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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 product is a medical device product and is not covered by the CLP-regulation; EU 1272/2008 (Classification & Labelling of Chemical Products). The product consists of a kit for diagnosis using ELISA analysis.
1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET	VLVbio AB Hästholsvägen 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	In emergency situations, contact National Poisons Information Service: In England and Wales: NHS 111 - dial 111. In Scotland: NHS 24 - dial 111. Emergency telephone number In Ireland, dial 112 or 999.

SECTION 2. HAZARDS IDENTIFICATION**2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE (CLP)**

Health hazards:

The product is classified as hazardous to health. The classifications are referred to the content of sulphuric acid in the stop solution component:

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

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

Environmental hazards

The product is not classified as hazardous to the environment.

Physical hazards

The product is not classified for physical hazards.

2.2 LABEL ELEMENTS

Hazard Pictograms

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Signal word

WARNING

Substances that contribute to the classification

Sulphuric acid.

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

P260 Avoid breathing fumes.

P280 Wear protective gloves/protective clothing/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

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Other regulations

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Other information

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2.3 OTHER HAZARDS

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 MIXTURES

Description of the mixture.

Medical device product - kit for diagnosis using ELISA analysis.

Substance	EC No.	CAS No.	REACH No. ²	Conc. w/w %	Classification (CLP) ¹	
Kathon* (octhilonone (ISO); 2-octyl-2H-isothiazol-3-one	247-761-7	26530-20-1	01- 2120768921- 45-xxxx	<0.1	Acute Tox. 4 Acute Tox. 3 Skin Sens. 1 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H302 ^a H311 ^a H317 ^a H331 ^a H400 ^a H410 ^a

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Tartrazin**	217-699-5	1934-21-0	01-2120116875-52-xxxx	0.02	Skin Sens. 1	H317 ^c
3,3',5,5' Tetramethyl-benzidin***	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}
^d Sulphuric acid****	231-639-5	7664-93-9	01-2119458838-20-xxxx	5.5	Skin Corr. 1A	H314 ^a

a) Harmonised classification according to Annex VI, part 3, table 3.1 and 3.2, Regulation (EC) No 1272/2008 (CLP).
b) Classification according to one of the most used alternatives in ECHA's Classification & Labelling Inventory.
c) Classification according to the manufacturer.
d) Substance for which there are occupational exposure limits in the work environment (EH40/2005 Workplace exposure limits, 2018).

* Kathon is included in M65 HRP Conjugate (2), M65 Conjugate Dilution Buffer (3), M65 Standard A-G (4), M65 Control Low and High (5), Wash Solution (8).

Hazardous components are 5-chloro-2 methyl-2H-isothiazol-3-one (EC No. 247-500-7) and 2-methyl-2H -isothiazol-3-one (EC No. 220-239-6) as a mixture, 1:3 (CAS No. 55965-84-9), conc. 1–2.5%.

Concentration of the dangerous substances in component numbers 1–5 and 8: ≤ 0.004%, Conc. 0.0015% ≤ c < 0.06%.

** Tartrazin is included in M65 Standard A-G, M65 Control Low and High

*** 3,3',5,5' Tetramethyl-benzidin is included in the TMB substrate.

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

The product kit also contains: M6 Coated Microstrips, Wash tablet and Sealing Tape.

Other information

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 and rest. 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 several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Contact a doctor.

Ingestion

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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 burning in the nose and throat, coughing and sore throat. Long-lasting or/and repeating exposure may cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Contact

Causing pain, redness and irritation.

Eye Contact

Causes redness, 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 RELEVANT

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.

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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

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 2014: 43 "Chemical safety risks" must be followed. (Thermosets)

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.

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

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

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

This information refers to Great Britain. For other countries, refer to national legislation.

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.

Individual protection measures and personal protective equipment

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.

8.3 ENVIRONMENTAL EXPOSURE CONTROLS

Avoid release to the environment.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Component number	1	2	3	4-5	6	7	8	9
Appearance	Solid (Microstrips)	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Solid (tape)
Colour	Colourless	Colourless	Blue	Yellow	Colourless to light yellow	Colourless	Colourless	Colourless
Odour	No smell	No smell	No smell	No smell	No smell	No smell	No smell	No smell
pH	N/A	7.1 ± 0.05	7.0 ± 0.1	7.0 ± 0.1	3.55 ± 0.20	≤ 1	7.5 ± 0.05	N/A
Melting point/freezing point	N/A	0 °C	0 °C	0 °C	0 °C	0 °C	0 °C	N/A
Initial boiling point and boiling range	N/A	100 °C	100 °C	100 °C	100 °C	101 °C	100 °C	N/A
Flash point	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Evaporation rate	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flammability	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Upper/lower flammability or explosive limits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Vapour pressure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Vapour density	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Relative density	N/A	N/A	N/A	N/A	N/A	1.03 g/cm ³ (20 °C)	N/A	N/A
Solubility in water	N/A	soluble	soluble	soluble	soluble	soluble	soluble	N/A
Partition coefficient: n-octanol /water	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Auto-ignition temperature	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Decomposition temperature	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Viscosity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Explosive properties	Not explosive	Not explosive	Not explosive	Not explosive	Not explosive	Not explosive	Not explosive	Not explosive
Oxidising properties	N/A	N/A	N/A	N/A	N/A	Oxidising potential	N/A	N/A

9.2 OTHER INFORMATION

Component 7 Can be corrosive to metals.

