

SAFETY DATA SHEET

Encephalitozoon cuniculi whole cell antigen

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

1.1. Product identifier

Trade name

Encephalitozoon cuniculi whole cell antigen

Product no.

18-2002

Document number

34-0311

Unique formula identifier (UFI)

2P18-5H13-N00J-8X7N

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

Relevant identified uses of the substance or mixture

None known.

Restricted to professional users.

Uses advised against

None known.

1.3. Details of the supplier of the safety data sheet

Company and address

Medicago AB

Danmark Berga 13

74176 Uppsala

Sweden

+46 18 56 11 80

www.medicago.se

E-mail

info@medicago.se

Revision

02/07/2025

SDS Version

1.0

Date of previous version

24-0010u02 (2014-07-11)

1.4. Emergency telephone number

Healthcare professionals: Dial 0344 892 0111 to reach The National Poisons Information Service (NPIS) (24 hour service)

General public:

England - Dial 111 to reach NHS 111 (24 hour service)

Scotland - Dial 112 to reach NHS 24 (24 hour service)

Wales - Dial 111 or 0845 4647 to reach NHS Direct (24 hour service)

See section 4 "First aid measures".

SECTION 2: Hazards identification

Classified according to Regulation (EC) No. 1272/2008 (CLP) as retained and amended in UK law.

2.1. Classification of the substance or mixture

Acute Tox. 3; H301, Toxic if swallowed.

Acute Tox. 4; H312, Harmful in contact with skin.

Skin Sens. 1; H317, May cause an allergic skin reaction.

Acute Tox. 4; H332, Harmful if inhaled.

Muta. 2; H341, Suspected of causing genetic defects.

Carc. 1B; H350, May cause cancer.

2.2. Label elements

Hazard pictogram(s)



Signal word

Danger

Hazard statement(s)

Toxic if swallowed. (H301)
Harmful in contact with skin or if inhaled. (H312+H332)
May cause an allergic skin reaction. (H317)
Suspected of causing genetic defects. (H341)
May cause cancer. (H350)

Precautionary statement(s)

General

-

Prevention

Obtain special instructions before use. (P201)
Wash hands and exposed skin thoroughly after handling. (P264)
Wear eye protection/protective gloves/protective clothing. (P280)

Response

IF SWALLOWED: Immediately call a POISON CENTER/doctor. (P301+P310)
Specific treatment (see instructions on this label). (P321)

Storage

-

Disposal

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

Hazardous substances

formaldehyde 37%

Additional labelling

Restricted to professional users.

UFI: 2P18-5H13-N00J-8X7N

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) 2023/707.

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 |
|-------------------|---|-------|--|----------|
| formaldehyde 37% | CAS No.: 50-00-0 EC No.: 200-001-8 UK-REACH: Index No.: 605-001-00-5 | 1-3% | EUH071 Acute Tox. 2, H300 Acute Tox. 2, H310 Skin Corr. 1B, H314 (SCL: 25.00 %) Skin Irrit. 2, H315 (SCL: 5.00 %) Skin Sens. 1A, H317 Eye Irrit. 2, H319 (SCL: 5.00 %) Acute Tox. 2, H330 STOT SE 3, H335 (SCL: 5.00 %) Muta. 2, H341 Carc. 1B, H350 | [1], [3] |

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.

[3] According to UK REACH, Annex XVII, the substance is subject to restrictions.

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 injured person into fresh air. Make sure the injured person is continuously monitored. Prevent shock by keeping the injured person warm and calm. If breathing ceases, give mouth-to-mouth resuscitation. If unconscious, roll the injured person into recovery position. Call an ambulance.

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

In the case of ingestion, contact a doctor immediately. If the person is conscious, give them water. DO NOT try to induce vomiting unless this is recommended by a doctor. Hold head facing down to prevent vomit from returning to the mouth and throat. Prevent shock by keeping the injured person warm and calm. Initiate immediate resuscitation if breathing stops. If unconscious, roll the injured person into recovery position. Call an ambulance.

Burns

Not applicable.

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

Sensitisation: This product contains substances, which may trigger allergic reaction upon dermal contact.

Manifestation of allergic reactions typically takes place within 12-72 hours after exposure.

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

IF exposed or concerned:

Get immediate medical advice/attention.

If skin irritation or rash occurs: Get medical advice/attention.

Information to medic

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Alcohol-resistant foam, carbon dioxide, powder, water mist.

Unsuitable extinguishing media: Waterjets should not be used, since they can spread the fire.

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 National Poisons Information Service (dial 111, 24 h service) 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.
Avoid inhalation of vapours from spilled material.
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

Store locked up. A sign warning of toxic materials shall be affixed the room and cupboard containing the product(s). 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 conditions

No specific requirements.

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

formaldehyde 37%
Long term exposure limit (8 hours) (ppm): 2
Long term exposure limit (8 hours) (mg/m³): 2,5
Short term exposure limit (15 minutes) (ppm): 2
Short term exposure limit (15 minutes) (mg/m³): 2,5

The Control of Substances Hazardous to Health Regulations 2002. SI 2002/2677 The Stationery Office 2002.
EH40/2005 Workplace exposure limits (Fourth Edition 2020).

