

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

1.1. Product Identifier

SDS # BIO-011-EU

Product Codes IgG 14 Foods Additives ELISA PRODUCT CODE #: 7151
IgG 90 Foods ELISA PRODUCT CODE#: 7180
IgG 45 Foods French ELISA PRODUCT CODE #: 7185
IgG 4 Foods ELISA PRODUCT CODE #: 7187
IgG 7 Foods ELISA PRODUCT CODE #: 7189
IgG 90 Foods ELISA PRODUCT CODE #: 7190
IgG 90 Med Foods ELISA PRODUCT CODE #: 7191
IgG 90 Custom Foods ELISA PRODUCT CODE #: 7193
IgG 14 Custom Foods ELISA PRODUCT CODE #: 7194
IgG 45 Custom Foods ELISA PRODUCT CODE #: 7195
IgG 21 Custom Foods ELISA PRODUCT CODE #: 7198
IgG 90 Foods Korean ELISA PRODUCT CODE #: 7199

Product Name IgG Foods ELISA Kits

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Recommended Use For research or in vitro diagnostic use only

Uses Advised Against Not for use on or in humans

1.3. Details of the Supplier of the Safety Data Sheet

Supplier

Biomerica
17571 Von Karman Avenue
Irvine, CA 92614, USA

For further information, please contact

Contact Point Biomerica: (949) 645-2111
Email Address bmra@biomerica.com

1.4. Emergency telephone number

Emergency Telephone (24 hr) INFOTRAC 1-352-323-3500 (International)
1-800-535-5053 (North America)

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Regulation (EC) No 1272/2008

| | |
|---------------------------|------------|
| Skin corrosion/irritation | Category 2 |
|---------------------------|------------|

Classification according to 67/548/EEC

Full text of R-phrases: see section 16

Hazard Symbols

Not dangerous

2.2. Label Elements

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



Signal Word

Warning

Hazard Statements

H315 - Causes skin irritation

Precautionary Statements - EU (§28, 1272/2008)

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P332 + P313 - If skin irritation occurs: Get medical advice/attention

P362 - Take off contaminated clothing and wash before reuse

2.3. Other Hazards

General Hazards

Calibrators are formulated with a buffer base, animal or human serum. The kit components that are made with human serum are tested by a United States Food and Drug Administration (USFDA) licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen, and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product, in the United States Center for Disease Control (USCDC) and National Institute of Health (USNIH) manual "Biosafety in Microbiological Laboratories", 1988. All bovine serum products used are derived from animals of US origin, processed in USDA licensed facilities. Wash Buffer, Serum Diluent and Calibrators in kits are formulated with Sodium Azide as a preservative. Concentrated Sodium Azide may react with copper and lead plumbing to form explosive metal azides. It may also react with acids to form explosive hydrazoic acid. If drain disposed, flush with large amounts of water to prevent azide build-up. Avoid contact with Stop Solution containing 1N H2SO4 (Sulfuric Acid), an irritant to the skin and mucous membranes. Substrate Solution A contains Dimethyl Sulfoxide. In case of contact with any of these reagents, wash thoroughly with water.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

| Chemical Name | EC No | CAS No | Weight-% | Classification according to 67/548/EEC | Classification according to Regulation (EC) No. 1272/2008 [CLP] | REACH Registration Number |
|--------------------|---------|------------|----------|--|---|---------------------------|
| Dimethyl sulfoxide | Present | 67-68-5 | 40-50 | - | Not determined | Not determined |
| Sulfuric Acid | Present | 7664-93-9 | <5 | C; R35 | Skin Corr. 1A (H314) | Not determined |
| Sodium azide | Present | 26628-22-8 | <0.1 | T+; R28 R32 N; R50-53 | Acute Tox. 2 (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH032) | Not determined |

Full text of R-phrases: see section 16

Full text of H- and EUH-phrases: see section 16

Additional Information

Substances without a classification are included, because they have established occupational exposure limits

Section 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

| | |
|---------------------|--|
| Eye Contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get immediate medical advice/attention. |
| Skin Contact | Take off contaminated clothing. Wash with soap and water. |
| Inhalation | Remove to fresh air. If person is having difficulty breathing, give oxygen and call a physician immediately. |
| Ingestion | Flush mouth with copious amounts of water, provided that the person is conscious, and seek medical attention. |

4.2. Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms Causes skin irritation.

