

## SAFETY DATA SHEET

Mercodia Diabetes Antigen Control (Low/High)/Human

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

**1.1 Product Identifier**                      Mercodia Diabetes Antigen Control (Low/High)/Human  
 10-1164-01 and 10-1134-01

- <sup>A)</sup>20-2668                      Control Low (L)
- <sup>B)</sup>20-2670                      Control High (H)

**1.2 Relevant identified use of the substance or mixture and uses advised against**  
 Mercodia Diabetes Antigen Control is designed to be used as a two-level control for human insulin, C-peptide and proinsulin. It is manufactured from human serum and human insulin, C-peptide and proinsulin.

**1.3 Details of the supplier of the safety data sheet**  
 Mercodia AB  
 Sylveniusgatan 8A  
 754 50 UPPSALA, SWEDEN  
 tel: +46 (0) 18-57 00 70  
 fax: +46 (0) 18-57 00 80  
 e-mail: info@mercodia.se

**1.4 Emergency telephone**                      tel: +46 (0) 18-57 00 70

### SECTION 2: Hazards identification

**2.1 Classification of the substance or mixture**  
 Included in solutions <sup>A) and B)</sup>  
 H317 skin sensitization - Category 1  
 See Section 16 for the full text of the H statements declared above.  
 See Section 11 for more detailed information on health effects and symptoms.

**2.2 Label elements**



Signal word:    Warning  
 Hazard statement:                                      H317 – May cause an allergic skin reaction

**Precautionary statements**

Prevention    P280 – Wear protective gloves.  
    P261 - Avoid breathing vapour.  
    P272 - Contaminated work clothing should not be allowed out of the workplace.

Response    P302 + P352 - if on skin: Wash with plenty of soap and water.

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Storage	P333 + P313 - If skin irritation or rash occurs: Get medical attention.
Disposal	Not applicable.
Hazardous ingredients	P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
<b>Special packaging requirements</b>	
Tactile warning of danger	Not applicable
<b>2.3 Other hazards</b>	
	None known

#### SECTION 3: Composition / information on ingredients

##### 3.2 Mixtures

##### Hazardous ingredients:

Kathon CG <sup>1)</sup>	Conc %	Classification <sup>2)</sup>
Index-No: 613-167-00-5	0.15 <sup>1)</sup>	Acute Toxicity 3; H331
CAS-No: 55965-84-9		Acute Toxicity 3; H311
EC-No: -		Acute Toxicity 3; H301
		Skin Corrosion 1B; H314
		Skin Sensitisation 1; H317
		Aquatic Acute 1; H400
		Aquatic Chronic 1; H410

- 1) Included in solutions <sup>A)</sup> and <sup>B)</sup>.  
Kathon CG is a mixture of substances where two of the components, 5-chloro-2-methyl-4-isothiazolin-3-one (EG-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (EG-nr 220-239-6), in a mixture with the proportion 3:1 has a CAS No 55965-84-9. The content of this mixture in the Kathon CG is 1.5 w-% which gives the content of 0.0023 w-% of the dangerous mixture in the product.
- 2) Classification according to (EC)1272/2008. See description of Hazard statements and precautionary statements in section 16.

#### SECTION 4: First aid measures

##### 4.1 Description of first aid measures

<b>Inhalation:</b>	Breathe fresh air and rest. If breathing is difficult, give oxygen.
<b>Skin contact:</b>	Remove contaminated clothing. Wash the affected area with soap and water.
<b>Eye contact:</b>	Rinse immediately with copious amount of water for at least 15 minutes with the eyelid held wide open. Consult a doctor

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**Ingestion:** if symptoms persist.  
Rinse mouth and throat with water. Consult a doctor if symptoms persist. Never give anything to drink / eat to an unconscious person.

#### 4.2 Most important symptoms and effects, both acute and delayed

##### Potential acute health effects

Eye contact: No known significant effects or critical hazards  
Inhalation: No known significant effects or critical hazards  
Skin contact: May cause an allergic skin reaction  
Ingestion: No known significant effects or critical hazards

#### 4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments: No specific treatment.

### SECTION 5: Fire-fighting measures

#### 5.1 Extinguishing media

Water, carbon dioxide, powder, foam.

#### 5.2 Special hazards arising from the substance or mixture

Decomposition products may include the following materials:  
carbon dioxide and carbon monoxide

#### 5.3 Advice for firefighters

No action shall be taken involving any personal risk or without suitable training.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

See "Precautions for safe handling", section 7.1 and "Exposure controls" section 8.2.

#### 6.2 Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

#### 6.3 Methods and material for containment and cleaning up

Clean up with absorbent paper and dispose of in a sealed container.

#### 6.4 Reference to other sections

See Section 1 for emergency contact information.  
See Section 8 for information on appropriate personal protective equipment.  
For current waste regulations, see section 13.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Put on appropriate personal protective equipment (see Section 8).

Ensure good ventilation. Direct physical contact with all components in this product should be avoided.

#### 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed and at 2-8°C.

#### 7.3 Specific end use (s)

Industrial applications. Professional applications.

### SECTION 8: Exposure control/personal protection

#### 8.1 Control parameters

The mixture contains no substances with occupational exposure limits.

#### 8.2 Exposure controls

Ensure good ventilation. Avoid, if possible, direct contact with the product. An emergency shower and/or an eye bath should be available in the workplace.

#### Engineering controls:

Not applicable for the mixtures.

#### Eye/face protection:

Use chemical safety goggles where splashing is possible.

#### Skin protection

#### Hand protection:

Chemical resistant gloves (butyl rubber, PE or PVC) may be used if risk of direct contact may occur.

#### Respiratory protection:

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification.

