

SAFETY DATA SHEET

Anti-h Calcitonin 4050, Anti-h Calcitonin 4051, Anti-h Renin 10851

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

1.1. Product identifier

Trade name

Anti-h Calcitonin 4050, Anti-h Calcitonin 4051, Anti-h Renin 10851

Product no.

700019, 700020, 700026

Unique formula identifier (UFI)

1JNN-3PPA-4ND2-237H

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

Relevant identified uses of the substance or mixture

Raw material for in vitro diagnostic use

Restricted to professional users.

Uses advised against

None known.

1.3. Details of the supplier of the safety data sheet

Company and address

Oy Medix Biochemica Ab

Klovinpellontie 3

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FINLAND

+358 9 547680

medix@medixbiochemica.com

E-mail

medix@medixbiochemica.com

Revision

14/03/2024

SDS Version

1.0

1.4. Emergency telephone number

HUS Poison Information Center, 24h 0800 147 111

Poison Information Center / HUS, Tukholmankatu 17, 00029 HUS (Helsinki)

See first aid measures section 4.

SECTION 2: Hazards identification

Classified according to Regulation (EC) No. 1272/2008 (CLP).

2.1. Classification of the substance or mixture

Repr. 1B; H360FD, May damage fertility. May damage the unborn child.

2.2. Label elements

Hazard pictogram(s)



Signal word

Danger

Hazard statement(s)

May damage fertility. May damage the unborn child. (H360FD)

Precautionary statement(s)

General

-

Prevention

Obtain special instructions before use. (P201)

Wear eye protection/protective gloves/protective clothing. (P280)

Response

IF exposed or concerned: Get medical advice/attention. (P308+P313)

Storage

-

Disposal

Dispose of contents/container in accordance with local regulation (P501)

Hazardous substances

boric acid

Additional labelling

Restricted to professional users.

UFI: 1JNN-3PPA-4ND2-237H

2.3. Other hazards

Additional warnings

This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification.

This product does not contain any substances considered to be endocrine disruptors in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable. This product is a mixture.

3.2. Mixtures

Product/substance	Identifiers	% w/w	Classification	Note
boric acid	CAS No.: 10043-35-3 EC No.: 233-139-2 REACH: 01-2119486683-25-XXXX Index No.: 005-007-00-2	<0.7%	Repr. 1B, H360FD	[5]

See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

[5] Substance is included in the Candidate List of substances of very high concern (SVHC).

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet.

Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.

Inhalation

Upon breathing difficulties or irritation of the respiratory tract: Bring the person into fresh air and stay with him/her.

Skin contact

Remove contaminated clothing and shoes immediately. Ensure to wash exposed skin thoroughly with water and soap. Skin cleanser can be used. DO NOT use solvents or thinners.

If skin irritation occurs: Get medical advice/attention.

Eye contact

If in eyes: Flush eyes with water or saline water (20-30 °C) for at least 5 minutes. Remove contact lenses. Seek medical assistance and continue flushing during transport.

Ingestion

If the person is conscious, rinse the mouth with water and stay with the person. Never give the person anything to drink.

In case of malaise, seek medical advice immediately and bring the safety data sheet or label from the product. Do not induce vomiting, unless recommended by the doctor. Have the person lean forward with head down to avoid inhalation of or choking on vomited material.

Burns

Not applicable.

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

None known.

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

IF exposed or concerned:

Get immediate medical advice/attention.

Information to medics

Bring this safety data sheet or the label from this product.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Not applicable.

5.2. Special hazards arising from the substance or mixture

Fire will result in dense smoke. Exposure to combustion products may harm your health. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-extinguishing water to enter the sewage system and nearby surface waters.

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact. Upon direct exposure contact the Poison Information Center on: 09-471977, in order to obtain further advice.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid direct contact with spilled substances.

Contaminated areas may be slippery.

6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc. In the event of leakage to the surroundings, contact local environmental authorities.

6.3. Methods and material for containment and cleaning up

Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Wherever possible cleaning should be performed with normal cleaning agents. Avoid use of solvents.

6.4. Reference to other sections

See section 13 "Disposal considerations" on handling of waste.

See section 8 "Exposure controls/personal protection" for protective measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid direct contact with the product.

