

Pre-treatment Micro Tube for RENISCHEM® L-FABP POC Kit

Updated: 1st September 2022

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1	Product identifier Product Name CAS No. EINECS No.	Pre-treatment Micro Tube for RENISCHEM® L-FABP POC Kit Not applicable - Mixture Not applicable - Mixture
1.2	Relevant identified uses of the substance or mixture and uses advised against Identified Use(s) Uses Advised Against	Constituent reagents of in vitro diagnostic medical device Anything other than the above.
1.3	Details of the supplier of the safety data sheet Company Identification Telephone Fax E-Mail (competent person)	CMIC HOLDINGS Co., Ltd. Mass Bldg. 2F, 2-16-10 Yushima, Bunkyo-ku, Tokyo 113-0034, Japan +81-3-6779-8017 +81-3-6893-1578 l-fabp@cmic.co.jp
1.4	Emergency telephone number Emergency Phone No. Languages spoken	+81-3-6779-8017 English (Monday to Friday, 9:00-17:00 JST)

SECTION 2: HAZARDS IDENTIFICATION

2.1	Classification of the substance or mixture	
2.1.1	Regulation (EC) No. 1272/2008 (CLP)	Not classified as hazardous for supply/use.
2.2	Label elements Product Name Hazard Pictogram(s) Signal Word(s) Hazard Statement(s) Precautionary Statement(s) Supplemental information	According to Regulation (EC) No. 1272/2008 (CLP) Pre-treatment Micro Tube for RENISCHEM® L-FABP POC Kit None assigned None assigned None assigned None assigned None known
2.3	Other hazards	None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1	Substances Not applicable
3.2	Mixtures Substances in preparations / mixtures

EC Classification Regulation (EC) No. 1272/2008 (CLP)

Chemical identity of the substance	%W/W	CAS No.	EC No.	REACH Registration No.	Hazard classification

Pre-treatment Micro Tube for RENISCHEM[®] L-FABP POC Kit

Updated: 1st September 2022

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Lithium hydroxide	< 0.5	1310-66-3	215-183-4	Not yet assigned in the supply chain	Acute Tox. 4; H302 Skin Corr. 1; H314 Eye Dam. 1; H318
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For full text of H/P Statements see section 16.

SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Self-protection of the first aider

No action should be taken involving personal risk. Use personal protective equipment as required. Ensure adequate ventilation. Do not breathe dust/fume/gas/mist/vapours/spray. Wear suitable protective clothing and gloves. Avoid contact with skin and eyes. Contaminated clothing should be laundered before reuse.

Inhalation

IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.

Skin Contact

IF ON SKIN (or hair): Gently wash with plenty of soap and water. Remove contaminated clothing and wash clothing before reuse. If skin irritation occurs, get medical advice/attention.

Eye Contact

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

Ingestion

IF SWALLOWED: Rinse mouth. Give plenty of water to drink. Get medical advice/attention if you feel unwell.

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

Unlikely to be required but if necessary treat symptomatically.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media
Unsuitable extinguishing Media

As appropriate for surrounding fire. Water spray, foam, dry powder or CO₂. Do not use water jet. Direct water jet may spread the fire.

5.2 Special hazards arising from the substance or mixture

May give off noxious and toxic fumes in a fire. Corrosive fumes of lithium oxide and/or lithium hydroxide are also released.

5.3 Advice for fire-fighters

Fire fighters should wear complete protective clothing including self-contained breathing apparatus. Keep containers cool by spraying with water if exposed to fire. Evacuate if necessary. Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

No action should be taken involving personal risk. Wear appropriate personal protective equipment, avoid direct contact. Ensure adequate ventilation. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes. Remove contaminated clothing and wash all affected areas with plenty of water.

6.2 Environmental precautions

Do not allow to enter drains, sewers or watercourses.

6.3 Methods and material for containment and cleaning up

Damp down to avoid dust generation. Use vacuum cleaner to collect spilt material. Recover the product where possible. Ventilate the area and wash spill site after material pick-up is complete.