DNEL

formaldehyde 37%

| Duration: | Route of exposure: | DNEL: |
|--|--------------------|-----------------------|
| Long term – Local effects - Workers | Dermal | 37 µg/cm ² |
| Long term – Systemic effects - Workers | Dermal | 240 mg/kg bw/day |
| Long term – Local effects - Workers | Inhalation | 375 µg/m ³ |
| Long term – Systemic effects - Workers | Inhalation | 9 mg/m ³ |

| | | |
|--------------------------------------|------------|-----------------------|
| Short term – Local effects - Workers | Inhalation | 750 µg/m ³ |
|--------------------------------------|------------|-----------------------|

PNEC

formaldehyde 37%

| Route of exposure: | Duration of Exposure: | PNEC: |
|-----------------------------------|-----------------------|-----------|
| Freshwater | | 440 µg/L |
| Freshwater sediment | | 2.3 mg/kg |
| Intermittent release (freshwater) | | 4.44 mg/L |
| Marine water | | 440 µg/L |
| Marine water sediment | | 2.3 mg/kg |
| Sewage treatment plant | | 190 µg/L |
| Soil | | 200 µg/kg |

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

Do not recirculate outlet air that contain the substances.

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 UKCA marked protective equipment.

Respiratory Equipment

| Type | Class | Colour | Standards |
|-----------------|-------|--------|-----------|
| Use in fumehood | | | |

Skin protection

| Recommended | Type/Category | Standards |
|--|---------------|-----------|
| Wear appropriate protection clothing, e.g. coveralls in polypropylene or working clothes in cotton or polyester. | - | - |



Hand protection

| Material | Glove thickness (mm) | Breakthrough time (min.) | Standards |
|----------|----------------------|--------------------------|---------------------------|
| Nitrile | 0,2 | > 480 | EN374-2, EN16523-1, EN388 |



Eye protection

| Type | Standards |
|------|-----------|
|------|-----------|

| | |
|-----------------------------------|-------|
| Safety glasses with side shields. | EN166 |
|-----------------------------------|-------|



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Liquid

Colour

No data available.

Odour / Odour threshold

No data available.

pH

No data available.

Density (g/cm³)

No data available.

Kinematic viscosity

No data available.

Particle characteristics

Does not apply to liquids.

Phase changes

Melting point/Freezing point (°C)

No data available.

Softening point/range (°C)

Does not apply to liquids.

Boiling point (°C)

No data available.

Vapour pressure

No data available.

Relative vapour density

No data available.

Decomposition temperature (°C)

No data available.

Data on fire and explosion hazards

Flash point (°C)

No data available.

Flammability (°C)

No data available.

Auto-ignition temperature (°C)

No data available.

Lower and upper explosion limit (% v/v)

No data available.

Solubility

Solubility in water

No data available.

n-octanol/water coefficient (LogKow)

No data available.

Solubility in fat (g/L)

No data available.

9.2. Other information

Oxidizing properties

No data available.

Other physical and chemical parameters

No data available.

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

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 as retained and amended in UK law

Acute toxicity

Toxic if swallowed.

Harmful in contact with skin.

Harmful if inhaled.

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

May cause an allergic skin reaction.

Germ cell mutagenicity

Suspected of causing genetic defects.

Carcinogenicity

May cause cancer.

Reproductive toxicity

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

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

Carcinogenic effects: This product contains substances considered or proven to be carcinogenic. The carcinogenic effects may be triggered subsequent to exposure through inhalation, skin contact or ingestion.

Endocrine disrupting properties

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

Other information

formaldehyde 37% has been classified by IARC as a group 1 carcinogen.

SECTION 12: Ecological information

12.1. Toxicity

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

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

Waste treatment methods

Product is covered by the regulations on hazardous waste.

HP 6 - Acute toxicity

HP 7 - Carcinogenic

HP 11 - Mutagenic

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

Regulation (EU) No 1357/2014 of 18 December 2014 on waste as retained and amended in UK law.

EWC code

Not applicable.

Specific labelling

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

This product is within scope of the regulations of transport of dangerous goods.

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.

Control of Major Accident Hazards (COMAH) - Categories / dangerous substances

formaldehyde 37%

UK-REACH, Annex XVII

formaldehyde 37% is subject to restrictions, UK-REACH annex XVII (entry 77).

Additional information

Not applicable.

Sources

The Management of Health and Safety at Work Regulations 1999.

The Health and Safety at Work etc. Act 1974 Regulations 2013.

Control of Major Accident Hazards (COMAH) Regulations 2015.

Regulation (EU) No 1357/2014 of 18 December 2014 on waste as retained and amended in UK law.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) as retained and amended in UK law.

Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as retained and amended in UK law.

15.2. Chemical safety assessment

No

SECTION 16: Other information

Full text of H-phrases as mentioned in section 3

H300, Fatal if swallowed.

H310, Fatal in contact with skin.

H314, Causes severe skin burns and eye damage.

H315, Causes skin irritation.

H317, May cause an allergic skin reaction.

H319, Causes serious eye irritation.

H330, Fatal if inhaled.

H335, May cause respiratory irritation.

H341, Suspected of causing genetic defects.

H350, May cause cancer.

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

GWP = Global warming potential

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 substance/mixture in regard of health hazards are in accordance with the calculation methods given by Regulation (EC) No. 1272/2008 (CLP) as retained and amended in UK law.

The safety data sheet is validated by

Dylan Anderson

Other

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

Country-language: GB-en