

BAX® SYSTEM X5 - L. MONO ASSAY

KIT2023

Date of compilation: 2022-12-28

Bill of materials

Name of substance	Identifier	Classification acc. to GHS	Pictograms	Page
BAX® LYSING AGENT 2 (1.1ML)				2 – 12
BAX® System Lysis Buffer				13 – 24
BAX® System Protease				25 – 36
BAX® System PCR Tablets				37 – 49

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

SECTION 1: Identification**1.1 Product identifier**

Trade name

BAX® LYSING AGENT 2 (1.1ML)

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.comWebsite: <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

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Pyrogen Free Water	CAS No 7732-18-5	≥ 90		
Mutanolysin	CAS No 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: Fire-fighting measures**5.1 Extinguishing media**

Suitable extinguishing media

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

Unsuitable extinguishing media

Water jet

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

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. 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

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 the effects

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

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****Appearance**

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

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

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	100 %
Solid content	0 %

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

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 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.

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

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.

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

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

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

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	0	material that will not burn under typical fire conditions
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	0	material that will not burn under typical fire conditions
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
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

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

Country	Inventory	Status
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, 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)
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
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.

BAX® LYSING AGENT 2 (1.1ML)

Version number: 1.1

Date of compilation: 2022-03-28

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 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.comWebsite: <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

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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.

BAX® System Lysis Buffer

Version number: 1.1

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 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)

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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 %

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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.

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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.

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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)
ECSC	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

BAX® System Lysis Buffer

Version number: 1.1

Date of compilation: 2022-03-21

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

Date of compilation: 2022-03-21

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.comWebsite: <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

BAX® System Protease

Version number: 1.1

Date of compilation: 2022-03-21

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

BAX® System Protease

Version number: 1.1

Date of compilation: 2022-03-21

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.

BAX® System Protease

Version number: 1.1

Date of compilation: 2022-03-21

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/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	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/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

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)

BAX® System Protease

Version number: 1.1

Date of compilation: 2022-03-21

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)

BAX® System Protease

Version number: 1.1

Date of compilation: 2022-03-21

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

Version number: 1.1

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.

BAX® System Protease

Version number: 1.1

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.

BAX® System Protease

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).

BAX® System Protease

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).

BAX® System Protease

Version number: 1.1

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		

BAX® System PCR Tablets

Version number: 1.0

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.

BAX® System PCR Tablets

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.

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

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
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/m³	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)

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

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

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

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)

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

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

BAX® System PCR Tablets

Version number: 1.0

Date of compilation: 2022-03-21

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.