



## Safety data sheet

This SDS is an English translation of Regulation (EU) n° 2015/830, without any country-specific legislation

### BioWest - Serum, Gamma Irradiated SxxxG

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

**1.1 Product identifier:** Serum, Gamma Irradiated

CAS: Non-applicable

EC: Non-applicable

Index: Non-applicable

REACH: Non-applicable

**Other means of identification:**

Non-applicable

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

Relevant uses: Used in biotechnology. For professional users/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 Nuaillé - 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:**

None

**2.3 Other hazards:**

Product fails to meet PBT/vPvB criteria

#### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS \*\*

**3.1 Substance:**

**Chemical description:** Organic compounds

**Components:**

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

Identification	Chemical name/Classification	Concentration
CAS: Non-applicable EC: Non-applicable Index: Non-applicable REACH: Non-applicable	<b>Sérum d'origine animale</b> Regulation 1272/2008	Not classified <b>100 %</b>

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

**3.2 Mixture:**

Non-applicable

\*\* Changes with regards to the previous version

#### SECTION 4: FIRST AID MEASURES

**4.1 Description of first aid measures:**

Consult a doctor in case of discomfort showing the SDS for the product.

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**BioWest - Serum, Gamma Irradiated  
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In case of symptoms, move the person affected into fresh air.

**By skin contact:**

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

**By eye contact:**

Rinse with water until the product has been eliminated. In case of problems, consult a doctor showing the SDS for the product.

**By ingestion/aspiration:**

In case of consumption in large quantities, it is recommended to seek medical assistance.

**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:****Suitable extinguishing media:**

Product is non-flammable, with a low risk of fire due to the flammability characteristics of the product in normal conditions of storage, handling and use. In the case of the existence of sustained combustion as a result of improper handling, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

**Unsuitable extinguishing media:**

Non-applicable

**5.2 Special hazards arising from the substance or mixture:**

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

**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:****For non-emergency personnel:**

Isolate leaks provided that there is no additional risk for the people performing this task.

**For emergency responders:**

Wear protective equipment. Keep unprotected persons away. See section 8.

**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:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

**6.4 Reference to other sections:**

See sections 8 and 13.

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**BioWest - Serum, Gamma Irradiated  
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Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

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

It is recommended to transfer at a slow speed to avoid the creation of electrostatic charges that could affect flammable products. Consult section 10 for conditions and materials that should be avoided.

**C.- Technical recommendations on general occupational hygiene**

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

**D.- Technical recommendations to prevent environmental risks**

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

**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 (European OEL, not country-specific legislation):

There are no applicable occupational exposure limits for the substances contained in the product

**DNEL (Workers):**

Non-applicable

**DNEL (General population):**

Non-applicable

**PNEC:**

Non-applicable

**8.2 Exposure controls:****A.- Individual protection measures, such as personal protective equipment**

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. 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.- Eye and face protection**

Non-applicable

**E.- Body protection**

Non-applicable

**F.- Additional emergency measures**

It is not necessary to take additional emergency measures.

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)**

**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 <sup>3</sup> (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:	Liquid
Appearance:	Fluid
Colour:	 Amber
Odour:	Characteristic
Odour threshold:	Non-applicable *

**Volatility:**

Boiling point at atmospheric pressure:	Non-applicable *
Vapour pressure at 20 °C:	Non-applicable *
Vapour pressure at 50 °C:	<300000 Pa (300 kPa)
Evaporation rate at 20 °C:	Non-applicable *

**Product description:**

Density at 20 °C:	1000 kg/m <sup>3</sup>
Relative density at 20 °C:	1
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	6,8 - 7,8
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 *

**Flammability:**

Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

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

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**BioWest - Serum, Gamma Irradiated  
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Median equivalent diameter: Non-applicable

**9.2 Other information:****Information with regard to physical hazard classes:**

Explosive properties: Non-applicable \*

Oxidising properties: Non-applicable \*

Corrosive to metals: Non-applicable \*

Heat of combustion: Non-applicable \*

Aerosols-total percentage (by mass) of flammable components: Non-applicable \*

**Other safety characteristics:**

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 indicated 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 (CO<sub>2</sub>), carbon monoxide and other organic compounds.**SECTION 11: TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects:**

LD50 oral &gt; 2000 mg/kg (rat)

**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
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

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

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**BioWest - Serum, Gamma Irradiated  
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- Contact with the skin: Based on available data, the classification criteria are not met
  - Contact with the eyes: Based on available data, the classification criteria are not met
  - D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
    - Carcinogenicity: Based on available data, the classification criteria are not met  
IARC: Non-applicable
    - Mutagenicity: Based on available data, the classification criteria are not met
    - Reproductive toxicity: Based on available data, the classification criteria are not met
  - E- Sensitizing effects:
    - Respiratory: Based on available data, the classification criteria are not met
    - Skin: Based on available data, the classification criteria are not met
  - F- Specific target organ toxicity (STOT) - single exposure:  
Based on available data, the classification criteria are not met
  - 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
    - Skin: Based on available data, the classification criteria are not met
  - H- Aspiration hazard:  
Based on available data, the classification criteria are not met
- Other information:**  
Non-applicable
- Specific toxicology information on the substances:**  
Not available

**SECTION 12: ECOLOGICAL INFORMATION**

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

- 12.1 Toxicity:**  
Not available
- 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 06	organic wastes other than those mentioned in 16 03 05	Non dangerous

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

Non-applicable

**Waste management (disposal and evaluation):**

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#### SECTION 13: DISPOSAL CONSIDERATIONS (continued)

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. Waste should not be disposed of to drains. 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 2021 and RID 2021:

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

##### Transport of dangerous goods by sea:

With regard to IMDG 40-20:

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

##### Transport of dangerous goods by air:

With regard to IATA/ICAO 2023:

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

**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.

**Relevant instructions for use:**

This product is collected from healthy animals declared fit for human consumption at the time of slaughter.

This product is produced in accordance with regulations to limit the risk of transmission of bovine spongiform encephalopathy.

Tests to detect certain viruses were carried out on the product (see the relevant data sheet for a list of tested viruses).

**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:**

The SDS shall be supplied in an official language of the country where the product is placed on the market. 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:**

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#### SECTION 16: OTHER INFORMATION (continued)

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:**

Non-applicable

**Advice related to training:**

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: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

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 -