6.4 Reference to other sections

See Also Section: 8, 13.

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ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

SECTION 7: HANDLING AND STORAGE

7.1	Precautions for safe handling	Provide adequate ventilation when using the material and follow the principles of good occupational hygiene to control personal exposures. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not breathe dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Remove contaminated clothing and wash clothing before reuse.
7.2	Conditions for safe storage, including any incompatibilities	Keep only in original packaging. Keep in a well ventilated place. Keep container closed. Store in a cool/low-temperature, well-ventilated (dry) place away from heat and ignition sources. Keep from direct sunlight.
	Storage temperature	Stable at ambient temperatures. (1 - 30 °C)
	Incompatible materials	Acids, Strong oxidising agents, metal compounds, Combustible materials.
7.3	Specific end use(s)	None known.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1	Control parameters	
8.1.1	Occupational Exposure Limits	The UK HSE (EH40) recommends the following limits for dusts: 10 mg/m3 (8hr TWA) total inhalable dust; 4 mg/m3 (8hr TWA) total respirable dust.
8.1.2	Biological limit value	Not established.
8.1.3	PNECs and DNELs	Not applicable
8.2	Exposure controls	
8.2.1	Appropriate engineering controls	Provide adequate ventilation when using the material and follow the principles of good occupational hygiene to control personal exposures. Take action to prevent static discharges. Keep away from fire, sparks and heated surfaces.
8.2.2	Individual protection measures, such as personal protective equipment (PPE)	Use personal protective equipment as required. Take care for general good hygiene and housekeeping. Always wash hands before smoking, eating and drinking.

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

Eye/face protection



When handling this substance, e.g. sampling, wear goggles giving complete eye protection. (EN166)

Skin protection



Hand protection: Wear impervious gloves (EN374).
Recommended: Nitrile rubber. Protective index 6, corresponding > 480 minutes of permeation time according to EN 374

Body protection: Wear dust-resistant protective clothing.

Respiratory protection



Wear suitable respiratory protective equipment if processing involves working in areas where dusts or vapours are likely to be evolved. In case of inadequate ventilation wear respiratory protection. Recommended: EN143 Type A-P2

Thermal hazards

Not applicable.

8.2.3 **Environmental Exposure Controls**

Avoid release to the environment. Do not allow to enter drains, sewers or

Pre-treatment Micro Tube for RENISCHEM[®] L-FABP POC Kit

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watercourses.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1	Information on basic physical and chemical properties	
	Appearance	Blue Powder / Solid
	Odour	Odourless
	Odour Threshold	Not established
	pH	Not established
	Melting Point/Freezing Point	Not established
	Initial boiling point and boiling range	Not established
	Flash point	Not established
	Evaporation Rate	Not established
	Flammability (solid, gas)	Not established
	Upper/lower flammability or explosive limits	Not established
	Vapour pressure	Not established
	Vapour density	Not established
	Relative density	Not established
	Solubility(ies)	Not established
	Partition coefficient: n-octanol/water	Not available
	Auto-ignition temperature	Not established
	Decomposition Temperature	Not established
	Viscosity	Not established
	Explosive properties	Not established
	Oxidising properties	Not established
9.2	Other information	None

SECTION 10: STABILITY AND REACTIVITY

10.1	Reactivity	Stable under normal conditions.
10.2	Chemical stability	Stable under normal conditions.
10.3	Possibility of hazardous reactions	Hazardous polymerisation will not occur. May give off noxious and toxic fumes in a fire. Corrosive fumes of lithium oxide and/or lithium hydroxide are also released.
10.4	Conditions to avoid	Avoid prolonged storage at elevated temperature. Keep from direct sunlight.
10.5	Incompatible materials	Acids, Strong oxidising agents, metal compounds, Combustible materials.
10.6	Hazardous decomposition product(s)	Combustion products: None known

