

SAFETY DATA SHEET



Human Urine Protein Calibrator or Control

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

1.1 Product identifier

Product name : Human Urine Protein Calibrator or Control
Part No. : X0975, X0976, X0977

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

Identified uses
Laboratory use Container type: Bottle X0975 // Human Urine Protein Calibrator // 1 ml per unit X0976 // Human Urine Protein Low Control // 1 ml per unit X0977 // Human Urine Protein High Control // 1 ml per unit Reference number: SDS359

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]

Not classified.

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 : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazardous ingredients : No hazardous ingredient

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Human Urine Protein Calibrator or Control**SECTION 2: Hazards identification**

Supplemental label elements : Safety data sheet available on request.

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
Trometamol	EC: 201-064-4 CAS: 77-86-1	<10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 See Section 16 for the full text of the H statements declared above.	[1]

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. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. 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. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayedPotential acute health effects

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SECTION 4: First aid measures

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- 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.

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
nitrogen oxides

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. 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

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SECTION 6: Accidental release measures

- 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).
- 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.

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.

SECTION 8: Exposure controls/personal protection

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. 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**
- 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.
- 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** : Not available.
- Odour** : Not available.
- Odour threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.
- 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** : Not available.
- 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.

Human Urine Protein Calibrator or Control**SECTION 9: Physical and chemical properties****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** : 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
Trometamol	LD50 Dermal	Rat	>5000 mg/kg	-
	LD50 Oral	Rat	5000 mg/kg	-

Acute toxicity estimates

Not available.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Trometamol	Skin - Moderate irritant	Rabbit	-	25 Percent	-
	Skin - Severe irritant	Rabbit	-	500 milligrams	-

Sensitiser**Conclusion/Summary** : Not available.Chronic toxicity / Carcinogenicity / Mutagenicity / Teratogenicity / Reproductive toxicity

Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name	Category	Route of exposure	Target organs
Trometamol	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Not available.**Date of issue/Date of revision** : 29/01/2016

SECTION 11: Toxicological information**Potential acute health effects**

- Inhalation** : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
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.
Skin contact : No specific data.
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** : No known significant effects or critical hazards.
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**

Product/ingredient name	Result	Species	Exposure
Trometamol	Acute EC50 >980 mg/l Fresh water Acute NOEC 520 mg/l Fresh water	Daphnia Daphnia	48 hours 48 hours

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Trometamol	-1.56	-	low

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.

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SECTION 12: Ecological information

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 : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

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. 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 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 : All components are listed or exempted.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

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SECTION 15: Regulatory information

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

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

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	: All components are listed or exempted.
Canada	: All components are listed or exempted.
China	: All components are listed or exempted.
Japan	: Japan inventory (ENCS) : Not determined. Japan inventory (ISHL) : Not determined.
Malaysia	: Not determined.
New Zealand	: All components are listed or exempted.
Philippines	: All components are listed or exempted.
Republic of Korea	: All components are listed or exempted.
Taiwan	: All components are listed or exempted.
Turkey	: Not determined.
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

✔ 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
Not classified.	

Full text of abbreviated H statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Full text of classifications [CLP/GHS] : Eye Irrit. 2, H319 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
Skin Irrit. 2, H315 SKIN CORROSION/IRRITATION - Category 2
STOT SE 3, H335 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

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SECTION 16: Other information

Date of previous issue : No previous validation.

Version : 1

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