




## MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No 1272/2008 and EC (No) 453/2010 and Directive 67/548/EEC or 1999/45/EC

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
<b>Product identifier</b>	
<b>Product number</b> 10020	
<b>Product name</b> M65 <sup>®</sup> ELISA	
<b>Relevant identified uses of the substance or mixture and uses advises against</b> For in vitro use only. See Instruction for use for information and intended use of this product.	
<b>Details of the supplier of the safety data sheet</b>	
<b>Vivalavida AB</b> Löfströms allé 5A 172 66 Sundbyberg Sweden	Phone +46 (0)8 122 053 00 Email: <a href="mailto:info@vlvbio.com">info@vlvbio.com</a> Website: <a href="http://www.vlvbio.com">www.vlvbio.com</a>
<b>Emergency telephone number</b> +46 (0)8 122 053 00 (08:00 to 16:30)	

2. HAZARDS IDENTIFICATION	
<b>Classification according to Regulation (EC) No 1272/2008 (CLP)</b>	<b>Classification according to Directives 67/548/EEC or 1999/45/EC</b>
<p><b>Kathon CG:</b> 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 &lt; 0.06%</p>	
<b>Classification of the substance or mixture</b> Skin Sens. Category 1 (H317)	<b>Classification</b> R43
<b>Label elements</b> Hazard pictogram: N/A	<b>Labelling</b> Hazard symbol: N/A
<b>Hazard statement(s)</b> H317: May cause an allergic skin reaction.	<b>R-phrases(s)</b> R43: May cause sensitization by skin contact.
<b>Precautionary statement(s)</b> P280: Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352: IF ON SKIN: Wash with plenty of water and soap. P314: Get medical advice/attention if you feel unwell.	<b>S-phrases(s)</b> S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S28: After contact with skin wash immediately with plenty of water and soap. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
<p><b>Sulphuric acid:</b> EC No. 231-639-5, CAS No. 7664-93-9 Concentration of the dangerous substance in component number 7: 5.5 % 5 % ≤ Conc. &lt; 15 %</p>	
<b>Classification of the substance or mixture</b> Skin Irrit. Category 2 (H315) Eye Irrit. Category 2 (H319)	<b>Classification</b> Xi; R36/38
<b>Label elements</b> <b>Hazard pictogram:</b> GHS07 	<b>Labelling</b> <b>Hazard symbol</b> 
<b>Signal word:</b> Warning	<b>Xi Irritant</b>

<p><b>Hazard statement(s)</b>  H290: May be corrosive to metals.  H315: Causes skin irritation.  H319: Causes serious eye irritation.</p> <p><b>Precautionary statement(s)</b>  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P302 + P352: IF ON SKIN: Wash with plenty of water and soap.  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p>	<p><b>R-phrases(s)</b>  R36/38: Irritating to eyes and skin.</p> <p><b>S-phrases(s)</b>  S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.  S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.</p>
<p><b>3,3',5,5' Tetramethylbenzidin:</b> EC No. 259-364-6, CAS No. 54827-17-7  Component number 6: Conc. ≤ 0,05 %  Not applicable or no information (concentration &lt; 0.1%).</p>	
<p><b>Tartrazin:</b> EC No. 217-699-5, CAS No. 1934-21-0  Component numbers 4–5: Conc. ≤ 0.01 %  Not applicable or no information (concentration &lt; 0.1%).</p>	
<p><b>Material of animal origin</b>  Should be considered as potentially infectious. Components 1–5 contain material of animal origin.</p>	
<p><b>Other hazards:</b> Not known</p>	

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures					
Component number	Component Name	Hazard	Classification (pure form) according to:		Concentration
			Regulation 1272/2008 (EG)	Directive 67/548/EEC or 999/45/EC	
1	M6 Coated Microstrips	N/A	N/A	N/A	N/A
2	M65 HRP Conjugate	Kathon CG <sup>1)</sup>	H331, H311, H301, H314, H317, H400, H410 	T; R23/24/25; C; R34, R43; N; R50-53 	0.05 %
3	M65 Conjugate Dilution Buffer	Kathon CG <sup>1)</sup>	See component 2	See component 2	0.15 %
4	M65 Standard A 0 U/L M65 Standard B 125 U/L M65 Standard C 250 U/L M65 Standard D 500 U/L M65 Standard E 750 U/L M65 Standard F 1 200 U/L M65 Standard G 2 000 U/L	Kathon CG <sup>1)</sup>	See component 2		0.05 %
		Tartrazin	H317 	Xn; R42/43 	0.01 %
5	M65 Control Low M65 Control High	Kathon CG <sup>1)</sup> Tartrazin	See component 2 and 4	See component 2 and 4	0.05 % 0.01 %
6	TMB Substrate	3,3',5,5' Tetramethyl- benzidin	H315, H319, H335 	Xi; R36/37/38 	≤ 0.05 %
7	Stop Solution	Sulphuric acid <sup>2)</sup>	H314 	C, R35 	5.5 % (1.0 M)
8	Wash Solution	Kathon CG <sup>1)</sup>	See component 2	See component 2	0.05 %
9	Sealing Tape	N/A	N/A	N/A	N/A