4.3. Indication of any Immediate Medical Attention and Special Treatment Needed

Notes to Physician Treat symptomatically.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media

Chemical or water fire extinguisher.

Unsuitable Extinguishing Media

None known.

5.2. Special Hazards Arising from the Substance or Mixture

Calibrators, Serum Diluent and Wash Buffer in kits are formulated with Sodium Azide as a preservative. Sodium Azide may react with copper and lead plumbing to form explosive metal azides that are sensitive to mechanical shock, concussion, friction and sparks. May react with acids to form explosive hydrazoic acid. Dimethyl Sulfoxide in Substrate Solution A is combustible.

| | |
|--------------------------------------|-------------|
| Hazardous Combustion Products | None known. |
|--------------------------------------|-------------|

5.3. Advice for Firefighters

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment as required.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures**Personal Precautions**

Wear gloves, impermeable shoe covers, and laboratory coat. Take care not to contaminate body. Ensure adequate ventilation.

For Emergency Responders

Use personal protection recommended in Section 8.

6.2. Environmental Precautions

Contain the spill to the smallest area possible.

6.3. Methods and Material for Containment and Cleaning Up

| | |
|--------------------------------|---|
| Methods for Containment | Prevent further leakage or spillage if safe to do so. |
|--------------------------------|---|

| | |
|-----------------------------|--|
| Methods for Clean-Up | Neutralize a Stop Solution spill with dilute base, then absorb the material with disposable towels. Soak a calibrator or control spill area with a 10% bleach solution and wipe up with disposable towels. Dispose of all contaminated trash in accordance with local regulations. |
|-----------------------------|--|

6.4. Reference to Other Sections

See Section 13: DISPOSAL CONSIDERATIONS.

Section 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling**Advice on Safe Handling**

Use personal protection recommended in Section 8. Take care not to splash, spill, or splatter standards, stop solution, or controls. Avoid contact with skin and eyes.

General Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for Safe Storage, Including any Incompatibilities**Storage Conditions**

Store kit reagents in 2-8°C in refrigerators designated and labeled to contain human blood products.

7.3. Specific End Use(s)

Specific Use(s)

For research or in vitro diagnostic use only.

Risk Management Methods (RMM)

The information required is contained in this Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Exposure Limits

| Chemical Name | European Union | United Kingdom | France | Spain | Germany |
|---|---|---|--|---|---|
| Dimethyl sulfoxide 67-68-5 | | | | | TWA: 50 ppm TWA: 160 mg/m ³ Ceiling / Peak: 100 ppm Ceiling / Peak: 320 mg/m ³ Skin |
| Sulfuric Acid 7664-93-9 | | TWA: 0.05 mg/m ³ | TWA: 0.05 mg/m ³ STEL: 3 mg/m ³ | TWA: 0.05 mg/m ³ | TWA: 0.1 mg/m ³ Ceiling / Peak: 0.1 mg/m ³ Skin |
| Sodium azide 26628-22-8 | S* TWA 0.1 mg/m ³ STEL 0.3 mg/m ³ | STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin | TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ | S* STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ | TWA: 0.2 mg/m ³ Ceiling / Peak: 0.4 mg/m ³ |
| Component | Italy | Portugal | Netherlands | Finland | Denmark |
| Dimethyl sulfoxide 67-68-5 (40-50) | | | | TWA: 50 ppm Skin | TWA: 50 ppm TWA: 160 mg/m ³ |
| Sulfuric Acid 7664-93-9 (<5) | | TWA: 0.2 mg/m ³ | TWA: 0.05 mg/m ³ | TWA: 0.05 mg/m ³ STEL: 0.1 mg/m ³ | TWA: 0.05 mg/m ³ |
| Sodium azide 26628-22-8 (<0.1) | TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin | Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm | Skin STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ | TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin | TWA: 0.1 mg/m ³ Skin |
| Chemical Name | Austria | Switzerland | Poland | Norway | Ireland |
| Dimethyl sulfoxide 67-68-5 | Skin TWA: 50 ppm TWA: 160 mg/m ³ | Skin STEL: 100 ppm STEL: 320 mg/m ³ TWA: 50 ppm TWA: 160 mg/m ³ | | | |
| Sulfuric Acid 7664-93-9 | STEL 0.2 mg/m ³ TWA: 0.1 mg/m ³ | STEL: 0.1 mg/m ³ TWA: 0.1 mg/m ³ | STEL: 3 mg/m ³ TWA: 1 mg/m ³ TWA: 0.05 mg/m ³ | TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ | TWA: 1 mg/m ³ |
| Sodium azide 26628-22-8 | Skin STEL 0.3 mg/m ³ TWA: 0.1 mg/m ³ | STEL: 0.4 mg/m ³ TWA: 0.2 mg/m ³ | STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin | Skin Ceiling: 0.3 mg/m ³ | TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin |

8.2. Exposure Controls

Engineering Controls

Apply technical measures to comply with the occupational exposure limits.

Personal Protective Equipment

Eye/Face Protection

Wear approved safety goggles where a splash hazard exists.

Hand Protection

Wear non-permeable rubber, neoprene, latex, or nitrile disposable gloves. Change gloves when they become contaminated.

Skin and Body Protection

Wear laboratory coat.

Respiratory Protection

In case of fire, wear self-contained breathing apparatus.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

| | | | |
|-----------------------|---|------------------------|----------------|
| Physical State | Liquid | Odour | None |
| Appearance | Clear (Green for Calibrators and Serum Diluent) liquid Red for Conjugate | Odour Threshold | Not determined |
| Colour | Clear (Green for Calibrators and Serum Diluent) Red for Conjugate | | |

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|------------------------------|--------------------|-------------------------|
| pH | 5.5-7.4 | Stop Solution pH <2 |
| Melting Point/Freezing Point | Not applicable | |
| Boiling Point/Boiling Range | Not applicable | |
| Flash Point | Not applicable | |
| Evaporation Rate | Not determined | |
| Flammability (Solid, Gas) | Not flammable | |
| Flammability Limits in Air | | |
| Upper Flammability Limits | Not applicable | |
| Lower Flammability Limit | Not applicable | |
| Vapour Pressure | Not determined | |
| Vapour Density | Not determined | |
| Relative Density | 1-3 mg/mL | |
| Water Solubility | Completely soluble | |
| Solubility(ies) | Not determined | |
| Partition Coefficient | Not determined | |
| Auto-ignition Temperature | Will not occur | |
| Decomposition Temperature | Not determined | |
| Kinematic Viscosity | Not determined | |
| Dynamic Viscosity | Not determined | |
| Explosive Properties | Not determined | |
| Oxidising Properties | Not determined | |

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Not reactive under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of Hazardous Reactions

Possibility of Hazardous Reactions

None under normal processing.

10.4. Conditions to Avoid

None known.

10.5. Incompatible Materials

Lead. Copper.

10.6. Hazardous Decomposition Products

None known.

Section 11: TOXICOLOGICAL INFORMATION**11.1. Information on Toxicological Effects****Acute Toxicity****Product Information**

Potential biohazard.

| | |
|-------------------------------|---|
| Eye Contact | Avoid contact with eyes. |
| Skin Contact | Causes skin irritation. |
| Inhalation | Avoid breathing vapors or mists. |
| Ingestion | Do not taste or swallow. |
| Unknown Acute Toxicity | 0.18% of the mixture consists of ingredient(s) of unknown toxicity. |

The following values are calculated based on chapter 3.1 of the GHS document:

| | |
|-------------|-----------|
| Oral LD50 | 21,968.00 |
| Units | mg/kg |
| Dermal LD50 | 88,889.00 |
| Units | mg/kg |
| Inhalation | |
| Gas | 99,999.00 |
| Units | mg/L |
| Mist | 99,999.00 |
| Units | mg/L |
| Vapor | 99,999.00 |
| Units | mg/L |