Avoid contact during pregnancy and while nursing.

Smoking, drinking and consumption of food is not allowed in the work area.

See section 8 "Exposure controls/personal protection" for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Recommended storage material

Always store in containers of the same material as the original container.

Storage temperature

Refrigerator, 2 to 8°C

Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The product contains no substances listed in the Finnish list of substances with occupational exposure limit values.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

Apply general control to prevent unnecessary exposure

General recommendations

Smoking, drinking and consumption of food is not allowed in the work area.

Exposure scenarios

There are no exposure scenarios implemented for this product.

Exposure limits

Occupational exposure limits have not been defined for the substances in this product.

Appropriate technical measures

Do not recirculate outlet air that contain the substances.

Apply standard precautions during use of the product. Avoid inhalation of vapours.

Hygiene measures

In between use of the product and at the end of the working day all exposed areas of the body must be washed thoroughly. Pay special attention to hands, forearms and face.

Measures to avoid environmental exposure

Keep damming materials near the workplace. If possible, collect spillage during work.

Individual protection measures, such as personal protective equipment

Generally

Use only CE marked protective equipment.

Respiratory Equipment

Work situation	Type	Class	Colour	Standards
In case of inadequate ventilation	In the case of aerosol or mist formation, filter type P2			

Skin protection

Recommended	Type/Category	Standards
Dedicated work clothing should be worn.	-	-



Hand protection

Material	Glove thickness (mm)	Breakthrough time (min.)	Standards
Nitrile	0,11 mm	480 min	EN374

Eye protection

Type	Standards
Safety glasses	EN166



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Liquid

Colour

Testing not relevant or not possible due to the nature of the product.

Odour / Odour threshold

Testing not relevant or not possible due to the nature of the product.

pH

8.0

Density (g/cm³)

Testing not relevant or not possible due to the nature of the product.

Kinematic viscosity

Testing not relevant or not possible due to the nature of the product.

Particle characteristics

Does not apply to liquids.

Phase changes

Melting point/Freezing point (°C)

Testing not relevant or not possible due to the nature of the product.

Softening point/range (waxes and pastes) (°C)

Does not apply to liquids.

Boiling point (°C)

Testing not relevant or not possible due to the nature of the product.

Vapour pressure

Testing not relevant or not possible due to the nature of the product.

Relative vapour density

Testing not relevant or not possible due to the nature of the product.

Decomposition temperature (°C)

Testing not relevant or not possible due to the nature of the product.

Data on fire and explosion hazards

Flash point (°C)

Testing not relevant or not possible due to the nature of the product.

Flammability (°C)

Testing not relevant or not possible due to the nature of the product.

Auto-ignition temperature (°C)

Testing not relevant or not possible due to the nature of the product.

Lower and upper explosion limit (% v/v)

Testing not relevant or not possible due to the nature of the product.

Solubility

Solubility in water

Testing not relevant or not possible due to the nature of the product.

n-octanol/water coefficient (LogKow)

Testing not relevant or not possible due to the nature of the product.

Solubility in fat (g/L)

Testing not relevant or not possible due to the nature of the product.

9.2. Other information

Other physical and chemical parameters

No data available.

Oxidizing properties

Testing not relevant or not possible due to the nature of the product.

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

The product is stable under the conditions, noted in section 7 "Handling and storage".

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Product/substance	boric acid
Species:	Rat
Route of exposure:	Oral
Test:	LD50
Result:	2.660 mg/kg

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

Respiratory sensitisation

Based on available data, the classification criteria are not met.

Skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

May damage fertility. May damage the unborn child.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards**Long term effects**

Reproductive toxicity: This product contains teratogenic substances, which may produce anomalies and/or developmental defects to the human offspring. Adverse effects include: death, growth retardation, congenital disorders, delayed mental development, and functional disorders. This product contains reprotoxic substances, which may harm the reproductive capacity. Adverse effects include: sterility, effects on the sexual function, lowered effective fertility and dysfunctional menstrual cycle.

Endocrine disrupting properties

This mixture/product does not contain any substances known to have hormone-disrupting properties in relation to health.

Other information

None known.

