

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



FENCOVIS® solution for injection

Version	Revision Date:	SDS Number:	Date of last issue: 25.10.2022
1.1	15.12.2022	000000057913	Date of first issue: 25.10.2022

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

1.1 Product identifier

Trade name : FENCOVIS® solution for injection

Synonyms : FENCOVIS®
with: inactivated bovine rotavirus strain TM-91, inactivated bovine coronavirus strain C-197 and inactivated E.Coli strain O8:K35, K99

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

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Safety Data Sheet only for the professional user., For veterinary use only, Refer to the product insert for complete instructions on usage

1.3 Details of the supplier of the safety data sheet

Company : Boehringer Ing. Pharma GmbH & Co.KG
Binger Straße 173
55216 Ingelheim
Germany

Telephone : +498007790900

E-mail address of person responsible for the SDS : EHS-Services@Boehringer-Ingelheim.com

1.4 Emergency telephone number

Int. Emergency Telephone number: +1 703-527-3887
German Emergency Telephone number: +49800 1817059

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

Additional Labelling

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		>= 5 % Skin Sens. 1; H317 >= 0,2 %	
		Acute toxicity estimate	
		Acute inhalation toxicity (vapour): 0,568666 mg/l	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
(show the package insert where possible).
First Aid responders should pay attention to self-protection and use the recommended protective clothing
Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
- If inhaled : Move to fresh air.
- In case of skin contact : Wash off immediately with plenty of water.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
- If swallowed : Rinse mouth.
Drink plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Observe the summary of product characteristics of proprietary medicinal products
Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water

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Dry chemical
Foam
Carbon dioxide (CO₂)

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes. Product itself is non-combustible; fire extinguishing method of surrounding areas must be considered.

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Complete suit protecting against chemicals

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Wear personal protective equipment.
Ensure adequate ventilation.
High risk of slipping due to leakage/spillage of product.

6.2 Environmental precautions

Environmental precautions : Do not flush into surface water or sanitary sewer system.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and transfer to properly labelled containers. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.

Advice on protection against : No special protective measures against fire required. The

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fire and explosion product is not flammable.

Hygiene measures : General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Refer to the product insert for instructions on storage.

Advice on common storage : Keep away from food, drink and animal feedingstuffs. Observe joint storage prohibition.

Storage class (TRGS 510) : 12

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
formaldehyde	50-00-0	TWA	0,3 ppm 0,37 mg/m ³	2004/37/EC
	Further information: Dermal sensitisation, Carcinogens or mutagens			
		STEL	0,6 ppm 0,74 mg/m ³	2004/37/EC
	Further information: Dermal sensitisation, Carcinogens or mutagens			
		AGW	0,3 ppm 0,37 mg/m ³	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(l)			
	Further information: Carcinogenic substance Cat. 1A or 1B or carcinogenic activity or procedure according to § 2 (3) No. 4 of the Hazardous Substances Ordinance - in addition, § 10 GefStoffV must be observed, When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child, Substance sensitizing through the skin			

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
sodium chloride	Workers	Inhalation	Long-term systemic effects	2068,62 mg/m ³
	Workers	Inhalation	Acute systemic effects	2068,62 mg/m ³
	Workers	Skin contact	Long-term systemic effects	295,52 mg/kg

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	Workers	Skin contact	Acute systemic effects	295,52 mg/kg
formaldehyde	Workers	Inhalation	Long-term systemic effects	9 mg/m3
	Workers	Inhalation	Long-term local effects	0,375 mg/m3
	Workers	Inhalation	Acute local effects	0,75 mg/m3
	Workers	Dermal	Long-term systemic effects	240 mg/kg
	Workers	Dermal	Long-term local effects	0,037 mg/cm2

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4,86 mg/kg

8.2 Exposure controls

Engineering measures

Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Eye/face protection : Safety glasses with side-shields
(Not necessary when using full face mask)

Hand protection

Material : Nitrile rubber
Glove thickness : 0,43 mm
Protective index : Class 6

Remarks : The break through time depends amongst other things on the material, the thickness and the type of glove and therefore has to be measured for each case.

Skin and body protection : Laboratory: laboratory coat; Factory: disposable Overall.

Respiratory protection : Breathing apparatus needed only when aerosol or mist is formed.
Half protecting mask with filter:
ABEK-P2-filter

Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	No data available
Odour	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	6,8 - 7,8
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	Not applicable
Relative vapour density	:	No data available
Particle characteristics		
Particle size	:	Not applicable

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9.2 Other information

Explosives	:	Not tested
Oxidizing properties	:	No data available
Self-ignition	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Components:

formaldehyde:

Acute oral toxicity : Assessment: The component/mixture is toxic after single ingestion.

Acute inhalation toxicity : LC50 (Rat): 463 ppm
Exposure time: 4 h
Test atmosphere: vapour

Acute toxicity estimate: 0,568666 mg/l
Test atmosphere: vapour
Method: Calculation method

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Carcinogenicity - Assessment : Sufficient evidence of carcinogenicity in animal experiments

Reproductive toxicity

Not classified based on available information.

Components:

formaldehyde:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Not classified based on available information.

Components:

formaldehyde:

Assessment : The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

formaldehyde:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

Aspiration toxicity

Not classified based on available information.

Components:

formaldehyde:

No data available

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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12.4 Mobility in soil

Components:

formaldehyde:

Distribution among environmental compartments : log Koc: 1,202

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Components:

formaldehyde:

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

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IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
formaldehyde (Number on list 72, 28)
thiomersal (Number on list 18)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

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The components of this product are reported in the following inventories:

TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	All components of this product are on the Canadian DSL
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	On the inventory, or in compliance with the inventory
PICCS	:	On the inventory, or in compliance with the inventory
IECSC	:	On the inventory, or in compliance with the inventory
NZIoC	:	On the inventory, or in compliance with the inventory
TECI	:	Not in compliance with the inventory

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of H-Statements

H220	:	Extremely flammable gas.
H301	:	Toxic if swallowed.
H311	:	Toxic in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H330	:	Fatal if inhaled.
H335	:	May cause respiratory irritation.
H341	:	Suspected of causing genetic defects.
H350	:	May cause cancer.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Carc.	:	Carcinogenicity
Eye Dam.	:	Serious eye damage
Flam. Gas	:	Flammable gases
Muta.	:	Germ cell mutagenicity
Skin Corr.	:	Skin corrosion
Skin Sens.	:	Skin sensitisation
STOT SE	:	Specific target organ toxicity - single exposure
2004/37/EC	:	Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens

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at work
DE TRGS 900 : Germany. TRGS 900 - Occupational exposure limit values.
2004/37/EC / STEL : Short term exposure limit
2004/37/EC / TWA : Long term exposure limit
DE TRGS 900 / AGW : Time Weighted Average

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Training advice : Provide adequate information, instruction and training for operators.

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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