

**MATERIAL SAFETY DATA SHEET ACCORDING TO EEC REGULATIONS 2015/830****SECTION 1 – Identification of the substance/mixture and of the company/undertaking**

1.1. Product identifier ENCEPUR TICK-BORNE ENCEPHALITIS VACCINE

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

This safety data sheet is written to provide health, safety and environmental information for handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician.

1.3. Details of the supplier of the safety data sheet

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1.4. Emergency telephone number

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SECTION 2 - Hazards identification

2.1. Classification of the substance or mixture

Exempt from requirements - product regulated as a medicinal product

2.2. Label elements No CLP labelling required.

2.3. Other hazards Caution - Pharmaceutical agent.

SECTION 3 - Composition/information on ingredients

3.2. Mixtures

Ingredients	CAS Number	Concentration	CLP Classification
Inactivated TBE virus	-	<0.1%	Not classified Acute Tox. 3 H301 Acute Tox. 3 H311 Skin Corr. 1B H314
Formaldehyde	50-00-0	<0.01%	Skin Sens. 1 H317 Acute Tox. 3 H331 Muta. 2 H341 Carc. 1B H350
Tris HCl	1185-53-1	<1%	Not classified
Aluminium hydroxide	21645-51-2	<0.5%	Not classified
Chlortetracycline	57-62-5	In traces	Acute Tox. 4;H302,
Neomycin hydrochloride	1406-02-6	In traces	Not classified
Gentamycinsulfat	1405-41-0	In traces	Skin Sens. 1 H317 Resp. Sens. 1 H334

For full wording of the used H phrases see section 16.

Other components below reportable levels > 98

SECTION 4 - FIRST AID MEASURES

4.1. Description of first aid measures

Eye contact	Flush eyes with water for at least 15 minutes. Ensure irrigation under eyelids by occasionally lifting them. Get medical attention if irritation persists.
Skin contact	Wash with soap and water.
Inhalation	Move to environment with fresh air. Get medical attention if any symptoms occur.
Ingestion	Wash mouth thoroughly with water.

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

Eye contact	May cause eye irritation.
Skin contact	None known

Inhalation	None known
Ingestion	None known

4.3. Indication of any immediate medical attention and special treatment needed
No specific antidotes are recommended. Treat according to locally accepted protocols.

SECTION 5 - FIRE FIGHTING MEASURES

5.1. Extinguishing media Alcohol resistant foam. Water. Foam. Dry chemical powder. Carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture
During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters
Use standard firefighting procedures and consider the hazards of other involved materials

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment, and emergency procedures
Wear appropriate protective equipment and clothing during clean-up.
Ensure adequate ventilation.

6.2. Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up
Collect spills mechanically and dispose of according to local or national regulations.

6.4. Reference to other sections
For additional information on Exposure Controls/Personal Protection see Section 8. For additional information on Disposal Considerations see Section 13.

SECTION 7 - HANDLING AND STORAGE

7.1. Precautions for safe handling
Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities
Use care in handling/storage. Store in original tightly closed container. Store at 2 to 8 °C (36 to 46 °F). Do not freeze. Dispose of properly if frozen. To maintain product quality, do not store in heat or direct sunlight. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) See section 1

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters Formaldehyd 50-00-0

LTEL 0.37 mg/m³ 0.3 ppm

STEL 0.74 mg/m³ 0.6 ppm

8.2. Exposure controls

Ventilation	General room ventilation is adequate unless the process generates dust, mist or fumes.
Respiratory protection	Normally not necessary.
Eye protection	Safety glasses are recommended if eye contact is possible.
Skin protection	Wear protective clothing when working with the material.
Hand protection	Wear disposable gloves when handling the material.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical form	Liquid prefilled syringe
Colour	turbid white/grey
Odour	Odourless
pH	7-8
Boiling point	No data available
Melting point	No data available
Flashpoint	No data available
Density	No data available
Vapour pressure	No data available
Vapour density	No data available.
Relative density	No data available.
Solubility (water)	No data available.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Explosive properties	No data available.
Oxidising properties	No data available.
9.2. Other information	No data available

SECTION 10 - STABILITY AND REACTIVITY

- 10.1. Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport
- 10.2. Chemical stability Stable under normal use conditions
- 10.3. Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.
- 10.4. Conditions to avoid
Do not freeze.
- 10.5. Incompatible materials
Strong oxidising agents.
- 10.6. Hazardous decomposition products
None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11 - Toxicological information

11.1. Information on toxicological effects

- Acute toxicity Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects. Health injuries are not known or expected under normal use.
- Skin corrosion/irritation Not classified based on available data.
- Serious eye damage/irritation
Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use. Not classified based on available data.
- Respiratory or Skin Sensitization
Not classified based on available data.
- Germ Cell Mutagenicity Not classified based on available data.
- Carcinogenicity Not classified based on available data.
- Reproductive toxicity Not classified based on available data.
- STOT-single exposure Not classified based on available data.
- STOT-repeated exposure Not classified based on available data.
- Aspiration Hazard Not classified based on available data.
- Other Adverse Effects: Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12 - ECOLOGICAL INFORMATION

- 12.1. Toxicity The product is not classified as environmentally hazardous.

12.2. Persistence and degradability

No data is available on the degradability of this product.

12.3. Bioaccumulative potential

No data available for the product

12.4. Mobility in soil No data available

12.5. Results of PBT and vPvB assessment

Not a PBT or vPvB substance

12.6. Other adverse effects

No data available

SECTION 13 - DISPOSAL INFORMATION

13.1. Waste treatment methods

Disposal of product as well as material that was in contact with the product must be disposed in accordance with applicable national regulations.

SECTION 14 - TRANSPORTATION INFORMATION

Not classified as dangerous goods.

SECTION 15 - REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

None special

15.2. Chemical safety assessment

Not applicable

SECTION 16 - OTHER INFORMATION

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Changes Section 3 composition.
 Section 8 Control parameters
 Section 16 list of H phrases

H Phrases from section 3:

H301 Toxic if swallowed.
H302 Harmful 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.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H341 Suspected of causing genetic defects.

H350 May cause cancer.

References

EC regulation 1907/2006

EC regulation 452/2010.

EU regulation 2015/830

ECHA C&L Inventory

Suppliers Safety Data Sheet

Abbreviations:

CLP: Regulation No. 1272/2008.

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

Training information

Follow training instructions when handling this material

Prepared by Herget.dk

Although the information, opinions and recommendations contained in this Material Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility for the accuracy, sufficiency, or reliability or for any loss or injury resulting from the use of the information. Newly discovered hazards are frequent, and this information may not be completely up to date.