

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 - ^{A)}20-2668 Control Low (L) - ^{B)}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 ^{A)} and ^{B)} 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)
Special packaging requirements	Not applicable
Tactile warning of danger	Not applicable
2.3 Other hazards	None known

SECTION 3: Composition / information on ingredients

3.2 Mixtures

Hazardous ingredients:

Kathon CG ¹⁾	Conc %	Classification ²⁾
Index-No: 613-167-00-5	0.15 ¹⁾	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

- Included in solutions ^{A)} and ^{B)}.
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.
- 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

Inhalation:	Breathe fresh air and rest. If breathing is difficult, give oxygen.
Skin contact:	Remove contaminated clothing. Wash the affected area with soap and water.
Eye contact:	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

Engineering 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.

Eye/face protection:

Not applicable for the mixtures.

Skin protection

Hand protection:

Use chemical safety goggles where splashing is possible.

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)

Colour:

After reconstitution

Slightly yellow and turbid

Odour:

Odourless

pH:

approximately 7

Melting point/Freezing point:

Approximately 0 °C

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Initial boiling point and boiling range:	Approximately 100 °C
Flash Point (°C)	Not available.
Evaporation rate:	Not available.
Flammability (solid, gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative Density (g/cm³)	Approx. 1.
Solubility (ies):	Soluble in water
Partition coefficient; N-octanol/water:	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.
9.2 Other information	No additional information.
SECTION 10: Stability and reactivity	
10.1 Reactivity	No specific test data related to reactivity available for this product or its ingredients
10.2 Chemical stability	Stable under normal conditions.
10.3 Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur
10.4 Conditions to avoid	No specific data
10.5 Incompatible materials	May react or be incompatible with oxidizing materials.
10.6 Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.
SECTION 11: Toxicological information	
11.1 Information on toxicological effects	
Acute toxicity	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
Irritation	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.
Sensitization	5-chloro-2-methyl-4-isothiazolin-3-one (EG-nr 247-500-7)

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Repeated dose toxicity	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.
Carcinogenicity	Not available.
Mutagenicity	Not available.
Toxicity for reproduction	Not available.
Potential acute health effects	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.
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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Packaging:	
Methods of disposal:	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.
Special precautions:	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	
Regulatory information	
ADR/RID / IMDG / IATA	Not regulated
14.6 Special precautions for user	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.
14.7 Transport in bulk according to Annex II of MARPOL and the IBC code	Not available.
SECTION 15: Regulatory information	
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
EU Regulation (EC) No. 1907/2006 (REACH) Annex XIV - List of substances subject to authorization Annex XIV	None of the components are listed
Substances of very high concerns	None of the components are listed
National inventory:	United States: All components are listed or exempted.
15.2 Chemical safety assessment	
	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.