

MATERIAL SAFETY DATA SHEET

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

1. Identification of the Product and of the Company

- 1.1 Product identifier: **6-Sulfatoxymelatonin ELISA (EK-M6S; EK-M6S-U).**
Product use: In vitro diagnostic and for research use reagents for the determination of melatonin in human saliva, serum, plasma, urine and other biological fluids.
- 1.1.1 Substance name: **2-Methyl-4-isothiazolin-3-one (MIT)** (< 0.1% w/v) CAS No.: 2682-20-4
Designation: Wash Buffer Concentrate (10x) (Ref. code: B-WB)
- 1.1.2 Substance name: **Sulfuric acid** (< 5% v/v aqueous solution) CAS No.: 7664-93-3
Designation: Stop Solution (Ref. code: B-STS)
- 1.2 Relevant identified uses of the substances or mixtures and uses advised against relevant uses
- 1.2.1 2-Methyl-4-isothiazolin-3-one is a substance approved for use as a biocide for product preservation. 10-fold diluted Wash Buffer Concentrate is used for washing the microtiter plates of the 6-Sulfatoxymelatonin ELISA kit before and after a total of two sequential incubation steps.
- 1.2.2 The color formation reaction of the TMB substrate of the ELISA kit can progress for a defined period of time after which this reaction is stopped with the Stop Solution (0.25 M sulfuric acid) by altering the pH of the test system.
- 1.3 Details of the supplier of the safety data sheet

Supplier: **NovoLytiX GmbH**
Benkenstrasse 254C
CH-4108 Witterswil
Switzerland
Email: info@novolytix.ch
Phone : +41 76 831 58 61
Fax : +41 61 530 11 06
www.novolytix.ch

Distributor: Please contact the regional and/or local distributor of NovoLytiX 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

- B-WB contains 2-Methyl-4-isothiazolin-3-one
- B-STS contains Sulfuric acid

2.1 Classification of the substances

Classification according to Regulation (EC) No 1272/2008 [CLP]	SCL and/or M-factor	Classification procedure
2-Methyl-4-isothiazolin-3-one <i>Skin Sens, Category 1A, H317</i>	<i>Not applicable</i>	<i>Practical experience / human evidence</i>
Sulfuric acid <i>Corrosive to metals, Category 1, H290</i> <i>Skin irritation, Category 1, H315</i> <i>Eye Irritation, Category 2, H319</i>	<i>Not applicable</i>	<i>Practical experience / human evidence</i>

2.1.1 Additional information

Full text of R-, H- and EUH-phrases: see section 16.

2.2 Label elements of the substance **2-Methyl-4-isothiazolin-3-one**

2.2.1 Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS] with a content of not more than 125 mL

Hazard pictograms:



GHS07

Signal word:

Warning

Hazard statements:

H317

May cause an allergic skin reaction.

Precautionary statements:

Prevention:

P261

Avoid breathing vapours / spray.

P272

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

P280

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

Response:

P333+P313

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

P362+P364

Take off contaminated clothing and wash it before reuse.

Supplemental Hazard information (EU): none.

2.3 Label elements of the substance **Sulfuric acid**

2.3.1 Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS] with a content of not more than 125 mL

Hazard pictograms:



GHS07

Signal word:

Attention

Hazard statements:

H290

May be corrosive to metals.

H315

Causes skin irritation.

H319

Causes serious eye irritation.

Precautionary statements:

Prevention:

P264

Wash hands thoroughly after handling.

P280

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

Response:

P3332+P313

IF SKIN IRRITATION OCCURS: Get medical advice / attention.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

P337+P313

IF EYE IRRITATION PERSISTS: Get medical advice / attention.

P362+P364:

Take off contaminated clothing and wash it before reuse.

Supplemental Hazard information (EU): none.

2.4 Other hazards

These substances/mixtures contain no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. Composition/information on ingredients

3.1 Description of the mixtures

- B-WB: Clear colorless aqueous buffer solution containing containing 2-Methyl-4-isothiazolin-3-one.
- B-STs: Clear colorless aqueous solution containing Sulfuric acid.

3.1.1 Hazardous ingredients of above mixtures

Substance name	CAS No.	INDEX No.	EC No.	Concentration	Classification according to Regulation (EC) No 1272/2008 [CLP]
2-Methyl-4-isothiazolin-3-one	2682-20-4	-	220-239-6	<0.1%	Skin Sens. 1A, H317
Sulfuric acid	7664-93-9	016-020-00-8	231-639-5	<5%	Corrosive to metals, Category 1, H290 Skin irritation, Category 1, H315 Eye Irritation, Category 2, H319

3.1.2 Additional information

For the full text of the H- and R-Statements mentioned in this Section: see Section 16. 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

4.1.1 General information

Consult a physician. Show this safety data sheet to the doctor / physician in attendance.

4.1.2 Following inhalation

If breathed in, move person into fresh air. If person is not breathing, give artificial respiration. Consult a physician in case of complaints.

4.1.3 Following skin contact

Take off immediately all contaminated clothing. Rinse skin with water / take a shower. Call a physician in case of complaints.

4.1.4 Following eye contact

Flush eyes with plenty of water. Cold water shall be used. Consult an ophthalmologist immediately.

4.1.5 Following ingestion

Make victim drink water (two glasses at most). Avoid vomiting (risk of perforation). Do not attempt to neutralize. Consult a physician immediately.

4.1.6 Self-protection of the first aider

First aider needs to protect himself.

4.2 Most important symptoms and effects, both acute and delayed

4.2.1 Symptoms: Irritation

4.2.2 Effects: Serious eye damage!

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the physician: See chapter 4.2.

Special treatment: No information available.

5. Firefighting measures

Only applicable if the storage room contains a larger quantity than 2000 of the respective EK-M6S / EK-M6S-U test kits. The mixtures are non-flammable.

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media: No limitations of extinguishing agents are given for this substance / mixture.

5.2 Special hazards arising from the substance / mixture

Hazardous combustion products: Not combustible.

5.3 Advice for fire-fighters

Stay in danger area only with self-contained breathing. Prevent skin and eye contact by keeping a safe distance. Wear suitable protective clothing.

5.4 Additional information

Cool closed containers exposed to fire with water spray. Prevent fire extinguishing water from contaminating surface water and/or the ground water system.

6. Accidental release measures

Only applicable if the storage contains a larger quantity than 2000 of the respective EK-DSM / EK-DSM-U test kits. Use appropriate tools to put the spilled liquid into a convenient waste disposal container.

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Protective equipment: See section 8.

Emergency procedures: Do not breathe vapors and/or 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: Wear adequate clothing, gloves and glasses.

6.2 Environmental precautions

Do not let product / substance penetrate 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 also sections 7 and 10).

6.3.2 For cleaning up: Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal. Clean up affected area.

6.4 Reference for 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

Use protective gloves and glasses. Observe label precautions (see section 2.2).

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 with water. Wash skin and rinse eyes after 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 is 2-8°C.
Requirements for storage rooms and vessels: Use only containers that are specifically approved for the substance / product.

7.3 Specific end uses

Apart from the uses described in section 1.2 no other specific uses are stipulated.

8. Exposure control/personal protection

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.
Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product / substance.

8.1 Control parameters

Occupational exposure limits: No data available.

8.2 Exposure controls

Do not let product / substance penetrate 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 from the respective supplier

8.2.2.1 Eye / face protection

Suitable eye protection: Tightly fitting safety glasses with side protection (EC standard EN166).

8.2.2.2 Skin protection

Hand protection: Gloves (natural rubber, latex, nitrile rubber, neoprene, PVC). The protective gloves to be used should comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching outer surface of the gloves) to avoid skin contact with the product / substance. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Body protection: Laboratory coat.

8.2.2.3 Respiratory protection

Not applicable for this product / substance, but required when dusts are or may be generated and if a larger quantity than 2000 of the respective EK-M6S / EK-M6S-U kits are stored in the same room.

Recommended Filter types: Filter ABEK (acc. to EN 14387) for liquid particles of toxic products / substances.
Filter P2 (acc. to DIN 3181) for solid and liquid particles of harmful products / substances.

The employer 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

Reagent	Appearance	Odour	Boiling Point	pH at 20°C	Rel. Density	Autoinflam-mability	Inflam-mability	Oxidizing Properties	Solubility in Water	Vapor Pressure
Wash Buffer Conc. (10x)	clear, colour-less solution	odourless	~100 °C	pH 7.3 – 7.5	~1.2 g/ml	n/a	n/a	n/a	soluble	n/a
Stop Solution	clear, colour-less solution	odourless	~100 °C	≤ 1	~1.1 g/ml	n/a	n/a	n/a	soluble	n/a

10. Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

The product is chemically stable under recommended storage and application conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Strong acids, strong bases, strong oxidizing reagents.

10.6 Hazardous decomposition products

No data available. 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 Guideline 401	-	-
Inhalative toxicity (gas)	LC50: 0,11 mg/l in 4h	Rat	OECD Test Guideline 403	-	-
Dermal	LD50: 242 mg/kg	Rat	OECD Test Guideline 402	Skin sensitization	-

11.2 Information on toxicological effects – Substance: Sulfuric acid

	Effect dose / -concentration	Species	Method	Symptoms / delayed effects	Remark
Acute oral toxicity	LD50: 2140 mg/kg	Rat	-	-	-
Acute inhalative toxicity (gas)	LC50: 510 mg/m ³ in 2h	Rat	-	-	-
Acute inhalative toxicity (gas)	LC50: 320 mg/m ³ in 2h	Mouse	-	-	-

12. Ecological Information

12.1 Toxicity

Toxicity to fish:

- 2-Methyl-4-isothiazolin-3-one: Mortality LC50 - Oncorhynchus mykiss (rainbow trout) – 4.77 mg/L/96 h (OECD test guideline 203)
- Sulfuric acid: Mortality LC50 – Bluegill/sunfish – 49 mg/L/48 h

12.2 Persistence and degradability

Biodegradability:

- 2-Methyl-4-isothiazolin-3-one: 55.8% - not readily biodegradable (OECD Test Guideline 301B)
- Sulfuric acid: No data available.

12.3 Bioaccumulative potential

- 2-Methyl-4-isothiazolin-3-one: Bioaccumulation in Lepomis macrochirus - 56 days - with a bioconcentration factor (BCF) of 5.75 – 48.1

- Sulfuric acid: No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

These substances / products do not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects

- 2-Methyl-4-isothiazolin-3-one: No information available.
- Sulfuric acid: Forms corrosive mixtures with water even if diluted. Harmful effect due to pH shift. Endangers drinking-water supplies if allowed to penetrate soil or water sources.

12.7 Additional ecotoxicological information

No data available.

13. Disposal

13.1 Waste treatment methods

- 2-Methyl-4-isothiazolin-3-one: Dispose in a safe manner in accordance with local/national regulations. Dispose of contents / container to comply with local, state and federal regulations.
- Sulfuric acid: Neutralize solution with an alkali to pH 7.

13.2 Product / Packaging disposal

Packaging materials and products / substances should be disposed of according to local, state and federal regulations.

14. Transportation Information

2-Methyl-4-isothiazolin-3-one	Land transport (ADR/RID)	Inland waterway transport (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA- DGR)
"Not regulated" for ICAO/IATA, IMDG, AND, ADR and RID classification.				
Sulfuric acid	Land transport (ADR/RID)	Inland waterway transport (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA- DGR)
14.1 UN No.	3264	3264	3264	3264
14.2 UN proper shipping name	Sulfuric Acid	Sulfuric Acid	Sulfuric Acid	Sulfuric Acid
14.3 Transport hazard class(es)	8	8	8	8
Hazard label(s)	-	-	-	-
14.4 Packing group	III	III	III	III
14.5 Environmental hazards	no	Water pollutant: no	Marine pollutant: no	no

14.1 Special precautions for user

No data available.

14.2 Additional information

No data available.

15. Regulatory Information

15.1 Safety, health and environmental regulations / legislation specific for the products / substances or mixtures thereof

Not applicable.

EU regulations

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

A chemical safety assessment was not carried out for these products / substances.

16. Other information

16.1 Full text of H- and R-Statements referred to in different sections of this document

- H290 May be corrosive to metals.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

16.2 Abbreviations and acronyms

- ADN: Inland Waterways Transport
ADR: Accord européen sur le transport des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DIN: Deutsche Industrie Norm (German industry standard)
DIR: Directive
EC: European Commission
EN: Europäische Norm (European standard)
EU: European Union
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
IATA-DGR: International Air Transport Association - Dangerous Goods Regulations
ICAO-TI: International Civil Aviation Organization - Technical Instructions
IUCID: International Uniform Chemical Information Database
IMDG: International Maritime code for Dangerous Goods
LC50: Lethal Concentration, 50 percent
LD50: Lethal Dose, 50 percent
n/a: not applicable
OECD: Organisation for Economic Co-operation and Development
RID: International Carriage of Dangerous Goods by Rail
PBT: Persistent, Bioaccumulative and Toxic
UN: United Nations
vPvB: very Persistent and very Bioaccumulative

16.3 Training advice

Provide adequate information, instruction and training for operators.

16.4 Change Log

Date	Version	Reason for change
2021-01-21	01	1 st version; copied information from the former BÜHLMANN EK-DSM MSDS
2022-06-26	02	- Totally revised MSDS acc. to the latest information by REACH - Freshly introduced are reagents/substances/mixtures containing $\geq 0.0015\%$ of 2-Methyl-4-isothiazolin-3-one (MIT)
2024-07-05	03.1	Correction of wrong information in the footer of each page
2024-09-15	04	Ref. code of Wash Buffer concentrate (10x) changed to B-WB

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