SECTION 11: TOXICOLOGICAL INFORMATION

11.1	Information on toxicological effects	
	Acute toxicity - Ingestion	Mixture: Based upon the available data, the classification criteria are not met. Calculated acute toxicity estimate (ATE) >20,000 mg/kg.
	Acute toxicity - Inhalation	Mixture: Based upon the available data, the classification criteria are not met. Calculated acute toxicity estimate (ATE) >3,500 mg/kg.
	Acute toxicity - Skin Contact	Mixture: Based upon the available data, the classification criteria are not met. Calculated acute toxicity estimate (ATE) > 5 mg/l
	Skin corrosion/irritation	Mixture: Based upon the available data, the classification criteria are not met.
	Serious eye damage/irritation	Mixture: Based upon the available data, the classification criteria are not met.
	Respiratory or skin sensitization	Mixture: Based upon the available data, the classification criteria are not met.
	Germ cell mutagenicity	Mixture: Based upon the available data, the classification criteria are not met.
	Carcinogenicity	Mixture: Based upon the available data, the classification criteria are not met.
	Reproductive toxicity	Mixture: Based upon the available data, the classification criteria are not met.
	STOT - single exposure	Mixture: Based upon the available data, the classification criteria are not met.
	STOT - repeated exposure	Mixture: Based upon the available data, the classification criteria are not met.
	Aspiration hazard	Mixture: Based upon the available data, the classification criteria are not met.

Pre-treatment Micro Tube for RENISCHEM[®] L-FABP POC Kit

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ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

11.2 Other information None.

SECTION 12: ECOLOGICAL INFORMATION

12.1	Toxicity	Mixture: Based upon the available data, the classification criteria are not met.
12.2	Persistence and degradability	No data for the mixture as a whole.
	Lithium hydroxide	Not applicable for inorganic substances
2.3	Bioaccumulative potential	No data for the mixture as a whole.
	Lithium hydroxide	Log Pow: -3.88 (ECHA registration dossier)
12.4	Mobility in soil	No data for the mixture as a whole.
	Lithium hydroxide	The substance has low mobility in soil.
12.5	Results of PBT and VPVB assessment	None of the substances in this product fulfil the criteria for being regarded as a PBT or vPvB substance.
12.6	Other adverse effects	None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods	Dispose of wastes in an approved waste disposal facility. Recover or recycle if possible.
13.2	Additional Information	None known

SECTION 14: TRANSPORT INFORMATION

Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods'.

	ADR/RID	IMDG	IATA/ICAO
14.1	UN number	Not classified	Not classified
14.2	UN proper shipping name	Not classified	Not classified
14.3	Transport hazard class(es)	Not classified	Not classified
14.4	Packing group	Not classified	Not classified
14.5	Environmental hazards	Not classified	Not classified
14.6	Special precautions for user	See Section: 2	
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable	

SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
15.1.1	EU regulations	
	Authorisations and/or Restrictions On Use	None
15.1.2	National regulations	
	Wassergefährdungsklasse (Germany)	Water hazard class: 2 (Self classification)
15.2	Chemical Safety Assessment	A chemical safety assessment is not required under REACH.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: Not applicable - V1.0

References:

Existing ECHA registration for Lithium hydroxide (CAS No. 1310-66-3).
Existing Safety Data Sheet (SDS)

EU Classification: This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830.

LEGEND

LTEL: Long Term Exposure Limit

STEL: Short Term Exposure Limit

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DNEL: Derived No Effect Level

PBT: PBT: Persistent, Bioaccumulative and Toxic

PNEC: Predicted No Effect Concentration

vPvB: very Persistent and very Bioaccumulative

Hazard classification / Classification code:

Acute Tox., Acute toxicity, Category 4

Skin Corr., Skin corrosion/irritation, Category 1

Eye Dam., Serious eye damage/irritation, Category 1

Hazard Statement(s)

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H318: Causes serious eye damage.

Training advice: Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

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