

# BAX® SYSTEM - L. MONO 24E KIT KIT2002

Date of compilation: 2025-07-22

#### **Bill of materials**

Name of substance	Identifier	Classification acc. to GHS	Pictograms	Page
BAX® System Lysis Buffer	Internal code ASY2011			2 - 13
BAX® System PROTEASE	Internal code ASY2012			14 - 22
BAX® Lysing Agent 1	Internal code ASY2010			23 - 33
BAX® LYSING AGENT 2 (1.1ML)	Internal code ASY2009			34 - 43



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## **BAX® System Lysis Buffer**

Version number: 2.0 Revision: 2025-01-02 Replaces version of: 2022-03-21 (1)

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

#### 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: Techsupport@hygiena.com Website: https://www.hygiena.com

e-mail (competent person) Techsupport@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: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification acc. to GHS

This mixture does not meet the criteria for classification.

#### 2.2 Label elements

Labelling not required

#### 2.3 Other hazards

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of  $\geq$  0,1%.

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

#### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture)

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## **BAX® System Lysis Buffer**

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#### 3.2 Mixtures

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 EC No 201-064-4	0.1 - < 1		
Tris HCl	CAS No	0.1 - < 1		
THISTICE	1185-53-1	0.1-\1		
	EC No 214-684-5			
Potassium Chloride	CAS No 7447-40-7	0.1 - < 1		
Reduced Triton X-100	CAS No 92046-34-9	0.0001 - < 0.1		
Magnesium Chloride Hexahydrate	CAS No 7791-18-6	0.0001 - < 0.1		
	EC No 232-094-6			

#### **Remarks**

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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## **BAX® System Lysis Buffer**

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#### **SECTION 5: Firefighting 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. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

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

#### 6.2 Environmental precautions

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

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

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

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

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

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

#### **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.

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## **BAX® System Lysis Buffer**

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#### Advice on general occupational hygiene

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

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

Control of effects

Protect against external exposure, such as frost

#### 7.3 Specific end use(s)

See section 16 for a general overview.

### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits) this information is not available

#### Relevant DNELs of components Name of substance **CAS No Endpoint Threshold** Protection goal, **Used** in **Exposure time** route of exposure level Tris 77-86-1 **DNEL** 117.5 mg/m<sup>3</sup> human, inhalatory chronic - systemic efworker (industry) fects Tris 77-86-1 **DNEL** 166.7 mg/kg human, dermal worker (industry) chronic - systemic efbw/day fects Tris HCI 1185-53-1 **DNEL** 152.8 mg/m<sup>3</sup> human, inhalatory worker (industry) chronic - systemic ef-216.6 mg/kg Tris HCI 1185-53-1 **DNEL** human, dermal worker (industry) chronic - systemic ef-

fects

bw/day

Relevant PNECs of components						
Name of substance	CAS No	Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
Tris	77-86-1	PNEC	300 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Magnesium Chloride Hexahydrate	7791-18-6	PNEC	3.21 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single in- stance)
Magnesium Chloride Hexahydrate	7791-18-6	PNEC	0.32 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single in- stance)
Magnesium Chloride Hexahydrate	7791-18-6	PNEC	90 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Magnesium Chloride Hexahydrate	7791-18-6	PNEC	288.9 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single instance)
Magnesium Chloride Hexahydrate	7791-18-6	PNEC	28.89 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single instance)
Magnesium Chloride Hexahydrate	7791-18-6	PNEC	662.8 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single instance)

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## **BAX® System Lysis Buffer**

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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

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

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#### Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	not determined
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#### Density and/or relative density

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

Particle characteristics	not relevant (liquid)
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#### 9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
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#### Other safety characteristics

Liquid content	99.27 %
Solid content	0.732 %

#### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

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

#### 10.2 Chemical stability

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

#### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4 Conditions to avoid

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

#### 10.5 Incompatible materials

Oxidisers

#### 10.6 Hazardous decomposition products

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

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## **BAX® System Lysis Buffer**

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#### **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 GHS

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 sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

#### Specific target organ toxicity - single exposure

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

#### Specific target organ toxicity - repeated exposure

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

#### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

There is no additional information.

