RELs

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

inhalable fraction

as mists

respirable fraction

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 ³ | 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) |

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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 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

Appearance

| | |
|----------------|----------------|
| Physical state | solid |
| Color | white |
| Odor | characteristic |

Other safety parameters

| | |
|---|----------------|
| pH (value) | not applicable |
| Melting point/freezing point | not determined |
| Initial boiling point and boiling range | not determined |
| Flash point | not applicable |

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| | |
|---------------------------------|---|
| Evaporation rate | Not determined |
| Flammability (solid, gas) | this material is combustible, but will not ignite readily |
| Explosion limits of dust clouds | not determined |
| Vapor pressure | not determined |
| Density | not determined |
| Vapor density | this information is not available |
| Relative density | Information on this property is not available |
| Solubility(ies) | not determined |

Partition coefficient

| | |
|-----------------------------|-----------------------------------|
| - n-octanol/water (log KOW) | this information is not available |
|-----------------------------|-----------------------------------|

| | |
|---------------------------|-----------------------------|
| Auto-ignition temperature | not determined |
| Viscosity | not relevant (solid matter) |
| Explosive properties | none |
| Oxidizing properties | none |

9.2 Other information

| | |
|-----------------|--------|
| 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.

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

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

Oxidizers

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 toxicological effects

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 acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

This mixture does not meet the criteria for classification.

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 sensitization

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.

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

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.

SECTION 14: Transport information

14.1 UN number

not subject to transport regulations

14.2 UN proper shipping name

not relevant

14.3 Transport hazard class(es)

not assigned

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 Transport in bulk according to Annex II of MARPOL and the IBC Code

The cargo is not intended to be carried in bulk.

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

Information for each of the UN Model Regulations

Transport of dangerous goods by road or rail (49 CFR US DOT) - Additional information

Not subject to transport 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 specific for the product in question

National regulations (United States)

Superfund Amendment and Reauthorization Act (SARA TITLE III)

- The List of Extremely Hazardous Substances and Their Threshold Planning Quantities (EPCRA Section 302, 304)

none of the ingredients are listed

- Specific Toxic Chemical Listings (EPCRA Section 313)

none of the ingredients are listed

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

- List of Hazardous Substances and Reportable Quantities (CERCLA section 102a) (40 CFR 302.4)

none of the ingredients are listed

Clean Air Act

none of the ingredients are listed

Right to Know Hazardous Substance List

- Hazardous Substance List (NJ-RTK)

| Name of substance | CAS No | Remarks | Classifications |
|-------------------|---------|---------|-----------------|
| Glycerol | 56-81-5 | | |

California Environmental Protection Agency (Cal/EPA): Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1987

none of the ingredients are listed

Industry or sector specific available guidance(s)

NPCA-HMIS® III

Hazardous Materials Identification System. American Coatings Association.

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

| Category | Rating | Description |
|---------------------|--------|--|
| Chronic | / | none |
| Health | 0 | no significant risk to health |
| Flammability | 1 | material that must be preheated before ignition can occur |
| Physical hazard | 0 | material that is normally stable, even under fire conditions, and will not react with water, polymerize, decompose, condense, or self-react. Non-explosive |
| Personal protection | - | |

NFPA® 704

National Fire Protection Association: Standard System for the Identification of the Hazards of Materials for Emergency Response (United States).

| Category | Degree of hazard | Description |
|----------------|------------------|---|
| Flammability | 1 | material that must be preheated before ignition can occur |
| Health | 0 | material that, under emergency conditions, would offer no hazard beyond that of ordinary combustible material |
| Instability | 0 | material that is normally stable, even under fire conditions |
| Special hazard | | |

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) |

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Legend

| | |
|------------|---|
| 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, including date of preparation or last revision

Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|------------------|---|
| 29 CFR 1910.1000 | 29 CFR 1910.1000, Tables Z-1, Z-2, Z-3 - Occupational Safety and Health Standards: Toxic and Hazardous Substances (permissible exposure limits) |
| 49 CFR US DOT | 49 CFR U.S. Department of Transportation |
| CAS | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances) |
| Ceiling-C | Ceiling value |
| DGR | Dangerous Goods Regulations (see IATA/DGR) |
| DNEL | Derived No-Effect Level |
| 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 |
| MARPOL | International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant") |
| NIOSH REL | National Institute for Occupational Safety and Health (NIOSH): Recommended Exposure Limits (RELs) |
| NLP | No-Longer Polymer |
| NPCA-HMIS® III | National Paint and Coatings Association: Hazardous Materials Identification System - HMIS® III, Third Edition |
| OSHA | Occupational Safety and Health Administration (United States) |
| PBT | Persistent, Bioaccumulative and Toxic |
| PEL | Permissible exposure limit |
| PNEC | Predicted No-Effect Concentration |
| ppm | Parts per million |

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| Abbr. | Descriptions of used abbreviations |
|-------|---|
| RTECS | Registry of Toxic Effects of Chemical Substances (database of NIOSH with toxicological information) |
| STEL | Short-term exposure limit |
| TWA | Time-weighted average |
| vPvB | Very Persistent and very Bioaccumulative |

Key literature references and sources for data

OSHA Hazard Communication Standard (HCS), 29 CFR 1910.1200.

Transport of dangerous goods by road or rail (49 CFR US DOT). 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.