SECTION 10. STABILITY AND REACTIVITY

10.1 REACTIVITY

May be corrosive to metals (component number 7)⁴.

10.2 CHEMICAL STABILITY

Stabile 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.

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10.6 HAZARDOUS DECOMPOSITION PRODUCTS

None known under normal handling and use ⁴

SECTION 11. TOXICOLOGICAL INFORMATION

The product is classified as hazardous to health. Specific effects are described below.

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity:	The product is not classified as acute toxic but contains Kathon which is classified as harmful if swallowed.
Sulphuric acid ²	LD ₅₀ oral rat: >2000 mg/kg LC ₅₀ inhalation rat: 0,375 mg/l/4h (OECD Guideline 403 (Acute Inhalation Toxicity))
Corrosive/Irritating on the skin	The product is a skin irritant.
Serious eye damage / irritation:	The product is irritating to the eyes.
Respiratory / skin sensitization:	The product is not classified as a sensitizer. Kathon is classified as sensitising and therefore, prolonged and repeated exposure on the skin may induce an allergic skin reaction or sensitisation.
Germ cell mutagenicity:	Not classified as mutagenic.
Carcinogenicity	Not classified as carcinogenic.
Toxic to reproduction	Not classified as toxic to reproduction.
Specific organ toxicity-single exposure:	Not considered to cause damage to organs after single exposure.
Specific organ toxicity-repeated exposure:	It is not considered to cause damage to organs after repeated exposure.
Aspiration Hazard: Specific effects None known.	Not classified as an aspiration hazard.

11.2 OTHER INFORMATION

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SECTION 12. ECOLOGICAL INFORMATION

The product is not classified as hazardous to the environment but contains smaller amounts of substances that are.

12.1 TOXICITY

The product is assessed to have low acute aquatic toxicity and low chronic aquatic toxicity.

Sulphuric acid ³	LC50 Fisk 96h: 42 mg/l (Art: Gambusia affinis)
	EC50 Daphnia 48h: >29 mg/l

12.2 PERSISTENCE AND DEGRADABILITY

The product is considered to be degradable³

12.3 BIOACCUMULATIVE POTENTIAL

No data.

12.4 MOBILITY IN SOIL

No data.

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 OTHER ADVERSE EFFECTS

None known.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Product

Classified as hazardous waste, with hazard class HP 4 (Irritant — skin irritation and eye damage) according to Commission Regulation (EU) No 1357/2014 on waste.

EWC-code: 16 03 05* (Organic waste containing hazardous substances) according to the European Waste Catalogue.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000D0532-20150601>

All disposal practices must be in accordance with local, regional, national and international regulations. Dispose of packaging or containers in accordance with local, regional, national and international regulations.

Packaging

Empty containers are treated as product.

All kit components and tested specimen should be considered as bio hazardous/infectious and should be disposed of in accordance with federal, state and local environmental regulations.

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SECTION 14. TRANSPORT INFORMATION

This product is not covered by the regulations for transportation of dangerous goods.

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) No 2015/830 of 28 May 2015 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).

EH40 (Second edition, published 2011) Occupational Exposure Limits, UK.

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): http://www.sepa.org.uk/media/163421/ewc_guidance.pdf

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

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

Avfallsförordningen SFS 2011:927.

Other information

The following constituent substances are listed in the Swedish Chemicals Agency's prioritization guide (PRIO): Kathon (octhlinone (ISO); 2-octyl-2H-isothiazol-3-one – Allergenic, Hazard to the environment with long-lasting effects⁵.

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

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H302	Harmful if swallowed	H335	May cause respiratory irritation
H314	Causes severe skin burns and eye damage	H400	Very toxic to aquatic life.
H315	Causes skin irritation	H311	Toxic in contact with skin.
H317	May cause an allergic skin reaction.	H331	Toxic if inhaled.
H410	Very toxic to aquatic life with long lasting effect.	H319	Causes serious eye irritation.

Abbreviations

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)
ICAO	Regulation for transport by air
IMDG	Regulation for transport by sea
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
PBT	Persistent Bio-accumulative and Toxic
RID	Regulations for transport by rail-road
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) *Safety data sheet of the manufacturer – M65 ELISA product number: 10020*
- 5) *Prioriteringsguiden (PRIO), Keml.*

Version description

This safety data sheet has been revised, in accordance with title IV and annex II in the regulation (EC) No 1907/2006 of the European parliament and of the council (REACH).

The information has been modified under the following sections in the safety data sheet: 1-16.

The safety data sheet is dated 06/05/2019 and replaces the SDS dated 22/05/2018.