#### Thermal hazards:

None known

#### Environmental exposure controls:

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

#### Appearance:

Lyophilized (Reconstitute in 0.5 ml water)

#### After recontitution

#### Colour:

Slightly yellow and turbid

#### Odour:

Odourless

#### pH:

approximately 7

#### Melting point/Freezing point:

Approximately 0 °C

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<b>Initial boiling point and boiling range:</b>	Approximately 100 °C
<b>Flash Point (°C)</b>	Not available.
<b>Evaporation rate:</b>	Not available.
<b>Flammability (solid, gas):</b>	Not available.
<b>Upper/lower flammability or explosive limits:</b>	Not available.
<b>Vapour pressure:</b>	Not available.
<b>Vapour density:</b>	Not available.
<b>Relative Density (g/cm<sup>3</sup>)</b>	Approx. 1.
<b>Solubility (ies):</b>	Soluble in water
<b>Partition coefficient; N-octanol/water:</b>	Not available.
<b>Auto-ignition temperature:</b>	Not available.
<b>Decomposition temperature:</b>	Not available.
<b>Viscosity:</b>	Not available.
<b>Explosive properties:</b>	Not available.
<b>Oxidising properties:</b>	Not available.
<b>9.2 Other information</b>	
	No additional information.
<b>SECTION 10: Stability and reactivity</b>	
<b>10.1 Reactivity</b>	No specific test data related to reactivity available for this product or its ingredients
<b>10.2 Chemical stability</b>	Stable under normal conditions.
<b>10.3 Possibility of hazardous reactions</b>	Under normal conditions of storage and use, hazardous reactions will not occur
<b>10.4 Conditions to avoid</b>	No specific data
<b>10.5 Incompatible materials</b>	May react or be incompatible with oxidizing materials.
<b>10.6 Hazardous decomposition products</b>	Under normal conditions of storage and use, hazardous decomposition products should not be produced.
<b>SECTION 11: Toxicological information</b>	
<b>11.1 Information on toxicological effects</b>	
<b>Acute toxicity</b>	5-chloro-2-methyl-4-isothiazolin-3-one (EG-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (EG-nr 220-239-6), in a mixture with the proportion 3:1, LD50 Oral, Rat, Dose 53 mg/kg
<b>Irritation</b>	5-chloro-2-methyl-4-isothiazolin-3-one (EG-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (EG-nr 220-239-6), in a mixture with the proportion 3:1. Not available.
<b>Sensitization</b>	5-chloro-2-methyl-4-isothiazolin-3-one (EG-nr 247-500-7)

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	and 2-methyl-2H-isothiazol-3-one (EG-nr 220-239-6), in a mixture with the proportion 3:1, Possible risk for allergic reaction may occur.
<b>Repeated dose toxicity</b>	Not available.
<b>Carcinogenicity</b>	Not available.
<b>Mutagenicity</b>	Not available.
<b>Toxicity for reproduction</b>	Not available.
<b>Potential acute health effects</b>	<b>5-chloro-2-methyl-4-isothiazolin-3-one (EG-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (EG-nr 220-239-6), in a mixture with the proportion 3:1.</b>
Eye contact	No known significant effects or critical hazards.
Inhalation	No known significant effects or critical hazards.
Skin contact	May cause an allergic skin reaction.
Ingestion	No known significant effects or critical hazards.

#### SECTION 12: Ecological information

##### 12.1 Toxicity

Data not available for the mixture. Is judged to be of low toxicity to aquatic organism.

##### 12.2 Persistence and degradability

Data not available for the mixture. The product contains mainly water. For the inorganic substances, existing in very small amounts, there are no criteria for biodegradability.

##### 12.3 Bioaccumulative potential

Not available.

##### 12.4 Mobility in soil

Not available.

##### 12.5 Results of PBT and vPvB assessment

Not applicable.

##### 12.6 Other adverse effects

No known significant effects or critical hazards.

#### SECTION 13: Disposal considerations

##### 13.1 Waste treatment methods

###### Product:

Discarded product (incl. Contaminated packaging) and related waste is not hazardous waste acc. to current waste legislation. For disposal contact approved waste Management Company. Requirements for certain permission exists – see current waste legislation.  
Propose EWC-code: 18 01 07 Wastes from natural care, diagnosis, treatment or prevention of disease in humans, chemicals other than those mentioned in 18 01 06.

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<b>Packaging:</b>	
<b>Methods of disposal:</b>	The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.
<b>Special precautions:</b>	This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

### SECTION 14: Transport information

<b>Regulatory information</b>	
<b>ADR/RID / IMDG / IATA</b>	Not regulated
<b>14.6 Special precautions for user</b>	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.
<b>14.7 Transport in bulk according to Annex II of MARPOL and the IBC code</b>	Not available.

### SECTION 15: Regulatory information

<b>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	
<b>EU Regulation (EC) No. 1907/2006 (REACH) Annex XIV - List of substances subject to authorization Annex XIV</b>	None of the components are listed
<b>Substances of very high concerns</b>	None of the components are listed
<b>National inventory:</b>	United States: All components are listed or exempted.
<b>15.2 Chemical safety assessment</b>	This product contains substances for which Chemical Safety Assessments might still be required.

### SECTION 16: Other information

Revised in section (-s):	Version 2016-06-28 is rewritten with the addition of pictograms for Kathon CG and all consequences thereof.
Key literature references and sources for data:	(EC) 1272/2008, Supplier's SDS

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List of hazard statements and precautionary statements:

- 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.

The above information is believed to be correct and may not be all conclusive; however, it should only be used as a guide. Mercodia AB or Mercodia Inc. shall not be held liable for any damage resulting from handling or contact with the above product.