

SAFETY DATA SHEET

For Research Use only in the US and Canada. Not for use in diagnostic procedures.

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M65® ELISA

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIER	M65®ELISA
Item number	10020
1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST	The ELISA kits are medical devices and are not covered by the CLP-regulation; EU 1272/2008 (Classification & Labelling of Chemical Products). However, relevant information of the products is provided in this safety data sheet.
1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET	VLVbio AB Hästholmsvägen 32 131 30 Nacka Sweden Phone +46 (0)8 122 053 00, Email: info@vlvbio.com ; www.vlvbio.com For questions regarding the safety data sheet, please contact: info@vlvbio.com
1.4 EMERGENCY TELEPHONE NUMBER	National Poisons Information Centre General public: Call (01) 809 2166, 8am to 10 pm, 7 days a week

SECTION 2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Health hazards:

The component 6 (Stop solution) is classified as hazardous to health according to Regulation (EC) No 1272/2008.

Causes skin irritation (Skin Irrit. 2; H315).

Causes serious eye irritation (Eye Irrit. 2; H319).

The components 1-5 (M65 HRP Conjugate, M65 Conjugate Dilution Buffer, Standard solutions A-G, M65 Control Low and M65 Control High and TMB Substrate) are not classified as hazardous to health according to Regulation (EC) No 1272/2008.

Environmental hazards

None of the components in M65 ELISA kit are classified as hazardous to the environment.

Physical hazards

None of the components in M65 ELISA kit are classified for physical hazards.

2.2 LABEL ELEMENTS (only applies to the component 6 - Stop solution)

Hazard Pictograms

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Signal word

WARNING

Contains: Sulphuric acid.

Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements

P280 Wear protective gloves/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305 +P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Other labelling

EUH208 - Contains Methyl-4-isothiazolin-3-one. May produce an allergic reaction.

The labelling is recommended on the following kits: *M65 HRP Conjugate, M65 Conjugate Dilution Buffer, Standard A-H and M65 Control Low and M65 Control High.*

Other regulations

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Other information

The product does not contain any SVHC-substances (= Substance of Very High Concern) $\geq 0,1\%$ from the candidate list of EU.

The components do not contain any substances which fulfills the criteria for PBT and vPvB according to annex XIII to the regulation (EG) nr 1907/2006 (REACH).

No substances have been identified to have endocrine disrupting properties according to Regulation (EU) 2017/2100 or (EU) 2018/605 in concentrations $\geq 0.1\%$ (w/w).

2.3 OTHER HAZARDS

No other hazards are related to the product.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

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3.2 MIXTURE

Description of relevant components of the kit.

Medical device product - ELISA kit for Research Use Only.

Separate kit-component	Substance	EC No.	CAS No.	REACH No. ²	Conc. w/w %	Classification (CLP) ¹
1. M65 ELISA Conjugate	5-Chloro-2-methyl-4-isothiazolin-3-one,	247-500-7	26172-55-4	-	≥ 0.00055 – 0.00063	Acute Tox. 2 H300 ^b Acute Tox. 2 H310 ^b Acute Tox. 2 H330 ^b Skin Corr. 1B H314 ^b Skin Sens. 1 H317 ^b Eye Dam. 1 H318 ^b Aquatic H400 ^b Acute 1
	Methyl-4-isothiazolin-3-one	220-239-6	2682-20-4	-	≥ 0.00015 – 0.00023	Acute Tox. 3 H301 ^a Acute Tox. 3 H311 ^a Skin Corr. 1B H314 ^a Eye Dam. 1 H318 ^a Skin Sens. 1A H317 ^a Acute Tox. 2 H330 ^a Aquatic H400 ^a Acute 1 M: 10 H410 ^a Aquatic Chronic 1
2. M65 ELISA Conjugate Dilution Buffer	5-Chloro-2-methyl-4-isothiazolin-3-one,	247-500-7	26172-55-4	-	≥ 0.0017 – 0.0019	See classification M65 HRP Conjugate
	Methyl-4-isothiazolin-3-one	220-239-6	2682-20-4	-	≥ 0.00045 – 0.00068	
3. M65 ELISA Standard A - H	5-Chloro-2-methyl-4-isothiazolin-3-one,	247-500-7	26172-55-4	-	≥ 0.002– 0.0025	See classification M65 HRP Conjugate

