

MATERIAL SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH)
and Commission Regulation (EU) No. 878/2020

1. Identification of the Product and of the Company

1.1 Product identifier

BÜHLMANN CALEX® Cap
(Ref. Code: B-CALEX-C50, B-CALEX-C200,
B-CALEX-C500, B-CALEX-C50-U,
B-CALEX-C200-U, B-CALEX-C500-U)

Product use: In vitro diagnostic reagents
intended for the preparation of
human stool samples to be used
with BÜHLMANN assays.

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

Designation: BÜHLMANN CALEX® Cap

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.

1.3 Details of the supplier of the safety data sheet

Supplier: **BÜHLMANN Laboratories AG**
Baselstrasse 55
4124 Schönenbuch, Switzerland
Tel. + 41 61 487 12 12
Fax.+ 41 61 487 12 34
www.buhlmannlabs.ch
E-Mail: info@buhlmannlabs.ch

Distributor: Please contact the regional distributor of BÜHLMANN products in your country.

1.4 Emergency phone Number

Tox Info Suisse

24-hour emergency number: 145 (from abroad: +41 44 251 51 51)

further information: +41 44 251 66 66

2. Hazardous identification

2.1 Classification of the substance 2-Methyl-4-isothiazolin-3-one

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>

Hazard pictograms:



GHS07

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.

2.2 Label elements according to Regulation (EC) No 1272/2008 [CLP/GHS] with a content of not more than 125 ml

Product identifier: BÜHLMANN CALEX® Cap

Hazard pictograms:

**GHS07**

Signal word: Warning

Hazard statements: not applicable

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 Description of the mixture

Clear colorless solution.

3.1.1 Hazardous ingredients

Substance name	CAS No.	INDEX No.	EC No.	Concentration	Classification according Regulation (EC) No. 1272 [CLP]
2-Methyl-4-isothiazolin-3-one	2682-20-4	613-326-00-9	220-239-6	<0.1 - >0.05%	Concentration limits: $\geq 0,0015\%$: Skin Sens. 1A, H317

3.1.2 Additional information

This mixture does not contain further substances fulfilling the criteria of hazard class "acute toxicity" according to CLP regulation.

4. First aid Measures

4.1 Description of first aid measures

General informations	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
Following inhalation	Move to fresh air. If unconscious, place in recovery position and seek medical advice. Consult a physician in case of complaints.
Following skin contact	Rinse skin with water/ shower. Consult a physician in case of complaints.
Following eye contact	Rinse out with plenty of water. Remove contact lenses. Immediately call in ophthalmologist.
Following ingestion	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 1000) of BÜHLMANN CALEX® Cap.

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 Additional 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 1000) of BÜHLMANN CALEX® Cap.

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 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.

6.1.2 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

6.3.1 For containment

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

6.3.2 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

Observe label precautions. Do not breathe vapours dust.

7.1.1 Protective measures

Advice on safe handling: Avoid contact with skin, eyes and clothing.

7.1.2 Advice on general occupational hygiene

Change contaminated clothing and immerse in water. Wash skin after came into direct contact with the substance.

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

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Do not let product enter drains.

8.2.1 Appropriate engineering controls

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

8.2.2 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.

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Avoid contact with eyes and skin

Eye / Face protection

Suitable eye protection: Tightly fitting safety glasses with side protection (EU standard - EN 166)

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 1000) of BÜHLMANN CALEX® Cap.

Recommended Filter type: Filter P3 (acc. to EN 143).

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
BÜHLMANN CALEX® Cap	clear, colourless solution	odourless	~100 °C	~ 7.4	~1 g/ml	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

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

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 waste water, when in compliance with local regulations.

13.1.1 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 have the transport characteristics "Not regulated" for ICAO/IATA, IMDG, ADR and RID Classification.

	Land transport (ADR/RID)	Inland water- way transport (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
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

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

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

16. Other information

16.1 Change log

Date	Version	Reason for change
30.09.2022	04	Chap. 1.2 Note on chase buffer deleted as not part of the kit. Chap. 2.1 and 3.1.2: Note that the full R, H and EUH phrases in Chapter 16 are deleted, as the full R, H and EUH phrases are reproduced in the MSDS.
30.06.2023	05	MSDS adapted to the new Commission Regulation (EU) No. 878/2020 Chap. 7.3, 12.6, 14.6 and 14.7 are new Alignment of texts in all MSDSs containing 2-Methyl-4-isothiazolin-3-one (MIT)

16.2 Abbreviations and acronyms

ADR:	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
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.

The information provided in this Material Safety Data Sheet (MSDS) is believed to be accurate and represents the best information currently available to us. However, we make no warranty or merchantability or any other warranty, expressed or implied, with respect to such information, and we assume no liability for its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.