

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

1.1. Product identifier

Substance name/Mixture designation**EXEM FOAM GEL 5 ML + WATER****Chemical name / Synonyms:**

ExEm Foam (air polymer-type A) intrauterine foam

Index number:

None

Registration number:

None.

CAS number:

None

Component/components: Hydroxy-ethyl-cellulose: 9004-62-0;
Glycerol: 56-81-5; Water: 7732-18-5**EINECS/ELINCS/LIST number:**None.
Component/components: Hydroxy-ethyl-cellulose: 231-791-2;
Glycerol: 200-289-5; Water: 217-576-6**UFI number**

None

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

Preparation.

Intrauterine foam, an ultrasound contrast agent.

1.3. Details of the supplier of the safety data sheet

Gedeon Richter Plc. H-1103 Budapest, Gyömr i út 19-21. Tel:

(+ 36-1)-431-4000; Fax: (+ 36-1)-260-4891

Gedeon Richter Plc. H-2510 Dorog, Esztergomi út 27. Tel:

(+ 36-33)-550-100

Gedeon Richter Plc. H-4031 Debrecen, Richter Gedeon utca 20.

Person responsible for information:

Responsible Department:

Chemical safety corporate team / EHS department

e-mail: REACH@richter.hu

phone No. + 36-1-4315360

1.4. Emergency telephone number

Hungarian Appointed Body: National Public Health Center

Albert Flórián Street 2-6, H-1097 Budapest, Hungary

Phone: + 36 (1) 476 1136, + 36 1 476 6464 (0-24h)

E-mail: clp.ca (at) nnk.gov.hu

Website: <https://www.nnk.gov.hu/>

SECTION 4: First aid measures

4.1. Description of first aid measures

4.1.1. General information

During our productional practice there has been no need of first aid due to any reason caused by the substance.

After inhalation:

None under normal use. Get medical attention if symptoms occur.

After skin contact:

Does not have an effect on the skin.

After eye contact:

None under normal use. Get medical attention if symptoms occur.

After swallowing:

None under normal use. Get medical attention if symptoms occur.

4.1.2. Information for doctor

The physician must be informed on the time, type and extent of exposure. If needed, show the safety data sheet to the physician.

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

No information are available for health effects of occupational exposure.

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

Treat symptomatically. No specific information is available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

The extinguishing media must be chosen depending on the characteristics of burning substance.

Unsuitable extinguishing media:

Full water-jet are not suitable for extinguishing.

5.2. Special hazards arising from the substance or mixture

Decomposition products: toxic gases/vapours.

5.3. Advice for firefighters

Outdoors stay on the weather-side and extinguish from there. In closed places, and in case of wreck, wear fireproof working clothes and use self-contained breathing apparatus.

Other information

Class of flammability hazard (according to Hungarian decree): Non-flammable

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Only the trained personnel in charge is allowed to be present at the site of spilling, wearing the prescribed protective equipments.

6.2. Environmental precautions

Hinder the spilled substance from entering the soil, sewers or living water.

6.3. Methods and material for containment and cleaning up

Spilt substance must be enclosed and soaked up by sand or earth, then it must be collected into spare empties and transported to the place of disposal. Wash the contaminated area with plenty of water.

6.4. Reference to other sections

Not relevant.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle it with the compliance of good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Store it in a cool, dry, well-ventilated, free from direct sunlight place.
Store in a tightly fitting package.

7.3. Specific end use(s)

Preparation.
Intrauterine foam, an ultrasound contrast agent.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values: AK (in Hungary): None
CK (in Hungary): None

Biological limit values: None.

Derived no effect level (DNEL) / Derived minimal effect level (DMEL): No data are available.

Predicted no-effect concentration (PNEC): environment: freshwater 0.885 mg/l
environment: sewage treatment plant; 1000 mg/l
environment: sediment; freshwater 3.3 mg/kg dwt
The values apply to glycerol.

8.2. Exposure controls

Appropriate engineering controls

Ensure safe workplace and technical conditions which do not endanger health.

Individual protection measures / personal protective equipment

The personal protective equipment for the working process are determined by internal standards.

Eye/face protection:

Not required.

Skin protection:

The body surface well protected, closed work clothes.

Hand protection:

Not required under normal circumstances.

Respiratory protection:

Not required under normal circumstances.

Environmental exposure controls

In case of proper handling and using no environmental damage may be expected.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Structural formula:

Molecular formula: Not applicable.

Molecular weight: Not applicable.

State, appearance: Liquid. Gel.

Colour: clear, colourless

Odour: Practically odourless.

Odour threshold: Unknown.

pH value or range: 6 - 7.5

Melting point / melting range: Unknown

Initial boiling point and boiling range: Unknown

Flash point:

Open cup: Unknown

Closed cup: Unknown

Evaporation rate: Unknown

Ignition temperature (MAIT/AIT): Unknown

Flammability Non-flammable.

Explosive limits:

Lower: Unknown

Upper: Unknown

Vapour pressure (at 20 °C): Unknown

Relative vapour density: Unknown

Density: Unknown

Solubility(ies):

in water: Miscible with water.

at 20 °C: Unknown

at 100 °C: Unknown

in organic solvents: Unknown.

Partition coefficient: Unknown

n-octanol/water (logP):

Decomposition temperature: Unknown

Viscosity (kinematic): Unknown

Particle characteristics: Not applicable.

Oxidising properties: Unknown.

9.2. Other information

Are not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

See details: in points 10.3/10.4/10.5.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

Dangerous reaction unknown.

10.4. Conditions to avoid

Sensitive to the following physical effects: intense heat, intense light.

10.5. Incompatible materials

strong basics, strong oxidisers, strong acids

10.6. Hazardous decomposition products

The substances are listed in section 5.2.

SECTION 11: Toxicological information

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

11.1.1. Substances

Acute toxicity

Effects of swallowing:

None of the component of the mixture classified into this class.
Glycerol: LD50 (oral, rat): 12600 mg/kg

Effects of inhalation:

None of the components are classified into this class.

Effects if absorbed through the skin:

None of the component of the mixture classified into this class.
Glycerol: LD50 (skin, rabbit): > 10000 mg/kg

skin corrosion/irritation:

None of the component of the mixture was classified as skin irritant.

serious eye damage/irritation:

None of the component of the mixture was classified as eye irritant.

respiratory or skin sensitisation:

Neither component of the mixture was classified as sensitizing.

Germ cell mutagenicity:

None of the components of the mixture are classified as genotoxic/mutagenic substance.

Carcinogenicity:

The measured results applies to glycerol
Genotoxicity/Mutagenity: In vitro, Bacterial reverse mutation test (Ames-test) *Salmonella typhimurium* - negative.

Reproductive toxicity:

None of the components of the mixture are classified as carcinogenic substance.

None of the components of the mixture are classified as reprotoxic substance.

STOT-single exposure:

Not known target organ related toxicity - after single exposure.

STOT-repeated exposure:

Not known target organ related toxicity - after repeated exposure.

SAFETY DATA SHEET

According to the Regulation (EC) No. 1907/2006

Date of issue: 14.08.2024

Date of previous version: Has no previous version.



Version: 1

Aspiration hazard: No data are available for its effect.**11.2. Information on other hazards****Endocrine disrupting properties:** Unknown**Other information:** Unknown

SECTION 12: Ecological information

12.1. Toxicity

It is forbidden to let it into fresh-water, public sewage-system and soil.

Toxicity to fish:

Carassius auratus auratus (goldfish) LC50: > 5000 mg/l
Cyprinodon variegatus (sheepshead minnow) LC50: 11000 mg/l/96h
Oncorhynchus mykiss (Salmo gairdneri, rainbow trout) LC50: > 885 mg/l/96h
Test data applies to glycerol.
Oncorhynchus mykiss (Salmo gairdneri, rainbow trout) LC50: > 100 mg/l/96h
Danio rerio (Brachydanio rerio, zebra danio) LC50: > 500 mg/l/96h
Lepomis macrochirus (bluegill) LC50: > 100 mg/l/96h
Test data applies to hydroxy-ethyl-cellulose.

Toxicity to Daphnia:

Daphnia magna EC50: > 10000 mg/l/24h
Daphnia magna EC50: 1995 mg/l/48h
Test data applies to glycerol.

Toxicity to algae / other aquatic plants:

Scenedesmus quadricauda (green algae) ECx/ICx: > 10000 mg/l
Test data applies to glycerol.

Toxicity to bacteria:

Pseudomonas putida (Pseudomonas cyanogena) ECx/ICx: > 10000 mg/l
Test data applies to glycerol.
EC50/IC50: > 1000 mg/l
Test data applies to hydroxy-ethyl-cellulose.

12.2. Persistence and degradability

The components of the mixture are readily biodegradable.

12.3. Bioaccumulative potential

The components of the mixture do not bioaccumulate.

12.4. Mobility in soil

Since substance is miscible with water, its mobility in soil and water is probably considerable.

12.5. Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Endocrine disrupting properties

Unknown

12.7. Other adverse effects

Unknown.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Suggestions for disposal procedures of the substance/ product:

Incineration in a special waste incineration plant.

Suggestions for disposal procedures of contaminated packaging (vessels):

Flammable empties must be incinerated in waste incineration plant, in compliance with local regulations.

SECTION 14: Transport information

By domestic regulations and international agreements the mixture is not qualified as hazardous commodity.

14.1. UN number or ID number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

None

14.4. Packing group

None

Road/railway transport ADR/RID

Label(s): None

Kemler number: None

Class group: None

Tunnel restriction code: None

Further information: None.

Air transport ICAO-TI and IATA-DGR

Packing instruction numbers: Not qualified as hazardous commodity.

Sea transport IMDG-Code

Stowage and segregation category: None

EmS: None

Marine pollutant: Not qualified as hazardous commodity.

14.5. Environmental hazards

Not qualified as hazardous commodity.

14.6. Special precautions for user

No specific information is available.

14.7. Maritime transport in bulk according to IMO instruments

Not relevant.

SECTION 15: Regulatory information

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

national (Hungary):

Act XXV of 2000 and its amendments on Chemical Safety. Several times modified 44/2000.(XII.27.) EÜM (Ministry of Health) Decree.

international:

Regulation (EC) No. 1272/2008 and its amendments of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Regulation (EC) No. 1907/2006 and its amendments of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

15.2. Chemical safety assessment

Not required.

SECTION 16: Other informations

The information conveyed by the above publication is in concordance with our experience and knowledge up to the present and has the scope of presenting our product in respect of the possible safety requirements.