

BioWest - DMEM Low Glucose w/ L-Glutamine w/o Sodium Bicarbonate w/ Sodium Pyruvate P0061

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

- 1.1 Product identifier:** BioWest - DMEM Low Glucose w/ L-Glutamine w/o Sodium Bicarbonate w/ Sodium Pyruvate P0061
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Used in biotechnology. For professional user/industrial user only.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
Biowest SAS
Rue de la Caille
49340 Nuaille - France
Phone.: 00 33 2 41 46 42 42 - Fax: 00 33 2 41 46 40 50
biowest@biowest.net
www.biowest.net
- 1.4 Emergency telephone number:** ORFILA: 01 45 42 59 59



SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) No 1272/2008:
The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Hazard statements:
Non-applicable
Precautionary statements:
Non-applicable
Supplementary information:
EUH210: Safety data sheet available on request
- 2.3 Other hazards:**
Product fails to meet PBT/vPvB criteria

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Non-applicable
- 3.2 Mixture:**
Chemical description: Mixture composed of inorganic substances
Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

| Identification | Chemical name/Classification | Concentration |
|---|---|--|
| CAS: 10043-52-4 EC: 233-140-8 Index: 017-013-00-2 REACH: 01-2119494219-28-XXXX | Calcium chloride <input type="checkbox"/> ⁺ <input type="checkbox"/> Regulation 1272/2008 Eye Irrit. 2: H319 - Warning | ATP CLP00  1 - <2.5 % |
| CAS: 69847-45-6 EC: 274-152-3 Index: Non-applicable REACH: 01-2120765348-44-XXXX | Disodium L-tyrosinate <input type="checkbox"/> ⁺ <input type="checkbox"/> Regulation 1272/2008 Eye Irrit. 2: H319; Skin Irrit. 2: H315 - Warning | Self-classified  1 - <2.5 % |

Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2015/830

To obtain more information on the hazards of the substances consult sections 8, 11, 12, 15 and 16.

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or if necessary shower the affected person thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use full jet water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

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SECTION 6: ACCIDENTAL RELEASE MEASURES (continued)

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

DNEL (Workers):

| Identification | | Short exposure | | Long exposure | |
|--|------------|----------------|----------------------|----------------|---------------------|
| | | Systemic | Local | Systemic | Local |
| Calcium chloride CAS: 10043-52-4 EC: 233-140-8 | Oral | Non-applicable | Non-applicable | Non-applicable | Non-applicable |
| | Dermal | Non-applicable | Non-applicable | Non-applicable | Non-applicable |
| | Inhalation | Non-applicable | 10 mg/m ³ | Non-applicable | 5 mg/m ³ |

DNEL (General population):

| Identification | | Short exposure | | Long exposure | |
|--|------------|----------------|---------------------|----------------|-----------------------|
| | | Systemic | Local | Systemic | Local |
| Calcium chloride CAS: 10043-52-4 EC: 233-140-8 | Oral | Non-applicable | Non-applicable | Non-applicable | Non-applicable |
| | Dermal | Non-applicable | Non-applicable | Non-applicable | Non-applicable |
| | Inhalation | Non-applicable | 5 mg/m ³ | Non-applicable | 2,5 mg/m ³ |

PNEC:

Non-applicable

8.2 Exposure controls:

A.- General security and hygiene measures in the work place

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Non-applicable

D.- Ocular and facial protection

Non-applicable

E.- Body protection

Non-applicable

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

| | |
|---------------------------|-----------------------------|
| V.O.C. (Supply): | 0 % weight |
| V.O.C. density at 20 °C: | 0 kg/m ³ (0 g/L) |
| Average carbon number: | Non-applicable |
| Average molecular weight: | Non-applicable |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

| | |
|--------------------------|--|
| Physical state at 20 °C: | Solid |
| Appearance: | Powdery |
| Colour: |  Gold |
| Odour: | Not available |
| Odour threshold: | Non-applicable * |

Volatility:

| | |
|--|------------------|
| Boiling point at atmospheric pressure: | Non-applicable * |
| Vapour pressure at 20 °C: | Non-applicable * |
| Vapour pressure at 50 °C: | Non-applicable * |
| Evaporation rate at 20 °C: | Non-applicable * |

Product description:

| | |
|-------------------------------|--------------------------|
| Density at 20 °C: | 1894,7 kg/m ³ |
| Relative density at 20 °C: | 1,895 |
| Dynamic viscosity at 20 °C: | Non-applicable * |
| Kinematic viscosity at 20 °C: | Non-applicable * |

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

| | |
|--|------------------|
| Kinematic viscosity at 40 °C: | Non-applicable * |
| Concentration: | Non-applicable * |
| pH: | 6 - 6,6 |
| Vapour density at 20 °C: | Non-applicable * |
| Partition coefficient n-octanol/water 20 °C: | Non-applicable * |
| Solubility in water at 20 °C: | Non-applicable * |
| Solubility properties: | Non-applicable * |
| Decomposition temperature: | Non-applicable * |
| Melting point/freezing point: | Non-applicable * |
| Explosive properties: | Non-applicable * |
| Oxidising properties: | Non-applicable * |
| Flammability: | |
| Flash Point: | Non-applicable |
| Flammability (solid, gas): | Non-applicable * |
| Autoignition temperature: | 480 °C |
| Lower flammability limit: | Non-applicable * |
| Upper flammability limit: | Non-applicable * |
| Explosive: | |
| Lower explosive limit: | Non-applicable * |
| Upper explosive limit: | Non-applicable * |
| 9.2 Other information: | |
| Surface tension at 20 °C: | Non-applicable * |
| Refraction index: | Non-applicable * |

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

| Shock and friction | Contact with air | Increase in temperature | Sunlight | Humidity |
|--------------------|------------------|-------------------------|----------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

10.5 Incompatible materials:

| Acids | Water | Oxidising materials | Combustible materials | Others |
|--------------------|----------------|---------------------|-----------------------|-------------------------------|
| Avoid strong acids | Not applicable | Not applicable | Not applicable | Avoid alkalis or strong bases |

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

| Identification | Acute toxicity | | Genus |
|-----------------|------------------|----------------|--------|
| | Calcium chloride | LD50 oral | |
| CAS: 10043-52-4 | LD50 dermal | 5100 mg/kg | Rabbit |
| EC: 233-140-8 | LC50 inhalation | Non-applicable | |

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SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

| Identification | Acute toxicity | | Species | Genus |
|------------------|----------------|-------------------|---------------------------------|------------|
| Calcium chloride | LC50 | 4630 mg/L (96 h) | Pimephales promelas | Fish |
| CAS: 10043-52-4 | EC50 | 2400 mg/L (48 h) | Daphnia magna | Crustacean |
| EC: 233-140-8 | EC50 | 27000 mg/L (72 h) | Pseudokirchneriella subcapitata | Algae |

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

| Code | Description | Waste class (Regulation (EU) No 1357/2014) |
|----------|---|--|
| 16 03 04 | Inorganic wastes other than those mentioned in 16 03 03 | Non dangerous |

Type of waste (Regulation (EU) No 1357/2014):

Non-applicable

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2019 and RID 2019:

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SECTION 14: TRANSPORT INFORMATION (continued)

- | | |
|---|----------------|
| 14.1 UN number: | Non-applicable |
| 14.2 UN proper shipping name: | Non-applicable |
| 14.3 Transport hazard class(es): | Non-applicable |
| Labels: | Non-applicable |
| 14.4 Packing group: | Non-applicable |
| 14.5 Environmental hazards: | No |
| 14.6 Special precautions for user | |
| Special regulations: | Non-applicable |
| Tunnel restriction code: | Non-applicable |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | Non-applicable |
| 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: | Non-applicable |

Transport of dangerous goods by sea:

With regard to IMDG 38-16:

- | | |
|---|----------------|
| 14.1 UN number: | Non-applicable |
| 14.2 UN proper shipping name: | Non-applicable |
| 14.3 Transport hazard class(es): | Non-applicable |
| Labels: | Non-applicable |
| 14.4 Packing group: | Non-applicable |
| 14.5 Environmental hazards: | No |
| 14.6 Special precautions for user | |
| Special regulations: | Non-applicable |
| EmS Codes: | |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | Non-applicable |
| Segregation group: | Non-applicable |
| 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: | Non-applicable |

Transport of dangerous goods by air:

With regard to IATA/ICAO 2019:

- | | |
|---|----------------|
| 14.1 UN number: | Non-applicable |
| 14.2 UN proper shipping name: | Non-applicable |
| 14.3 Transport hazard class(es): | Non-applicable |
| Labels: | Non-applicable |
| 14.4 Packing group: | Non-applicable |
| 14.5 Environmental hazards: | No |
| 14.6 Special precautions for user | |
| Physico-Chemical properties: | see section 9 |
| 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: | Non-applicable |

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable
 Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable
 Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable
 Article 95, REGULATION (EU) No 528/2012: Non-applicable
 REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

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P0061****SECTION 15: REGULATORY INFORMATION (continued)****Seveso III:**

Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION**Legislation related to safety data sheets:**

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (Regulation (EC) No 2015/830)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Non-applicable

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Eye Irrit. 2: H319 - Causes serious eye irritation

Skin Irrit. 2: H315 - Causes skin irritation

Classification procedure:

Non-applicable

Advice related to training:

Minimal training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:<http://echa.europa.eu><http://eur-lex.europa.eu>**Abbreviations and acronyms:**

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -