

SAFETY DATA SHEET

according to the requirements of OSHA HCS2012

1. Identification of the Product and of the Company

1.1 Product identifier

BÜHLMANN fPELA® turbo
(Ref. Code: B-KPELA-RSET;
B-KPELA-CASET; B-KPELA-CONSET)

Product use: In vitro diagnostic reagents for
the quantitative determination of
pancreatic elastase in human fecal
extracts

Substance name: 2-Methyl-4-isothiazolin-3-one CAS No.: 2682-20-4

Designation: BÜHLMANN fPela® turbo consisting of:

BÜHLMANN fPela® turbo Reagent Kit (Ref. Code: B-KPELA-RSET)
BÜHLMANN fPela® turbo Calibrator Kit (Ref. Code: B-KPELA-CASET)
BÜHLMANN fPela® turbo Control Kit (Ref. Code: B-KPELA-CONSET)

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

2-Methyl-4-isothiazolin-3-one substance is approved for use as a biocide for product preservation.
For professional users only.

1.3 Details of the supplier of the safety data sheet

Distributor: BÜHLMANN Diagnostics Corp
105 State Route 101A, Suite 1
Amherst, NH 03031, USA
Tel. (844) 300-9799
Fax. (603) 732-0675
www.buhlmannlabs.com
E-Mail: info@buhlmannlabs.com

1.4 Emergency phone Number

emergency number: (844) 300-9799

2. Hazardous identification

2.1 Classification of the substance in accordance with 29 CFR 1910 (OSHA HCS)

Classification according to Regulation (EC) No 1272/2008 [CLP]	SCL and/or M-factor	Classification procedure
<i>Skin Sens. 1A</i>	-	<i>Practical experience / human evidence</i>

2.2 GHS Label elements, including precautionary statements

Hazard pictograms:



Signal word:

Warning

Hazard statements:

H317 May cause an allergic skin reaction.

Precautionary statements:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

By a conc. of 100% 2-Methyl-4-isothiazolin-3-one

H301	Acute Tox. 3
H330	Acute Tox. 2
H311	Acute Tox. 3
H314	Skin Corr. 1B
H318	Eye Dam. 1
H335	STOT SE 3 (Respiratory system)
H400	Aquatic Acute 1
H410	Aquatic Chronic 1

M-Factor (Acute aquatic toxicity): 10

M-Factor (Chronic aquatic toxicity): 1

3. Composition/information on ingredients**3.1 Substances**

Synonyms:	2-Methyl-4-isothiazolin-3-one
Formula:	C ₄ H ₅ NOS
Molecular weight:	115.15 g/mol
CAS-No.:	2682-20-4
EC-No.:	220-239-6

Appearance of the mixture:	Clear colourless solution
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Concentration in the mixture:	≥0,0025 - < 0,025 %
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4. First aid Measures**4.1 Description of first aid measures**

General advice	Move out of dangerous area. Show this safety data sheet to the doctor in attendance. Do not leave the victim unattended. First aider needs to protect himself. Remove clothing soiled with product immediately
if inhaled	Move to fresh air. If unconscious, place in recovery position and seek medical advice. Consult a physician in case of complaints.

- In case of skin contact Rinse skin with water/ shower. Consult a physician in case of complaints.
- In case of eye contact Rinse out with plenty of water. Remove contact lenses. Immediately call in ophthalmologist.
- If swallowed Keep respiratory tract clear. Rinse mouth with water. Call a physician immediately. Do not attempt to neutralize.
- Self-protection of the first aider First aider needs to protect himself.
- 4.2 Most important symptoms and effects, both acute and delayed
- | | |
|-----------|---------------------------------|
| Symptoms: | Irritation. |
| Effects: | Risk of allergic skin reaction! |
- 4.3 Indication of any immediate medical attention and special treatment needed
- | | |
|-----------------------|---------------------------|
| Notes for the doctor: | see chapter 4.2. |
| Special treatment: | No information available. |
- 5. Firefighting measures**
- Only applicable if in the storage room is a big quantity (more than 2000 Kit) of BÜHLMANN fPela® turbo
- 5.1 Extinguishing media
- | | |
|---------------------------------|--|
| Suitable extinguishing media: | Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. |
| Unsuitable extinguishing media: | For this substance/mixture no limitations of extinguishing agents are given. |
- 5.2 Special hazards arising from the substance or mixture
- Hazardous combustion products: Not combustible. Ambient fire may liberate hazardous vapours.
Fire may cause evolution of: Carbon oxides, Nitrogen oxides (NO_x), Sulfur oxides
- 5.3 Advice for fire-fighters
- Special protective equipment for firefighters
Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.
- 5.4 Further information
- Cool closed containers exposed to fire with water spray. Prevent fire extinguishing water from contaminating surface water or the ground water system. Suppress (knock down) gases/vapours/mists with a water spray jet.
- 6. Accidental Release Measures**
- Only applicable if in the storage room is a big quantity (more than 2000 Kit) of BÜHLMANN fPela® turbo
- 6.1 Personal precautions, protective equipment and emergency procedures
- For non-emergency personnel
- | | |
|-----------------------|---|
| Protective equipment: | Protective equipment see section 8. |
| Emergency procedures: | Do not breathe vapours, aerosols. Avoid substance contact.
Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, and consult an expert. |
- For emergency responders
- Personal protective equipment: Gloves

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and material for containment and cleaning up

For containment

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10).

For cleaning up

Take up with liquid-absorbent (e.g. sand, silica gel, acid binder, universal binder, sawdust). Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about protective equipment see section 8
Indications about waste treatment see section 13.

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling: Work under hood. Do not inhale substance/mixture.
Avoid contact with skin, eyes and clothing.

Hygiene measures: Immediately change contaminated clothing.
Apply preventive skin protection.
Wash hands and face after working with substance.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Tightly closed. Dry.
Recommended storage temperature sees product label.

Requirements for storage rooms and vessels: Use only containers that are specifically approved for the substance/product.
Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

No further relevant information available

8. Exposure control/personal protection

8.1 Control parameters

Ingredients with workplace control parameters: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Do not let product enter drains.

Appropriate engineering controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Personal protective equipment

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Avoid contact with eyes and skin

Eye / Face protection

Suitable eye protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Tightly fitting safety goggles.

Skin protection

Hand protection: Gloves (Natural rubber, Nitrile rubber, Neoprene, PVC)

Respiratory protection

Required when vapours/aerosols are generated if the release in the room came from a big quantity (more than 2000) of BÜHLMANN fPela® turbo.
Recommended Filter type: Filter P3.

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Reagent	Appearance	Odour	Boiling Point	pH by 20°C	Rel. Density	Solubility in Water
Reagent Kit (R1)	clear, colourless solution	odourless	~100 °C	~6	~ 1 g/cm ³	soluble
Reagent Kit (R2)	Milky/white mixture	odourless	~100 °C	~8.7	~ 1 g/cm ³	soluble
Calibrator Kit	clear, colourless solution	odourless	~100 °C	N.A.	~ 1 g/cm ³	soluble
Control Kit	clear, colourless solution	odourless	~100 °C	N.A.	~ 1 g/cm ³	soluble

10. Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

No decomposition if stored and applied as directed

10.4 Conditions to avoid

No information available

10.5 Incompatible materials

Oxidizing agents.

10.6 Hazardous decomposition products

In the event of fire: See section 5.

11. Toxicological Information

11.1 Information on toxicological effects

Substance: 2-Methyl-4-isothiazolin-3-one

	Effect dose / -concentration	Species	Method	Symptoms / delayed effects	Remark
Acute oral toxicity	LD50: 285,5 mg/kg	Rat	(OECD Test Guide- line 401	-	-
Inhalative toxicity (gas)	LC50: 0,11 mg/l in 4h	Rat	OECD Test Guide- line 403	-	-
Dermal	LD50: 242 mg/kg	Rat	OECD Test Guide- line 402	Skin sensitiza- tion	-

11.1.1 Substances

Skin irritation: May cause skin irritation and/or dermatitis
Skin sensitization: May cause an allergic skin reaction.
Eye irritation: May cause irreversible eye damage

12. Ecological Information

12.1 Toxicity

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 4,77 mg/l
End point: mortality
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203

12.2 Persistence and degradability

Test Type: aerobic
Inoculum: activated sludge
Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 29 d
Method: OECD Test Guideline 301B
Remarks: The 10-day time window criterion is not fulfilled.

12.3 Bioaccumulative potential

Bioaccumulation Lepomis macrochirus - 56 d
(2-Methyl-4-isothiazolin-3-one)
Bioconcentration factor (BCF): 5,75

12.4 Mobility in soil

No information available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Endocrine disrupting properties

This product does not contain substances with endocrine disrupting properties

12.7 Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. Disposal

13.1 Waste treatment methods

Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as wastewater, when in compliance with local regulations.

Product / Packaging disposal

Empty containers retain product residues. Follow label warnings even after container is emptied.
Packaging material should be disposed according to local State and Federal regulations.

14. Transportation Information

2-Methyl-4-isothiazolin-3-one with the very low concentration in our product have the transport characteristics "Not regulated" for ICAO/IATA, IMDG and DOT Classification.

	DOT (US)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA)
14.1 UN No.	-	-	-
14.2 UN Proper shipping name	-	-	-
14.3 Transport hazard class(es)	-	-	-
Hazard label(s)	-	-	-
14.4 Packing group	-	-	-
14.5 Environmental hazards	-	-	-

14.6 Special Precautions for user

None

14.7 Maritime transport in bulk according to IMO instruments

not applicable

15. Regulatory Information

SARA 302 Components

This material does not contain any components with a section 302 EHS TPQ.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

16. Other information

16.1 Change log

Date	Version	Reason for change
09.04.2024	01	New SDS version for 2-Methyl-4-isothiazolin-3-one (MIT) according the requirements of OSHA HCS2012

16.2 Abbreviations and acronyms

IMDG:	International Maritime Code for Dangerous Goods
IATA:	International Air Transport Association
GHS:	Globally Harmonised System of Classification and Labelling of Chemicals
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
LC50:	Lethal concentration, 50 percent
LD50:	Lethal dose, 50 percent
PBT:	Persistent, Bioaccumulative and Toxic
vPvB:	very Persistent and very Bioaccumulative

16.3 Training advice

Provide adequate information, instruction and training for operators.

16.4 Further information

The information in this Safety Data Sheet meets the requirements of the United States OCCUPATIONAL SAFETY AND HEALTH ACT and regulations promulgated thereunder (29 CFR 1910.1200 et. seq.) This document is intended only as a guide to the appropriate precautionary handling of the material by a person trained in, or supervised by a person trained in, chemical handling. The user is responsible for determining the application.

The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. BÜHLMANN Laboratories AG, BÜHLMANN Diagnostics Corp and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

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End of Safety Data Sheet