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

#### 12.2 Persistence and degradability

Data are not available.

#### 12.3 Bioaccumulative potential

Data are not available.

#### 12.4 Mobility in soil

Data are not available.

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#### 12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance at a concentration of  $\geq 0.1\%$ .

#### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

#### 12.7 Other adverse effects

Data are not available.

#### **SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods

Sewage disposal-relevant information

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

Waste treatment of containers/packagings

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

#### Remarks

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

#### **SECTION 14: Transport information**

14.1	UN number or ID number	not subject to transport regulations

**14.2 UN proper shipping name** not relevant

**14.3 Transport hazard class(es)** none

**14.4 Packing group** not assigned

**14.5 Environmental hazards** non-environmentally hazardous acc. to the danger-

ous goods regulations

#### 14.6 Special precautions for user

There is no additional information.

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

The cargo is not intended to be carried in bulk.

#### **Information for each of the UN Model Regulations**

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

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

Not subject to ICAO-IATA.

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## **BAX® System Lysis Buffer**

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### **SECTION 15: Regulatory information**

## 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

#### **Deco-Paint Directive**

#### **Industrial Emissions Directive (IED)**

VOC content	99.65 %
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## Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

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

none of the ingredients are listed

#### **Water Framework Directive (WFD)**

none of the ingredients are listed

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

none of the ingredients are listed

#### **National inventories**

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

#### <u>Legend</u>

AIIC Australian Inventory of Industrial Chemicals
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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<u>Legend</u>

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**

#### Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-rel- evant
1.1	Registration number (REACH): not relevant (mixture)		yes
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	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	yes
	e-mail: diagnostics.support@hygiena.com Website: https://www.hygiena.com	e-mail: Techsupport@hygiena.com Website: https://www.hygiena.com	
1.3	e-mail (competent person): diagnostics.support@hygiena.com	e-mail (competent person): Techsupport@hygiena.com	yes
2.1	Classification according to Regulation (EC) No 1272/2008 (CLP): This mixture does not meet the criteria for classific- ation in accordance with Regulation No 1272/2008/EC.	Classification acc. to GHS: This mixture does not meet the criteria for classific- ation.	yes
2.3	Other hazards: of no significance	Other hazards	yes
2.3		Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance at a concentration of ≥ 0,1%.	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
3.2		Description of the mixture: change in the listing (table)	yes
3.2		Remarks: For full text of abbreviations: see SECTION 16	yes
8.1	Control parameters: This information is not available.	Control parameters: Occupational exposure limit values (Workplace Exposure Limits)	yes

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## **BAX® System Lysis Buffer**

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Section	Former entry (text/value)	Actual entry (text/value)	Safety-rel- evant
		this information is not available	
8.1		Relevant DNELs of components: change in the listing (table)	yes
8.1		Relevant PNECs of components: change in the listing (table)	yes
9.2	Solvent content: 99.65 %	Liquid content: 99.27 %	yes
9.2	Solid content: 0.346 %	Solid content: 0.732 %	yes
11.1	Classification according to GHS (1272/2008/EC, CLP): This mixture does not meet the criteria for classific- ation in accordance with Regulation No 1272/2008/EC.	Classification acc. to GHS: This mixture does not meet the criteria for classific- ation.	yes
12.5	Results of PBT and vPvB assessment: Data are not available.	Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance at a concentration of ≥ 0,1%.	yes
12.6	Endocrine disrupting properties: None of the ingredients are listed.	Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
15.1	Restrictions according to REACH, Annex XVII: none of the ingredients are listed		yes
15.1	List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list: none of the ingredients are listed		yes
15.1		National inventories: change in the listing (table)	yes

## **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
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)

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Abbr.	Descriptions of used abbreviations
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

#### Key literature references and sources for data

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

#### **Classification procedure**

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

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

#### Disclaimer

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

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## **BAX® System PROTEASE**

Version number: 3.0 Revision: 2025-03-18 Replaces version of: 2023-10-23 (2)

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

#### 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: Techsupport@hygiena.com Website: https://www.hygiena.com

e-mail (competent person) Techsupport@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: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification (acc. to GB CLP)

This mixture does not meet the criteria for classification.

#### 2.2 Label elements

Labelling (acc. to GB CLP) not required

#### 2.3 Other hazards

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of  $\geq 0.1\%$ .

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

#### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture)

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## **BAX® System PROTEASE**

Version number: 3.0 Revision: 2025-03-18 Replaces version of: 2023-10-23 (2)

#### 3.2 Mixtures

Description of the mixture

This product does not meet the criteria for classification in any hazard class according to GHS.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### General notes

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

#### Following inhalation

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

#### Following skin contact

Wash with plenty of soap and water.

#### Following eye contact

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

#### Following ingestion

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

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

Symptoms and effects are not known to date.

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

none

#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

Water jet

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

Hazardous combustion products

Nitrogen oxides (NOx)

#### 5.3 Advice for firefighters

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

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

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## **BAX® System PROTEASE**

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#### For emergency responders

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

#### 6.2 Environmental precautions

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

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

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

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

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

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

#### **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

There is no additional information.

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials" (Section 10).

#### 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) 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.

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GB RFACE

## **BAX® System PROTEASE**

Version number: 3.0 Revision: 2025-03-18 Replaces version of: 2023-10-23 (2)

#### Skin protection

#### - Hand protection

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

#### - Other protection measures

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

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

#### Environmental exposure controls

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

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
Solubility(ies)	not determined

#### Partition coefficient

Vapour pressure

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

not determined

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GB RFACE

## **BAX® System PROTEASE**

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#### Density and/or relative density

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

Particle characteristics	not relevant (liquid)
	-

#### 9.2 Other information

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

#### Other safety characteristics

Liquid content	0.9929 %
Solid content	0.001082 %

### **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 GHS

This mixture does not meet the criteria for classification.

#### Acute toxicity

Shall not be classified as acutely toxic.

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GR REACH

## **BAX® System PROTEASE**

Version number: 3.0 Revision: 2025-03-18 Replaces version of: 2023-10-23 (2)

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

#### Serious eye damage/eye irritation

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

#### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

#### 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

Does not contain a PBT-/vPvB-substance at a concentration of  $\geq 0,1\%$ .

#### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

#### 12.7 Other adverse effects

Data are not available.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Sewage disposal-relevant information

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

#### Waste treatment of containers/packagings

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

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GB REACH

## **BAX® System PROTEASE**

Version number: 3.0 Revision: 2025-03-18 Replaces version of: 2023-10-23 (2)

#### 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)** none

**14.4 Packing group** not assigned

**14.5** Environmental hazards non-environmentally hazardous acc. to the danger-

ous goods regulations

14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

#### **Information for each of the UN Model Regulations**

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

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

Not subject to ICAO-IATA.

#### **SECTION 15: Regulatory information**

## 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

#### **Deco-Paint Directive**

VOC content	0.01009 %
-------------	-----------

#### **Industrial Emissions Directive (IED)**

VOC content	0.01009 %

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

none of the ingredients are listed

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

none of the ingredients are listed

#### Water Framework Directive (WFD)

none of the ingredients are listed

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

none of the ingredients are listed

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GB REACH

## **BAX® System PROTEASE**

Version number: 3.0 Revision: 2025-03-18 Replaces version of: 2023-10-23 (2)

#### National regulations (GB)

#### List of substances subject to authorisation (GB REACH, Annex 14) / SVHC - candidate list

none of the ingredients are listed

#### **National inventories**

Country	Inventory	Status
AU	AIIC	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

#### <u>Legend</u>

AIIC Australian Inventory of Industrial Chemicals
CICR Chemical Inventory and Control Regulation

CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

DSL Domestic Substances List (DSL)

ECSI EC Substance Inventory (EINECS, ELINCS, NLP)

IECSC Inventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances
KECI Korea Existing Chemicals Inventory
NZIOC New Zealand Inventory of Chemicals

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH Reg. REACH registered substances

TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance Control Act

#### 15.2 Chemical Safety Assessment

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

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GB REACH

## **BAX® System PROTEASE**

Version number: 3.0 Revision: 2025-03-18 Replaces version of: 2023-10-23 (2)

#### **SECTION 16: Other information**

#### **Abbreviations and acronyms**

Descriptions of used abbreviations	
Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)	
Dangerous Goods Regulations (see IATA/DGR)	
Endocrine disruptor	
European Inventory of Existing Commercial Chemical Substances	
European List of Notified Chemical Substances	
The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/720 (as amended)	
The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/758 (as amended)	
GHS "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United N	
A International Air Transport Association	
Dangerous Goods Regulations (DGR) for the air transport (IATA)	
International Civil Aviation Organization	
International Maritime Dangerous Goods Code	
No-Longer Polymer	
Persistent, Bioaccumulative and Toxic	
Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)	
Volatile Organic Compounds	
Very Persistent and very Bioaccumulative	

#### Key literature references and sources for data

The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/758 (as amended). The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/720 (as amended). GB mandatory classification and labelling.

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

#### Classification procedure

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

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

#### Disclaimer

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

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acc. to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® Lysing Agent 1**

Version number: 1.1 Date of compilation: 2023-05-09

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

#### 1.1 Product identifier

Trade name BAX® Lysing Agent 1

Product code(s) ASY2010

#### 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: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification acc. to GHS

This mixture does not meet the criteria for classification.

#### 2.2 Label elements

Labelling

not required

#### 2.3 Other hazards

This material is combustible, but will not ignite readily.

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of  $\geq$  0,1%.

**Endocrine disrupting properties** 

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq$  0,1%.

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## **BAX® Lysing Agent 1**

Version number: 1.1 Date of compilation: 2023-05-09

#### **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
Dimethyl sulfoxide	CAS No 67-68-5	≥ 90		
	EC No 200-664-3			

For full text of abbreviations: see SECTION 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### General notes

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

#### Following inhalation

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

#### Following skin contact

Wash with plenty of soap and water.

#### Following eye contact

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

#### Following ingestion

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

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

Symptoms and effects are not known to date.

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

none

#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

Water jet

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## **BAX® Lysing Agent 1**

Version number: 1.1 Date of compilation: 2023-05-09

#### 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. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

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

#### 6.2 Environmental precautions

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

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

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

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

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

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

### **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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acc. to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® Lysing Agent 1**

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

#### 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) 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
Dimethyl sulfoxide	67-68-5	DNEL	484 mg/m³	human, inhalatory	worker (industry)	chronic - systemic ef- fects
Dimethyl sulfoxide	67-68-5	DNEL	265 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
Dimethyl sulfoxide	67-68-5	DNEL	200 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic ef- fects

#### Relevant PNECs of components of the mixture

Name of substance	CAS No	Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
Dimethyl sulfoxide	67-68-5	PNEC	17 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single in- stance)
Dimethyl sulfoxide	67-68-5	PNEC	1.7 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single in- stance)
Dimethyl sulfoxide	67-68-5	PNEC	11 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single in- stance)
Dimethyl sulfoxide	67-68-5	PNEC	13.4 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single in- stance)
Dimethyl sulfoxide	67-68-5	PNEC	3.02 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single in- stance)

#### 8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

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## **BAX® Lysing Agent 1**

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#### Skin protection

#### - Hand protection

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

#### - Other protection measures

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

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

#### Environmental exposure controls

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

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	not determined
Odour	characteristic
Melting point/freezing point	18.5 °C
Boiling point or initial boiling point and boiling range	189 °C at 1,013 hPa
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	2.6 vol% - 28.5 vol%
Flash point	87 °C at 1,013 hPa
Auto-ignition temperature	300 °C (auto-ignition temperature (liquids and gases))
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
Solubility(ies)	not determined

#### Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	0.417 mmHg at 20 °C
Density and/or relative density	
Density	not determined
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)
Other information	
Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics	
Liquid content	100 %

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

9.2

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

#### 10.2 Chemical stability

Solid content

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

0 %

#### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4 Conditions to avoid

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

#### 10.5 Incompatible materials

Oxidisers

#### 10.6 Hazardous decomposition products

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

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## **BAX® Lysing Agent 1**

Version number: 1.1 Date of compilation: 2023-05-09

#### **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 GHS

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 sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

#### Specific target organ toxicity - single exposure

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

#### Specific target organ toxicity - repeated exposure

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

#### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

There is no additional information.

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

#### 12.2 Persistence and degradability

Data are not available.

#### 12.3 Bioaccumulative potential

Data are not available.

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acc. to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® Lysing Agent 1**

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#### 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of  $\geq 0.1\%$ .

#### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq$  0,1%.

#### 12.7 Other adverse effects

Data are not available.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Sewage disposal-relevant information

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

Waste treatment of containers/packagings

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

#### Remarks

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

#### **SECTION 14: Transport information**

14.1	UN number or ID number	not assigned
14.2	UN proper shipping name	not relevant
14.3	Transport hazard class(es)	none
14.4	Packing group	not assigned
14.5	Environmental hazards	non-environmentally hazardous acc. to the dangerous goods regulations

#### 14.6 Special precautions for user

There is no additional information.

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

The cargo is not intended to be carried in bulk.

#### **Information for each of the UN Model Regulations**

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

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

Not subject to ICAO-IATA.

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acc. to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® Lysing Agent 1**

Version number: 1.1 Date of compilation: 2023-05-09

### **SECTION 15: Regulatory information**

## Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

#### **Deco-Paint Directive**

VOC content	100 %
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#### **Industrial Emissions Directive (IED)**

VOC content	100 %

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

none of the ingredients are listed

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

none of the ingredients are listed

#### Water Framework Directive (WFD)

none of the ingredients are listed

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

None of the ingredients are listed.

#### **National inventories**

Country	Inventory	Status
AU	AIIC	all ingredients are listed
CA	DSL	all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	all ingredients are listed
JP	CSCL-ENCS	all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	all ingredients are listed
TR	CICR	all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	all ingredients are listed (ACTIVE)

Legend

AIIC Australian Inventory of Industrial Chemicals CICR

Chemical Inventory and Control Regulation
List of Existing and New Chemical Substances (CSCL-ENCS) CSCL-ENCS

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acc. to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® Lysing Agent 1**

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Legend

DSL

ECSI

**IECSC** 

Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China
National Inventory of Chemical Substances
Korea Existing Chemicals Inventory
New Zealand Inventory of Chemicals
Philipping Inventory of Chemicals INSQ KECI<sup>`</sup> NZIoC

**PICCS** Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH Reg. REACH registered substances

TCSI Taiwan Chemical Substance Inventory

Toxic Substance Control Act **TSCA** 

#### 15.2 Chemical safety assessment

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

#### **SECTION 16: Other information**

#### **Abbreviations and acronyms**

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

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acc. to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® Lysing Agent 1**

Version number: 1.1 Date of compilation: 2023-05-09

#### Key literature references and sources for data

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

#### **Classification procedure**

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

#### **Disclaimer**

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

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according to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® LYSING AGENT 2 (1.1ML)**

Version number: 1.1 Date of compilation: 2022-03-28

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

#### 1.1 Product identifier

Trade name BAX® LYSING AGENT 2 (1.1ML)

Registration number (REACH) not relevant (mixture)

Product code(s) ASY2009

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

Relevant identified uses Laboratory and analytical use

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

Qualicon Diagnostics LLC 941 Avenida Acaso Camarillo CA 93012 United States

Telephone: 1-302-695-5300 Telefax: 1-302-351-6454

e-mail: diagnostics.support@hygiena.com 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: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

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

#### 2.2 Label elements

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

#### 2.3 Other hazards

of no significance

#### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Not relevant (mixture)

#### 3.2 Mixtures

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according to Regulation (EC) No. 1907/2006 (REACH)

## **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: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

Water jet

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according to Regulation (EC) No. 1907/2006 (REACH)

## **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. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

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

#### 6.2 Environmental precautions

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

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

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

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

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

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

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Recommendations

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

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

Advice on general occupational hygiene

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

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

Control of effects

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according to Regulation (EC) No. 1907/2006 (REACH)

## **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

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

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## **BAX® LYSING AGENT 2 (1.1ML)**

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Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
Solubility(ies)	not determined
Partition coefficient  Partition coefficient n-octanol/water (log value)	this information is not available
Vapour pressure	not determined
Density and/or relative density	
Density	not determined
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)

#### 9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics	
Solvent content	100 %
Solid content	0 %

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according to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® LYSING AGENT 2 (1.1ML)**

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#### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

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

#### 10.2 Chemical stability

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

#### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4 Conditions to avoid

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

#### 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

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

### **SECTION 11: Toxicological information**

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

Test data are not available for the complete mixture.

#### Classification procedure

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

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

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

#### Acute toxicity

Shall not be classified as acutely toxic.

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

#### Serious eye damage/eye irritation

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

#### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

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according to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® LYSING AGENT 2 (1.1ML)**

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Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

There is no additional information.

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

#### 12.2 Persistence and degradability

Data are not available.

#### 12.3 Bioaccumulative potential

Data are not available.

#### 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

Data are not available.

#### 12.6 Endocrine disrupting properties

None of the ingredients are listed.

#### 12.7 Other adverse effects

Data are not available.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Sewage disposal-relevant information

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

Waste treatment of containers/packagings

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

#### **Remarks**

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

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according to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® LYSING AGENT 2 (1.1ML)**

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#### **SECTION 14: Transport information**

**14.1 UN number or ID number** not subject to transport regulations

**14.2 UN proper shipping name** not relevant

**14.3 Transport hazard class(es)** none

**14.4** Packing group not assigned

**14.5 Environmental hazards** non-environmentally hazardous acc. to the danger-

ous goods regulations

14.6 Special precautions for user

There is no additional information.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

#### **Information for each of the UN Model Regulations**

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

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

Not subject to ICAO-IATA.

#### **SECTION 15: Regulatory information**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

#### Restrictions according to REACH, Annex XVII

none of the ingredients are listed

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

none of the ingredients are listed

#### **Deco-Paint Directive**

VOC content 1.452 %	
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#### **Industrial Emissions Directive (IED)**

VOC content	1.452 %
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## Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

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

none of the ingredients are listed

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according to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® LYSING AGENT 2 (1.1ML)**

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#### **Water Framework Directive (WFD)**

none of the ingredients are listed

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

None of the ingredients are listed.

#### **National inventories**

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

Legend

AICS Australian Inventory of Chemical Substances

CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

DSL

**ECSI** 

**IECSC** 

Domestic Substances List (DSL)

Domestic Substances List (DSL)

EC Substance Inventory (EINECS, ELINCS, NLP)

Inventory of Existing Chemical Substances Produced or Imported in China National Inventory of Chemical Substances

Korea Existing Chemicals Inventory

New Zealand Inventory of Chemicals

Philippine Inventory of Chemicals and Chemical Substances (PICCS) **INSQ** KECI NZIoC

**PICCS** 

TCSI Taiwan Chemical Substance Inventory

**TSCA Toxic Substance Control Act** 

#### 15.2 Chemical Safety Assessment

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

#### **SECTION 16: Other information**

#### **Abbreviations and acronyms**

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

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according to Regulation (EC) No. 1907/2006 (REACH)

## **BAX® LYSING AGENT 2 (1.1ML)**

Version number: 1.1 Date of compilation: 2022-03-28

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

#### Key literature references and sources for data

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

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

#### **Classification procedure**

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

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

#### **Disclaimer**

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

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