Component Information

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---|-----------------------|--|-------------------------------------|
| Dimethyl sulfoxide | = 14500 mg/kg (Rat) | = 40 g/kg (Rat) | |
| Sulfuric Acid | = 2140 mg/kg (Rat) | | = 510 mg/m ³ (Rat) 2 h |
| Polyoxyethylene mono(octylphenyl) ether | = 1800 mg/kg (Rat) | | |
| Sodium azide | = 27 mg/kg (Rat) | = 50 mg/kg (Rat) = 20 mg/kg (Rabbit) | |

| | |
|--|---|
| Skin corrosion/irritation | Causes skin irritation. |
| Serious eye damage/eye irritation | Not classified. |
| Sensitization | Not classified. |
| Germ cell mutagenicity | Not classified. |
| Carcinogenicity | None known based on information supplied. |

| | |
|---------------------------------|--|
| Reproductive toxicity | Not classified. |
| STOT - single exposure | Not classified. |
| STOT - repeated exposure | Not classified. |
| Aspiration hazard | Not classified. |
| Symptoms | Please see section 4 of this SDS for symptoms. |

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

| Chemical Name | Algae/aquatic plants | Fish | Crustacea |
|--------------------|--|--|--------------------------------------|
| Dimethyl sulfoxide | 12350 - 25500: 96 h Skeletonema costatum mg/L EC50 | 34000: 96 h Pimephales promelas mg/L LC50 33 - 37: 96 h Oncorhynchus mykiss g/L LC50 static 40: 96 h Lepomis macrochirus g/L LC50 static 41.7: 96 h Cyprinus carpio g/L LC50 | 7000: 24 h Daphnia species mg/L EC50 |
| Sulfuric Acid | | 500: 96 h Brachydanio rerio mg/L LC50 static | 29: 24 h Daphnia magna mg/L EC50 |
| Sodium azide | | 0.8: 96 h Oncorhynchus mykiss mg/L LC50 0.7: 96 h Lepomis macrochirus mg/L LC50 5.46: 96 h Pimephales promelas mg/L LC50 flow-through | |

12.2. Persistence and Degradability

Not determined.

12.3. Bioaccumulative Potential

| Chemical Name | Partition Coefficient |
|--------------------|-----------------------|
| Dimethyl sulfoxide | -2.03 |

12.4. Mobility in Soil

Mobility

Not determined.

12.5. Results of PBT and vPvB Assessment

Not determined.

12.6. Other Adverse Effects

Not determined.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste from Residues / Unused Products Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging Improper disposal or reuse of this container may be dangerous and illegal.

Section 14: TRANSPORT INFORMATION

IMDG

14.1 UN/ID No Not regulated

RID

14.1 UN/ID No Not regulated

ADR

14.1 UN/ID No Not regulated

ICAO (air)

14.1 UN/ID No Not regulated

IATA

14.1 UN/ID No Not regulated

Section 15: REGULATORY INFORMATION

15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

National Regulations

Occupational Illnesses (R-463-3, France)

| Chemical Name | French RG number | Title |
|-------------------------------|------------------|-------|
| Dimethyl sulfoxide 67-68-5 | RG 84 | |

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

International Inventories

Not determined.

- TSCA -
- EINECS/ELINCS -
- DSL/NDSL -
- PICCS -
- ENCS -
- IECSC -
- AICS -
- KECL -

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

Section 16: OTHER INFORMATION**Full text of R-phrases referred to under sections 2 and 3**

R35 - Causes severe burns

Full text of H-Statements referred to under sections 2 and 3

H314 - Causes severe skin burns and eye damage

H300 - Fatal if swallowed

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

EUH032 - Contact with acids liberates very toxic gas

Classification Procedure

Calculation method

Issue Date: 17-Oct-2014

Revision Date: 16-Jan-2015

Revision Note: Removed kits no longer in use.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006, as amended by Regulation (EU) No. 453/2010

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet