

SAFETY DATA SHEET

Calibrator 0, 1, 2, 3, 4, 5

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

1.1 Product identifier

Product name : Calibrator 0, 1, 2, 3, 4, 5
Part No. : K2379

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Laboratory use
Container type: vial
K2379 // Calibrator 0 // Insulin ELISA Kit // 5 mL per unit
K2379 // Calibrator 1 // Insulin ELISA Kit // 1 mL per unit
K2379 // Calibrator 2 // Insulin ELISA Kit // 1 mL per unit
K2379 // Calibrator 3 // Insulin ELISA Kit // 1 mL per unit
K2379 // Calibrator 4 // Insulin ELISA Kit // 1 mL per unit
K2379 // Calibrator 5 // Insulin ELISA Kit // 1 mL per unit
Reference number: SDS380

1.3 Details of the supplier of the safety data sheet

Dako Denmark A/S
Produktionsvej 42
DK-2600 Glostrup
Tel. no.+45 44 85 95 00
www.Dako.com

e-mail address of person responsible for this SDS : SDS@Dako.com

1.4 Emergency telephone number

Emergency telephone number (with hours of operation) : CHEMTREC®: +(44)-870-8200418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

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

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 - May cause an allergic skin reaction.

Precautionary statements

Date of issue/Date of revision : 15/04/2016

SECTION 2: Hazards identification

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. P333 + P313 - If skin irritation or rash occurs: Get medical attention.
Storage	: Not applicable.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Hazardous ingredients	: reaction mass of: 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)
Supplemental label elements	: Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: Not applicable.
Special packaging requirements	
Tactile warning of danger	: Not applicable.

2.3 Other hazards

Other hazards which do not result in classification : None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Classification	Type
reaction mass of: 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)	CAS: 55965-84-9 Index: 613-167-00-5	<0.06	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) See Section 16 for the full text of the H statements declared above.	[1]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

[3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII

[4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

[5] Substance of equivalent concern

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

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.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

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: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

SECTION 5: Firefighting measures

5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.
- Hazardous combustion products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

5.3 Advice for firefighters

- Special precautions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

- : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

- : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

SECTION 7: Handling and storage

7.2 Conditions for safe storage, including any incompatibilities : Store between the following temperatures: 2 to 8°C (35.6 to 46.4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

7.3 Specific end use(s)

Recommendations : Industrial applications, Professional applications.

Industrial sector specific solutions : Not applicable.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limits**

No exposure limit value known.

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

SECTION 8: Exposure controls/personal protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**Appearance

- Physical state** : Liquid.
- Colour** : Yellow.
- Odour** : Odourless.
- Odour threshold** : Not available.
- pH** : 7
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : 100°C
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not applicable.
- Upper/lower flammability or explosive limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : 1
- Solubility(ies)** : Soluble in the following materials: cold water and hot 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.

Calibrator 0, 1, 2, 3, 4, 5

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** : The product is stable.
- 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 oxidising 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

Product/ingredient name	Result	Species	Dose	Exposure
reaction mass of: 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)	LD50 Oral	Rat	53 mg/kg	-

Acute toxicity estimates

Not available.

Irritation/Corrosion

Conclusion/Summary : Not available.

Sensitiser

Conclusion/Summary : Not available.

Skin : May cause sensitisation by skin contact.

Chronic toxicity / Carcinogenicity / Mutagenicity / Teratogenicity / Reproductive toxicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Inhalation : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Skin contact : May cause an allergic skin reaction.

Eye contact : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation : No specific data.

Ingestion : No specific data.

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SECTION 11: Toxicological information

Skin contact : Adverse symptoms may include the following:
irritation
redness

Eye contact : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure**Short term exposure**

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

SECTION 12: Ecological information**12.1 Toxicity**

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised 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. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled 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 authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Other EU regulations

Europe inventory : Not determined.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

SECTION 15: Regulatory information

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Inform Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

International lists

National inventory

Australia	: Not determined.
Canada	: Not determined.
China	: Not determined.
Japan	: Japan inventory (ENCS) : Not determined. Japan inventory (ISHL) : Not determined.
Malaysia	: Not determined.
New Zealand	: Not determined.
Philippines	: Not determined.
Republic of Korea	: Not determined.
Taiwan	: Not determined.
Turkey	: Not determined.
United States	: Not determined.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments might still be required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Skin Sens. 1, H317	Calculation method

Full text of abbreviated H statements : H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H331 Toxic if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Full text of classifications [CLP/GHS] : Acute Tox. 3, H301 ACUTE TOXICITY (oral) - Category 3
Acute Tox. 3, H311 ACUTE TOXICITY (dermal) - Category 3
Acute Tox. 3, H331 ACUTE TOXICITY (inhalation) - Category 3
Aquatic Acute 1, H400 ACUTE AQUATIC HAZARD - Category 1
Aquatic Chronic 1, H410 LONG-TERM AQUATIC HAZARD - Category 1
Skin Corr. 1B, H314 SKIN CORROSION/IRRITATION - Category 1B
Skin Sens. 1, H317 SKIN SENSITIZATION - Category 1

SECTION 16: Other information

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Date of previous issue : No previous validation.

Version : 1

Notice to reader

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