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	Methyl-4-isothiazolin-3-one	220-239-6	2682-20-4	-	≥ 0.0006 – 0.0009		
	Tartrazin	217-699-5	1934-21-0	01-2120116875-52-xxxx	0.01	Skin Sens. 1	H317 ^c
4.	5-Chloro-2-methyl-4-isothiazolin-3-one,	247-500-7	26172-55-4	-	≥ 0.002 – 0.0025	See classification M65 HRP Conjugate	
M65 ELISA Control Low	Methyl-4-isothiazolin-3-one	220-239-6	2682-20-4	-	≥ 0.0006 – 0.0009		
M65 ELISA Control High	Tartrazin	217-699-5	1934-21-0	01-2120116875-52-xxxx	0.01	Skin Sens. 1	H317 ^c
5.	3,3',5,5' Tetramethylbenzidin	259-364-6	54827-17-7	-	≤ 0.05	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3	H315 ^{b,c} H319 ^{b,c} H335 ^{b,c}
TMB Substrate							
6.	*Sulphuric acid ^d	231-639-5	7664-93-9	01-2119458838-20-xxxx	5.5	Skin Corr. 1A	H314 ^a
Stop solution							

a) *Harmonized classification according to Annex VI, part 3, table 3.1 and 3.2, Regulation (EC) No 1272/2008 (CLP).*
b) *Classification according to REACH registration.*
c) *Classification according to the manufacturer.*
d) *Exposure limits according to National regulations (Great Britain EH40, Workplace exposure limits).*

* Sulphuric acid is included in the Stop solution to 5.5 %, why the classification H314 of the mixture is not applicable.

Other information: The product kit also contains: M6 Coated Microstrips, Wash Tablet and Sealing Tape.
For a full text of H- phrases: See Section 16

SECTION 4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

Inhalation

Fresh air. If difficulties in breathing, get medical advice.

Skin contact

Rinse with water. Consult a doctor if symptoms persist.

Eye contact

After contact with eyes, flush cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Contact a doctor.

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Ingestion

Flush mouth with plenty of water (do not swallow), drink a couple of glasses of water. Do not induce vomiting. Consult a doctor if more than a small amount has been swallowed.

Information to medical advice

Treat symptomatically.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Inhalation: May cause light cough and transient irritations. Long-lasting and/or repeating exposure may cause allergy or asthma symptoms.

Skin Contact: Causing transient redness and irritations.

Eye Contact: Causes redness, light pain and transient irritation.

Ingestion: Smaller amounts are not expected to provide any acute or delayed symptoms.

Other:

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4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Eye wash should be available at the working place.

SECTION 5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media are powder, foam, carbon dioxide or water spray. No special extinguishing media needed. Use the same extinguishing media as recommended for the surroundings. Do not use direct water jet.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

In case of fire, toxic and corrosive fumes such as oxides of carbon, sulphur oxides or other combustion products may develop.

5.3 ADVICE FOR FIREFIGHTERS

Precautions according to the standard procedure for chemical fires.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Ensure adequate ventilation. Wear gloves and eye protection if splashing, or direct contact. When large spills, contact the fire department.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid discharge of large amounts into the sewer.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

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Absorb spillages with suitable inert absorbent material such as sand or active clay. Collect the spill and treat as hazardous waste.

Collected and treated as hazardous waste.

Rinse away residues with plenty of water.

6.4 REFERENCE TO OTHER SECTIONS

See Section 8 for Exposure controls / personal protection and Section 13 for disposal considerations.

SECTION 7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Avoid inhalation and direct contact with the product.

Do not eat, drink and smoke when handling the product. Normal hand hygiene.

Ensure that contaminated clothing does not come into contact with foodstuffs etc. and is washed before re-use.

When handling the product, the Work Environment Authority AFS 2011:19, latest version through AFS 2019:9, "Chemical safety risks" must be followed. (Thermosets)

When handling, national regulations related to work environment must be followed.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store in a cool dry place in a well-ventilated / not in direct sunlight / away from ignition sources. Do not freeze. Protect from light.

Vapor concentration on the floor and in low-lying spaces.

Must be stored according to national regulations for flammables.

7.3 SPECIFIC END USE

See Section 1.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Exposure limits according to Directives 2000/39/EC (IOELV Directives).

Sulphuric acid (The mist is defined as the thoracic fraction): 0.05 mg/m³ (TWA 8h)

Other information

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8.2 EXPOSURE CONTROLS

Appropriate technical measures

Methods are designed to prevent direct contact.

Possibility to rinse eyes shall be available at place of work. Ensure adequate ventilation. In case of insufficient ventilation, mechanical ventilation with local exhaust ventilation (LEV) should be used.

Personal protection

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Eye/face protection:	Protective glasses shall be used.
Skin protection:	Protective gloves meeting the requirements of Standard EN 374 shall be used. Recommended glove material: neoprene.
Respiratory protection:	Not normally required.
Other protection:	Not normally required.
Thermal hazard.	Not relevant.

Environmental exposure controls

Avoid release to the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Product description⁴

Physical state:	Component 1-6	<i>Liquid</i>
	Component 1	<i>Colourless</i>
	Component 2	<i>Blue</i>
Colour:	Component 3	<i>Yellow</i>
	Component 4	<i>Colourless to light yellow</i>
	Component 5	<i>Colourless</i>
	Component 6	<i>White</i>
Odour	Component 1-6	<i>No smell</i>
Melting-point / freezing-point: (all components)		N.A
Boiling point or initial boiling point and boiling range (all components):		N.A
Flammability:		N.A
Lower and upper explosion limit:		N.A
Flash point:		N.A
Auto-ignition temperature:		N.A
Decomposition temperature:		N.A
	<i>Component 1</i>	<i>7.0 ± 0.1</i>
	<i>Component 2</i>	<i>7.0 ± 0.1</i>
pH:	<i>Component 3-4</i>	<i>7.0 ± 0.1</i>
	<i>Component 5</i>	<i>3.55 ± 0.20</i>
	<i>Component 6</i>	<i>≤ 1</i>
Kinematic viscosity:		N.A
Solubility:		Soluble
Partition coefficient n-octanol/water (log value):		N.A
Vapour pressure:		N.A
Relative density (component 6)		1.03 g/cm ³
Particle characteristics:		N.A

9.2 OTHER INFORMATION

Component 6: Can be corrosive to metals.³

9.2.1 INFORMATION WITH REGARD TO PHYSICAL HAZARD CLASSES

Not relevant.

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9.2.2 OTHER SAFETY CHARACTERISTICS

Not relevant.

SECTION 10. STABILITY AND REACTIVITY

10.1 REACTIVITY

May be corrosive to metals.⁴

10.2 CHEMICAL STABILITY

Stable until expiry date stated on label if stored under specified conditions.⁴

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No hazardous reactions at normal usage and storage.⁴

10.4 CONDITIONS TO AVOID

No data available.⁴

10.5 INCOMPATIBLE MATERIALS

None.⁴

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

None.⁴

SECTION 11. TOXICOLOGICAL INFORMATION

The kit consists of several components whereas component 6 (stop solution) is hazardous for health.