SECTION 12: Ecological information**12.1. Toxicity**

Product/substance	boric acid
Species:	Fish, <i>Lepomis macrochirus</i>
Duration:	96 hours
Test:	LC0
Result:	> 1.021 mg/L

Product/substance	boric acid
Species:	Fish, <i>Ptychocheilus lucius</i>
Duration:	96 hours
Test:	LC50
Result:	279 mg/L

Product/substance	boric acid
Species:	Daphnia, <i>Daphnia magna</i>
Duration:	21 days
Test:	LC50
Result:	53,2 mg/L

Product/substance	boric acid
Species:	Daphnia, <i>Daphnia magna</i>
Duration:	48 hours
Test:	EC50
Result:	133 mg/L

12.2. Persistence and degradability

Based on available data, the classification criteria are not met.

12.3. Bioaccumulative potential

Based on available data, the classification criteria are not met.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification.

12.6. Endocrine disrupting properties

This mixture/product does not contain any substances considered to have endocrine-disrupting properties in relation to the environment.

12.7. Other adverse effects

None known.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Product is not covered by regulations on dangerous waste.

Dispose of contents/container to an approved waste disposal plant.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

EWC code

15 01 10* Packaging containing residues of or contaminated by dangerous substances

Contaminated packing

Packaging containing residues of the product must be disposed of similarly to the product.

SECTION 14: Transport information

	14.1 UN / ID	14.2 UN proper shipping name	14.3 Hazard class(es)	14.4 PG*	14.5 Env**	Other information:
ADR	-	-	-	-	-	-
IMDG	-	-	-	-	-	-
IATA	-	-	-	-	-	-

* Packing group

** Environmental hazards

Additional information

Not dangerous goods according to ADR, IATA and IMDG.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

No data available.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Restrictions for application**

Restricted to professional users.

People under the age of 18 shall not be exposed to this product.

Pregnant women and women breastfeeding must not be exposed to this product. The risk, and possible technical precautions or design of the workplace needed to eliminate exposure, must be considered.

Demands for specific education

No specific requirements.

SEVESO - Categories / dangerous substances

Not applicable.

Additional information

Not applicable.

Sources

25.4.2012 / 188 Ordinance of the Ministry of Social Affairs and Health on a list of examples of work that is dangerous for young workers.

Government Decree 603/2015 on factors posing a risk to reproductive health at work and risk prevention.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP).

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

No

SECTION 16: Other information

Full text of H-phrases as mentioned in section 3

H360FD, May damage fertility. May damage the unborn child.

Abbreviations and acronyms

ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road

ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

CAS = Chemical Abstracts Service

CE = Conformité Européenne (European conformity)

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

CSA = Chemical Safety Assessment

CSR = Chemical Safety Report

DMEL = Derived Minimal Effect Level

DNEL = Derived No Effect Level

EINECS = European Inventory of Existing Commercial chemical Substances

ES = Exposure Scenario

EUH statement = CLP-specific Hazard statement

EuPCS = European Product Categorisation System

EWC = European Waste Catalogue

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IARC = International Agency for Research on Cancer (IARC)

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

OECD = Organisation for Economic Co-operation and Development

PBT = Persistent, Bioaccumulative and Toxic

PNEC = Predicted No Effect Concentration

RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail

RRN = REACH Registration Number

SCL = A specific concentration limit

SVHC = Substances of Very High Concern

STOT-RE = Specific Target Organ Toxicity - Repeated Exposure

STOT-SE = Specific Target Organ Toxicity - Single Exposure

TWA = Time weighted average

UN = United Nations

UVBC = Unknown or variable composition, complex reaction products or of biological materials

VOC = Volatile Organic Compound

vPvB = Very Persistent and Very Bioaccumulative

Additional information

The classification of the mixture in regard of health hazards is in accordance with the calculation methods given by Regulation (EC) No. 1272/2008 (CLP).

The safety data sheet is validated by

QA Department

Other

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue triangle.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

The information provided in this Safety Data Sheet is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions and is not to be considered a warranty or quality specification. The information is believed to be correct at the date of publishing, but they are mentioned as guidelines and do not absolutely guarantee all properties of the product. Information above is not legally binding and Medix

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