

SAFETY DATA SHEET

Anti-h IgE 8518 SPRNE-1 (100106), TSH 5409 SPTNE-5 (100034)

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

1.1. Product identifier

Trade name

Anti-h IgE 8518 SPRNE-1 (100106), TSH 5409 SPTNE-5 (100034)

Product no.

100106, 100034

▼ Unique formula identifier (UFI)

9PCK-RDYQ-K26C-DT3W

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

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Revision

23/01/2024

SDS Version

2.0

Date of previous version

01/06/2023 (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

Acute Tox. 4; H302, Harmful if swallowed.

STOT RE 2; H373, May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

Hazard pictogram(s)



Signal word

Warning

Hazard statement(s)

Harmful if swallowed. (H302)

May cause damage to organs through prolonged or repeated exposure. (H373)

Precautionary statement(s)

General

-

Prevention

Do not breathe vapour/mist. (P260)

Wash hands and exposed skin thoroughly after handling. (P264)

▼ Response

Get medical advice/attention if you feel unwell. (P314)

Storage

-

▼ Disposal

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

▼ Hazardous substances

ethanediol;ethylene glycol

▼ Additional labelling

UFI: 9PCK-RDYQ-K26C-DT3W

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
ethanediol;ethylene glycol	CAS No.: 107-21-1 EC No.: 203-473-3 REACH: 01-2119456816-28-XXXX Index No.: 603-027-00-1	25%	Acute Tox. 4, H302 STOT RE 2, H373	[1]
Citric acid monohydrate	CAS No.: 5949-29-1 EC No.: 201-069-1 REACH: Index No.:	<0.8%	Eye Irrit. 2, H319 STOT SE 3, H335	
sodium azide	CAS No.: 26628-22-8 EC No.: 247-852-1 REACH: 01-2119457019-37-XXXX Index No.: 011-004-00-7	<0.1%	EUH032 Acute Tox. 2, H300 Acute Tox. 1, H310 Acute Tox. 2, H330 STOT RE 2, H373 (Brain) (Oral) Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1)	[1]

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

Other information

[1] European occupational exposure limit.

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 SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Rinse mouth.

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

Call a POISON CENTER/doctor if you feel unwell.

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.

If the product is exposed to high temperatures, e.g. in the event of fire, dangerous decomposition compounds are produced. These are:

Carbon oxides (CO / CO₂)

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.

Ensure adequate ventilation, especially in confined areas.

Contaminated areas may be slippery.

6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc.

Keep unauthorized persons away from the spill

6.3. Methods and material for containment and cleaning up

Limit spillage and collect using granular absorbent or similar materials, and dispose of it in accordance with the regulations on dangerous waste.

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

ethanediol;ethylene glycol

Long term exposure limit (8 hours) (ppm): 20

Long term exposure limit (8 hours) (mg/m³): 50

Short term exposure limit (15 minutes) (ppm): 40

Short term exposure limit (15 minutes) (mg/m³): 100

Annotations:

ih0: = Risk of dermal absorption.

sodium azide

Long term exposure limit (8 hours) (mg/m³): 0,1

Short term exposure limit (15 minutes) (mg/m³): 0,3

Annotations:

ih0: = Risk of dermal absorption.

Regulation of the Ministry of Social Affairs and Health on concentrations of chemical substances found to be harmful (654/2020).

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

Compliance with the given occupational exposure limits values should be controlled on a regular basis.

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

Professional users are subjected to the legally set maximum concentrations for occupational exposure. See occupational hygiene limit values above.

Appropriate technical measures

The formation of vapours must be kept at a minimum and below current limit values (see above). Installation of a local exhaust system if normal air flow in the work room is not sufficient is recommended. Ensure eyewash and emergency showers are clearly marked.

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
When there is risk of formation of mist/aerosol				

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

6.0-6.4

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	ethanediol;ethylene glycol
Species:	Rat, male/female
Route of exposure:	Oral
Test:	LD50
Result:	500,1 mg/kg

Product/substance	ethanediol;ethylene glycol
Species:	Rat, male/female
Route of exposure:	Inhalation
Test:	LC50
Result:	2,5 mg/L

Product/substance	ethanediol;ethylene glycol
Species:	Mouse, male/female
Route of exposure:	Dermal
Test:	LD50
Result:	3 500 mg/kg

Product/substance	Citric acid monohydrate
Test method:	OECD 401
Species:	Mouse, male/female
Route of exposure:	Oral
Test:	LD50
Result:	5.400 mg/kg

Product/substance	Citric acid monohydrate
Test method:	OECD 401
Species:	Rat, male
Route of exposure:	Oral
Test:	LD50
Result:	11.7 mg/kg

Product/substance	Citric acid monohydrate
Test method:	OECD 402
Species:	Rat, male/female
Route of exposure:	Dermal
Test:	LD50
Result:	2.0000 mg/kg

Product/substance	sodium azide
Species:	Rat
Route of exposure:	Oral
Test:	LD50
Result:	27 mg/kg

Product/substance	sodium azide
Species:	Rabbit

Route of exposure: Dermal
 Test: LD50
 Result: 20 mg/kg

Product/substance sodium azide
 Species: Rat, male/female
 Route of exposure: Inhalation
 Test: LC50 (4 hours)
 Result: 0,54-0,52 mg/L

Harmful if swallowed.

