

Emicizumab Calibrator Emicizumab Controls Level 1 & Level 2

Safety Data Sheet

Creation Date: 08/12/2017

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

1.1. Product identifier

Synonyms : Emicizumab Calibrator
Emicizumab Controls Level 1 & Level 2

Catalog Number : Emicizumab Calibrator Catalog Number -151-201
Emicizumab Controls Level 1 & Level 2 Catalog Number - 152-401

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

Not applicable

1.3. Details of the supplier of the safety data sheet

r2 Diagnostics Inc.
1801 Commerce Drive
South Bend, IN 46628
USA

1.4. Emergency telephone number

(574) 288-4377 or (888) 727-2729 (in U.S. and Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

Possible Biohazard. Although this material was prepared with plasma collected from donors screened for CJD and which was tested at source and found negative for HBsAg, RPR, antibodies to HIV and HCV and non-reactive for HIV-1 rNA and HCV rNA by FDA approved tests, it should be handled by personnel trained in the proper procedure for handling potential blood borne pathogens. All wastes should be labeled and handled according to established in house procedures as well as all international, national and local regulations.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

Substance/Mixture : Mixture

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section. Occupational exposure limits, if available, are listed in Section 8.

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SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention.
- First-aid measures after skin contact : After contact with skin, wash with copious amounts of water for at least 15 minutes. Seek medical attention.
- First-aid measures after eye contact : After contact with eyes, wash with copious amounts of water for at least 15 minutes. Seek medical attention.
- First-aid measures after ingestion : If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.

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

- Symptoms/injuries after inhalation : May cause respiratory irritation. Potential viral infection.
- Symptoms/injuries after skin contact : May cause irritation. Potential viral infection.
- Symptoms/injuries after eye contact : May cause irritation. Potential viral infection.
- Symptoms/injuries after ingestion : May be harmful if swallowed. Potential viral infection.

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

- Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments : No specific treatment.
- Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.
- Explosion hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : Firefighters should wear full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

Wear suitable protective clothing, gloves and eye/face protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Stop the flow of material, if this is without risk.
- Methods for cleaning up : Wear suitable protective equipment. Area of spill should be wiped up and cleaned with 10% household bleach. Ventilate area after pick up is complete.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Wear gloves. Avoid skin contact and do not ingest.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Lyophilized product stored at 2-8°C.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls	: General (mechanical) room ventilation is expected to be satisfactory for normal handling.
Hand protection	: Wear plastic or rubber gloves to minimize skin contact.
Eye protection	: Wear safety goggles (or full face shield) if splashing is possible.
Skin and body protection	: Wear lab coat and other suitable working clothes as needed to minimize exposure.
Respiratory protection	: None specified under normal product handling conditions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance/Colour	: Colorless to Yellow
Odour	: None
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No specific test data related to reactivity available for this product or its ingredients

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Dispose of contents/container in accordance with local/regional/national/international regulations.
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SECTION 14: Transport information

Special Shipping information: Ship ambient for all lyophilized products.

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

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14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 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

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

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15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

r2 Diagnostics, Inc. believes the above information to be correct but does not purport to be all inclusive and should be used as a guide. r2 Diagnostics, Inc. shall not be held liable for any damage resulting from the handling or contact with the above product.