11.1 INFORMATION ON HAZARD CLASSES AS DEFINED IN REGULATION (EC) NO 1272/2008

Acute toxicity:	Not classified as acutely toxic.
Sulphuric acid ³	LC ₅₀ inhalation rat: 510 mg/L/2h
Skin corrosion/irritation: H315	Solution 6 is a skin irritant.
Serious eye damage / irritation: H319	Solution 6 is irritating to the eyes.
Respiratory or skin sensitization: EUH208	Not classified as sensitising. Components 1-4 contain Methyl-4-isothiazolin-3-one in a small amount which may cause a skin sensitization and/or allergic contact dermatitis at repeated exposure.
Germ cell mutagenicity:	Not classified as mutagenic.
Carcinogenicity:	Not considered to be carcinogenic.
Reproductive toxicity:	Not classified as toxic to reproduction.
Specific organ toxicity-single exposure (STOT):	Not considered to cause damage to organs after single exposure.

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Specific organ toxicity-repeated exposure (STOT): It is not considered to cause damage to organs after repeated exposure.

Aspiration Hazard: Not considered an aspiration hazard.

Specific effects

None known.

11.2 INFORMATION ON OTHER HAZARDS

Endocrine disrupting properties: Not relevant.

SECTION 12. ECOLOGICAL INFORMATION

The product is not classified as hazardous to the environment and is not expected to result in any negative environmental consequences but should be handled according to good industrial standards.

12.1 TOXICITY

The components are not hazardous to the environment.

Sulphuric acid ³: LC₅₀ 96h: 42 mg/l (species: fish, *Gambusia affinis*).
EC₅₀ 24h: 29 mg/l (species: water flea, *Daphnia magna*).

12.2 PERSISTENCE AND DEGRADABILITY

No information available.

12.3 BIOACCUMULATIVE POTENTIAL

No information available.

12.4 MOBILITY IN SOIL

No information available.

12.5 RESULTS OF PBT AND vPvB ASSESSMENT

Based on available information, this mixture contains no substance that meets the PBT or vPvB criteria according to Annex XIII to Regulation (EC) No. 1907/2006 (REACH).

12.6 ENDOCRINE DISRUPTING PROPERTIES

No substances have been identified to have endocrine disrupting properties according to Regulation (EU) 2017/2100 or (EU) 2018/605 in concentrations $\geq 0.1\%$ (w/w).

12.7 OTHER ADVERSE EFFECTS

None known.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

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Classified as conventional waste, according to Commission Regulation (EU) No 1357/2014 on waste.
 EWC-code: 07 05 01* aqueous washing liquids and mother liquors, according to the European Waste Catalogue.
 All disposal practices must be in accordance with local, regional, national and international regulations.

Packaging

Packaging containing visible residues of hazardous substances is treated as product.
 EWC- code: 15 01 10* (Packaging containing residues of or contaminated by hazardous substances).
 Well emptied packaging can be treated as conventional waste and be left for incineration (energy recovery).
 Emptied and cleaned packaging can be treated as conventional waste and be left for recycling.
 EWC- code: 15 01 01 (Paper and cardboard packaging) / 15 01 02 (Plastic packaging) / 15 01 04 (Metal packaging).

SECTION 14. TRANSPORT INFORMATION				
This product is not covered by the regulations for transportation of dangerous goods.				
	ADR/RID	ADN	IMDG	IATA /ICAO
14.1 UN-number or ID number	Not relevant	Not relevant	Not relevant	Not relevant
14.2 UN proper shipping name	Not relevant	Not relevant	Not relevant	Not relevant
14.3 Transport hazard class(es)	Not relevant	Not relevant	Not relevant	Not relevant
14.4 Packing group	Not relevant	Not relevant	Not relevant	Not relevant
14.5 Environmental hazards	No	No	No	No
14.6 SPECIAL PRECAUTIONS FOR USER				
Tunnel restriction code:		N.A		
EmS code:		N.A		
Classification code:		N.A		
Limited amount:		N.A		
Reduced amount:		N.A		
14.7 MARITIME TRANSPORT IN BULK ACCORDING TO IMO INSTRUMENTS				
Not relevant.				