<p><b>According to Regulation (EC) No 1272/2008 (CLP), (pure form)</b></p> <p><b>Hazard Class and Category Code(s)</b></p> <p><sup>1)</sup> Acute toxicity 3  <sup>1)</sup> Skin Corrosive 1B  <sup>1)</sup> Skin Sensitisation 1  <sup>1)</sup> Acute aquatic hazard 1  <sup>1)</sup> Chronic aquatic (long term) hazard 1  <sup>2)</sup> Skin Corrosive 1A</p> <p><b>Hazard statement(s)</b></p> <p>H331 Toxic if inhaled.  H311 Toxic in contact with skin.  H301 Toxic if swallowed.  H314 Causes severe skin burns and eye damage.  H317 May cause an allergic skin reaction.  H400 Very toxic to aquatic life.  H410 Very toxic to aquatic life with long lasting effects.  H315 Causes skin irritation.  H319 Causes serious eye irritation.  H335 May cause respiratory irritation.</p>	<p><b>According to Directive 67/548/EEC or 1999/45/EC, (pure form)</b></p> <p><b>Classification Code(s)</b></p> <p>T Toxic  N Dangerous for the environment  C Corrosive  Xi Irritant  Xn Harmful</p> <p><b>R-phrases(s)</b></p> <p>R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.  R34 Causes burns.  R43 May cause sensitization by skin contact.  R50-53 Very toxic to aquatic organisms may cause long term adverse effects in the aquatic environment.  R42/43 May cause sensitization by inhalation and skin contact.  R36/37/38 Irritating to eyes, respiratory system and skin.  R35 Causes severe burns</p>
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#### 4. FIRST AID MEASURES

<p><b>Description of first aid measures</b></p> <p><b>After inhalation</b>  Remove the victim to fresh air.  If breathing is difficult, give oxygen.  If not breathing, give artificial respiration.  Seek medical advice if needed.</p> <p><b>After eye contact</b>  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: Get medical advice/attention.</p> <p><b>After swallowing</b>  Flush mouth with plenty of water (do not swallow), drink a couple of glasses of water. Do not induce vomiting.  Never give anything to drink to an unconscious person.  Seek medical advice if needed.</p> <p><b>After skin contact</b>  After contact with skin, wash with plenty of water and soap.  If skin irritation occurs: Get medical advice/attention.  Take off contaminated clothing and wash before reuse.</p> <p><b>Others</b>  In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</p>
<p><b>Most important symptoms and effects, both acute and delayed</b></p> <p>Causes skin irritation.  Causes serious eye irritation.</p>
<p><b>Indication of any immediate medical attention and special treatment needed</b></p> <p>No data available.</p>

#### 5. FIREFIGHTING MEASURES

<p><b>Extinguishing media</b></p> <p><b>Suitable extinguishing media</b>  Use fire extinguishing media appropriate for site conditions, preferably water spray, carbon dioxide, powder or foam.</p> <p><b>Unsuitable extinguishing media</b>  No restrictions.</p>
<p><b>Special hazards arising from the substance or mixture</b></p> <p>In case of fire may be liberated: Sulphur oxides.</p>
<p><b>Advise for firefighters</b></p> <p>No risk of fire or explosion.  No generation of hazardous or toxic gases in dangerous quantities.  Wear self-contained breathing apparatus and protective clothing to avoid all contact with skin and eyes.</p>

6. ACCIDENTAL RELEASE MEASURES
<p><b>Personal precautions protective equipment and emergency procedures</b></p> <p><b>For non-emergency personal</b> Use suitable personal protective equipment as required, protective gloves (nitrile gloves)/protective clothing/eye protection/face protection.</p> <p><b>For emergency responders</b> Use suitable personal protective equipment as required, protective gloves (nitrile gloves)/protective clothing/eye protection/face protection.</p>
<p><b>Environmental precautions</b> Prevent soil and water pollution.</p>
<p><b>Methods and material for containment and cleaning up</b> Absorb spills with absorbent material . Clean contaminated areas.</p>
<p><b>Reference to other sections</b> Personal protective equipment, see section 8. Dispose, see section 13.</p>