Skin corrosion/irritation

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

▼ Serious eye damage/irritation

Product/substance Citric acid monohydrate
 Test method: OECD 405
 Species: Rabbit
 Result: Adverse effect observed (Highly irritating)

▼ Respiratory sensitisation

Product/substance Citric acid monohydrate

▼ Skin sensitisation

Product/substance Citric acid monohydrate

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

Product/substance ethanediol;ethylene glycol

STOT-single exposure

Product/substance Citric acid monohydrate

STOT-repeated exposure

Product/substance ethanediol;ethylene glycol

Product/substance sodium azide
 Route of exposure: Oral
 Target organ: Hearing

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

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

11.2. Information on other hazards

Long term effects

None known.

▼ 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 ethanediol;ethylene glycol
 Species: Fish, Pimephales promelas
 Duration: 96 hours
 Test: LC50
 Result: 72.860 mg/L

Product/substance ethanediol;ethylene glycol
 Test method: OECD 202
 Species: Daphnia, Daphnia magna
 Duration: 48 hours
 Test: EC50
 Result: 100 mg/L

Product/substance ethanediol;ethylene glycol
 Species: Algae, Scenedesmus quadricauda
 Duration: 7 days

Test: IC5
Result: 10.000 mg/L

Product/substance ethanediol;ethylene glycol
Species: Bacteria
Compartment: Activated Sludge Plant
Duration: No data available.
Test: EC20

Product/substance Citric acid monohydrate
Species: Fish, *Leuciscus idus*
Duration: 96 hours
Test: LC50
Result: 440-760 mg/L

Product/substance Citric acid monohydrate
Species: Daphnia, *Daphnia magna*
Duration: 72 hours
Test: EC50
Result: ca. 120 mg/L

Product/substance Citric acid monohydrate
Species: Algae, *Microcystis aeruginosa*
Duration: No data available.
Result: 80 mg/L

Product/substance Citric acid monohydrate
Species: Bacteria, *Pseudomonas putida*
Duration: 16 hours
Result: 10.000 mg/L

Product/substance sodium azide
Test method: OECD 203
Species: Fish, *Oncorhynchus mykiss*
Duration: 96 hours
Test: LC50
Result: 2,75 mg/L

Product/substance sodium azide
Test method: OECD 201
Species: Algae, *Pseudokirchneriella subcapitata*
Duration: 96 hours
Result: 0,35 mg/L

12.2. ▼ Persistence and degradability

Product/substance ethanediol;ethylene glycol
Result: 90-100%
Conclusion: Readily biodegradable
Test: OECD 301 A

Product/substance Citric acid monohydrate
Result: 98% Readily eliminated from water
Conclusion: Readily biodegradable

12.3. ▼ Bioaccumulative potential

Product/substance ethanediol;ethylene glycol
Conclusion: No potential for bioaccumulation

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 covered by the regulations on hazardous waste. (*)

HP 5 - Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

HP 6 - Acute toxicity

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

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

▼EWC code

16 10 01* Aqueous liquid wastes containing dangerous substances

Notice Directive

on waste

2008/98/EC.

Waste material

must be disposed

of in accordance

with the national

and local

regulations.

Leave chemicals

in original

containers. No

mixing with other

waste. Handle

uncleaned

containers like

the product itself.

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.

Employment Contracts Act 55/2001 and amendment 750/2002.

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

EUH032, Contact with acids liberates very toxic gas.

H300, Fatal if swallowed.

H302, Harmful if swallowed.

H310, Fatal in contact with skin.

H319, Causes serious eye irritation.

H330, Fatal if inhaled.

H335, May cause respiratory irritation.

H373, May cause damage to organs through prolonged or repeated exposure.

H373, May cause damage to organs through prolonged or repeated exposure. (Brain) (Oral)

H400, Very toxic to aquatic life.

H410, Very toxic to aquatic life with long lasting effects.

▼ 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 Biochemica is not responsible for any harm related to use or handling of the product.

Country-language: FI-en