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SECTION 15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

This safety data sheet is prepared in accordance with the EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC) No 1907/2006 of 18 December 2006 concerning the registration, evaluation, authorization and restriction of chemicals (REACH) and Commission Regulation (EU) 2020/878 of 18 June 2020 amending the European Parliament and Council Regulation (EC) No 1907/2006 on the registration, evaluation, authorization and restriction of chemicals (REACH).

Regulations

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substance and mixtures (CLP).

Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste.

European Waste Catalogue (EWC-codes)

Exposure limits according to National regulations (Great Britain EH40, Workplace exposure limits).

GESTIS International Limit Values

National legislation

2021 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2021) and the Safety, Health and Welfare at Work (Carcinogens) Regulations (2001-2019)

Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 to 2021

Europaparlamentets och Rådets förordning (EG) nr 1272/2008, (CLP)

Kommissionens förordning (EU) nr 1357/2014, (Avfall).

Avfallsförordningen SFS 2011:927.

Other information

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15.2 CHEMICAL SAFETY ASSESSMENT

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16. OTHER INFORMATION

Classification procedure

Test data is prioritized when classifying the product. When no test data are available, the classification rules in regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP) been used.

Hazard statements in Section 3

H300 Fatal if swallowed.

H319 Causes serious eye irritation.

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H310	Fatal in contact with skin.	H317	May cause an allergic skin reaction.
H330	Fatal if inhaled.	H318	Causes serious eye damage.
H311	Toxic in contact with skin.	H335	May cause respiratory irritation.
H330	Fatal if inhaled.	H400	Very toxic to aquatic life.
H314	Causes severe skin burns and eye damage	H410	Very toxic to aquatic life with long lasting effects.
H315	Causes skin irritation		

Abbreviations

ADN	International Carriage of Dangerous Goods by Inland Waterways
ADR	International Carriage of Dangerous Goods by Road
BCF	Bio Concentration Factor
EC ₅₀	Effective Concentration (concentration that gives response in 50 % of test subjects)
ECHA	European Chemical Agency
EmS	Emergency Schedule Information
IARC	International Agency for Research on Cancer
IC ₅₀	Inhibitory Concentration (concentration that shows inhibition in 50 % of the test subjects)
IATA/ICAO	IATA Dangerous goods regulation / ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air
IMDG	International Maritime Dangerous Goods Code
KTV	Korttidsvärde (= en typ av hygieniskt gränsvärde)
LC ₅₀	Lethal Concentration (concentration causing the death of 50 % of a group of test animals)
LD ₅₀	Lethal Dose (dose causing the death of 50 % of a group of test animals)
LD _{Lo}	Lethal Dose Low (= Lowest dose of a toxic material at which the death of the exposed test animal occurs.
Log P _{ow}	Partition coefficient octanol - water
n.a.	not available
N/A	not applicable
NGV	Nivågränsvärde (= en typ av hygieniskt gränsvärde)
PBT	Persistent Bio-accumulative and Toxic
RID	International Carriage of Dangerous Goods by Rail
STEL	Short Term Exposure Limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
vPvB	very Persistent and very Bioaccumulative

Advice about education

The user of this product should have training that is relevant to the properties of the product and relevant use.

References

- 1) *Classification & Labelling Inventory Database, ECHA.*
- 2) *Registered substances, ECHA.*
- 3) *Kemiska Ämnen online, Prevent.*
- 4) *Information from the supplier: SDS VLVBio M65[®] ELISA, product number: 10020, date of issue: 2018-05-22 and SDS KATHON™ CG Preservative, revision date: 2023/01/20.*

Version description

This safety data sheet has been revised on account of updated template according to annex II in REACH regulation (1907/2006).

The safety data sheet is dated 11/03/2024 and it replaces version dated 10/04/2019.