7. HANDLING AND STORAGE
<p><b>Precautions for safe handling</b> Ensure good ventilation. Avoid spills. Do not eat and smoke in work areas. Avoid contact with skin and eyes. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.</p>
<p><b>Conditions for safe storage, including any incompatibilities</b> Store in well closed original container at 2–8 °C. Do not freeze. Protect from light (components 2 and 6).</p>
<p><b>Specific end use(s)</b> See Instructions for use for intended use of this product.</p>

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
<p><b>Control parameters</b> No data available.</p>
<p><b>Exposure controls</b></p> <p><b>Appropriate engineering controls</b> Ensure of good ventilation.</p> <p><b>Personal protective equipment</b></p> <p><u>Eye/face protection</u> Wear safety glasses.</p> <p><u>Body protection</u> Wear suitable protective clothing. Take off contaminated clothing and wash before use.</p> <p><u>Hand protection</u> Wear protective gloves (nitrile gloves).</p> <p><u>Respiratory protection</u> Not relevant.</p> <p><u>Thermal hazards</u> Not relevant.</p>
<p><b>Environmental exposure controls</b> Not applicable</p>

9. PHYSICAL AND CHEMICAL PROPERTIES								
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 <sup>3</sup> (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
Other information	-	-	-	-	-	Can be corrosive to metals	-	-

10. STABILITY AND REACTIVITY
<p><b>Reactivity</b> May be corrosive to metals (component number 7).</p>
<p><b>Chemical Stability</b> Stabile until expiry date stated on label if stored under specified conditions.</p>
<p><b>Possibility of hazardous reactions</b> No hazardous reactions at normal usage and storage.</p>
<p><b>Conditions to avoid</b> No data available.</p>
<p><b>Incompatible materials</b> None</p>
<p><b>Hazardous decomposition products</b> None</p>

11. TOXICOLOGICAL INFORMATION
<p><b>Information on toxicological effects</b></p> <p><b>Acute Toxicity</b> Acute inhalation toxicity LC50 rat: 510 mg/m<sup>3</sup>, 2 h (refers to pure substance, sulphuric acid, component number 7), (IUCLID).</p> <p><b>Irritation</b> Irritating to eyes and skin (component numbers 6 and 7).</p> <p><b>Corrosivity</b> No data available.</p> <p><b>Sensitisation</b> Skin sensitizer due to the content of Kathon CG (components numbers 2-5 and 8)</p> <p><b>Repeated dose toxicity</b> No data available.</p> <p><b>Carcinogenicity</b> No data available.</p> <p><b>Mutagenicity</b> No data available.</p> <p><b>Toxicity for reproduction</b> No data available.</p>

12. ECOLOGICAL INFORMATION				
<b>Toxicity</b> Refers to pure substance, sulphuric acid, component 7, (IUCLID). LC50 Gambusia affinis (fish): 42 mg/L; 96 h EC50 Daphnia magna (Water flea): 29 mg/L; 24 h				
<b>Persistence and degradability</b> No data available.				
<b>Bioaccumulative potential</b> No data available.				
<b>Mobility in soil</b> No data available.				
<b>Results of PBT and vPvB assessment</b> No data available.				
<b>Other adverse effects</b> No data available.				
13. DISPOSAL CONSIDERATIONS				
<b>Waste treatment methods</b> 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.				
14. TRANSPORT INFORMATION				
The product is not classified as dangerous goods.				
	ADR/RID	ADN/ADNR	IMDG	IATA
<b>UN-nummer</b>	Not regulated	Not regulated	Not regulated	Not regulated
<b>UN proper shipping name</b>	-	-	-	-
<b>Transport hazard class(es)</b>	-	-	-	-
<b>Packing group</b>	-	-	-	-
<b>Environmental hazards</b>	-	-	-	-
<b>Special precautions for users</b>	-	-	-	-
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	-	-	-	-
15. REGULATORY INFORMATION				
<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b> The product has been labelled in accordance with Regulation (EC) No 1272/2008 (CLP).				
<b>Chemical safety assessment</b> For this product a chemical safety assessment was not carried out.				
16. OTHER INFORMATION				
<b>A key or legend to abbreviations and acronyms in the safety data sheet</b> N/A = Not applicable or no information.				
<b>Training advice</b> Provide adequate information, instruction and training for operators. See instructions for use for this product.  All material of animal origin has been collected from healthy animals. The information provided in this MSDS is to information and belief at the date of the publication the best of our knowledge.				
<b>Revision 2012-09-14:</b> According to regulation (EC) No 1272/2008 and EC (No) 453/2010				
<b>Revision 2014-03-12:</b> Vivalavida AB contact information				
<b>Revision 2014-05-21:</b> New name for Coated Microstrips				