

**Manufacturer / Supplier:**

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20.11.2023

Reference No.	Description
<b>234013</b>	<b>Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges</b>

Components:

<i>Article description</i>	<i>Data sheet version</i>
Antibody-Coated Particle Solution	6
Enzyme-Labeled Antibody Solution	6

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

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

- **1.1 Product identifier**
- **Trade name:** *Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges, Antibody-Coated Particles Solution*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
*Not to be used for any purpose other than those mentioned below.*
- **Application of the substance / the preparation:** *Laboratory use. For product use see insert.*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
  - Fujirebio Inc.
  - 1-8-1 Akasaka, Minato-ku, Tokyo 107-0052, Japan
  - Tel: +81-3-6279-0899 Fax: +81-3-6279-0299
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- **Further information obtainable from:**
  - Fujirebio Inc.
  - 1-8-1 Akasaka, Minato-ku, Tokyo 107-0052, Japan
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  - E-mail: *fri\_info\_s@hugp.com*
- **1.4 Emergency telephone number:**
  - Fujirebio Inc. (Japan) Global Sales Department
  - Tel: +81-3-6279-0899
  - Mon - Fri 9:00am to 5:30pm (JST)
  -

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*The product is not classified, according to the CLP regulation.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 void**
- **Hazard pictograms void**
- **Signal word void**
- **Hazard statements void**
- **Additional information:**  
*EUH032 Contact with acids liberates very toxic gas.*
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

**SECTION 3: Composition/information on ingredients**

- **3.2 Mixtures**
- **Dangerous components:** *void*

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:** *No special measures required.*
- **After inhalation:** *Supply fresh air; consult doctor in case of complaints.*
- **After skin contact:**  
*Immediately wash with water and soap and rinse thoroughly.*  
*If skin irritation continues, consult a doctor.*
- **After eye contact:**  
*Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.*

(Contd. on page 2)

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges,  
Antibody-Coated Particles Solution**

(Contd. of page 1)

- **After swallowing:** Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray.  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** No special measures required.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store in a dry and well-ventilated area in the closed original packaging.
- **Information about storage in one common storage facility:**  
Do not store together with acids.  
At contact with acids, highly poisonous gases can be produced.
- **Further information about storage conditions:**  
Respect the expiry date and the additional instruction given in the package insert.
- **7.3 Specific end use(s)** Laboratory use.

### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not necessary if room is well-ventilated.

(Contd. on page 3)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges,  
Antibody-Coated Particles Solution**

(Contd. of page 2)

- **Hand protection**  
Wear protective gloves in order to be protected against chemical risks according to EN 420 and EN 374.
- **Material of gloves:**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material:**  
As the product is a preparation consisting of different substances, no specific information can be given about breakthrough times.  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **As protection from splashes gloves made of the following materials are suitable:**  
Nitrile rubber, NBR  
Recommended thickness of the material: 0.11 mm
- **Eye/face protection**  
Wear safety glasses in order to protect your eyes against chemical splashes according to EN 166.
- **Body protection:**  
Wear a laboratory coat for your protection against chemical splashes according to EN 340 and EN 369.
- **Environmental exposure controls** Comply with the current local and national environmental regulations.

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Liquid @23-27°C, Gel-like solid @2-8°C
- **Colour:** Slightly yellow
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Product is not flammable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** 6.0-8.0
- **Viscosity:**
- **Kinematic viscosity** Not determined.
- **Dynamic:** Not determined.
- **Solubility**
- **water:** Soluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not determined.
- **Density and/or relative density**
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **9.2 Other information**
- **Appearance:**
- **Form:** Gel-like liquid (25°C)
- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.

(Contd. on page 4)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges,  
Antibody-Coated Particles Solution**

(Contd. of page 3)

- |                                   |                 |
|-----------------------------------|-----------------|
| · <b>Solvent separation test:</b> |                 |
| · <b>Solids content:</b>          | 0.1 %           |
| · <b>Change in condition</b>      |                 |
| · <b>Evaporation rate</b>         | Not determined. |

- |  |      |
|--|------|
| · <b>Information with regard to physical hazard classes</b>                        |      |
| · <b>Explosives</b>  | void |
| · <b>Flammable gases</b>   | void |
| · <b>Aerosols</b>  | void |
| · <b>Oxidising gases</b>   | void |
| · <b>Gases under pressure</b>  | void |
| · <b>Flammable liquids</b>   | void |
| · <b>Flammable solids</b>  | void |
| · <b>Self-reactive substances and mixtures</b>                                     | void |
| · <b>Pyrophoric liquids</b>  | void |
| · <b>Pyrophoric solids</b>   | void |
| · <b>Self-heating substances and mixtures</b>                                      | void |
| · <b>Substances and mixtures, which emit flammable gases in contact with water</b> | void |
| · <b>Oxidising liquids</b>   | void |
| · <b>Oxidising solids</b>  | void |
| · <b>Organic peroxides</b>   | void |
| · <b>Corrosive to metals</b>   | void |
| · <b>Desensitised explosives</b>   | void |

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**  
Production of highly poisonous gases/vapours in contact with acids.  
Reacts with various metals.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** Production of explosive azides in contact with lead, copper and zinc.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:** No data available for this product.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

(Contd. on page 5)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges,  
Antibody-Coated Particles Solution**

(Contd. of page 4)

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

### SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:** Harmful to aquatic organisms

· **12.2 Persistence and degradability** No further relevant information available.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

· **12.7 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation**

Dispose of contents in accordance with local / regional/ national/ international regulations.

· **Uncleaned packaging:**

· **Recommendation:** Dispose of container in accordance with local/regional/national/international regulations.

### SECTION 14: Transport information

· **14.1 UN number or ID number**

-

· **ADR, ADN, IMDG, IATA**

void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA**

void

· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class**

void

· **14.4 Packing group**

· **ADR, IMDG, IATA**

void

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

· **UN "Model Regulation":**

void

### SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

(Contd. on page 6)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

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Version: 6 (replaces version 5)

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**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges,  
Antibody-Coated Particles Solution**

(Contd. of page 5)

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **National regulations:**

· **Waterhazard class:** Generally not hazardous for water.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

The data indicated in these documents is provided in good faith and according to the current state of our knowledge. We will accept no liability for the consequences if the product is used for applications different to that intended. It is the responsibility of the consumer to ensure that all regulations concerning protection of human beings and environment are complied with during the handling, storage and use of the products.

· **Classification according to Regulation (EC) No 1272/2008**

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· **Version number of previous version: 5**

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· **\* Data compared to the previous version altered.**



**Safety data sheet**  
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Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

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

- **1.1 Product identifier**
- **Trade name:** Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges  
Enzyme-Labeled Antibody Solution
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
Not to be used for any purpose other than those mentioned below.
- **Application of the substance / the preparation:** Laboratory use. For product use see insert.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
  - Fujirebio Inc.
  - 1-8-1 Akasaka, Minato-ku, Tokyo 107-0052, Japan
  - Tel: +81-3-6279-0899 Fax: +81-3-6279-0299
  - E-mail: fri\_info\_s@hugp.com
- **Further information obtainable from:**
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- **1.4 Emergency telephone number:**
  - Fujirebio Inc. (Japan) Global Sales Department
  - Tel: +81-3-6279-0899
  - Mon - Fri 9:00am to 5:30pm (JST)
  -

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 void**
- **Hazard pictograms void**
- **Signal word void**
- **Hazard statements void**
- **Additional information:**  
EUH032 Contact with acids liberates very toxic gas.  
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Mixtures**

- **Dangerous components:**

CAS: 145224-94-8	4-morpholineethanesulfonic acid, monohydrate	≤2.5%
EINECS: 224-632-3	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**  
Immediately wash with water and soap and rinse thoroughly.

(Contd. on page 2)



## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges  
Enzyme-Labeled Antibody Solution**

(Contd. of page 1)

*If skin irritation continues, consult a doctor.*

· **After eye contact:**

*Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.*

· **After swallowing:** *Do not induce vomiting; call for medical help immediately.*

· **4.2 Most important symptoms and effects, both acute and delayed** *No further relevant information available.*

· **4.3 Indication of any immediate medical attention and special treatment needed**

*No further relevant information available.*

### SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

*CO2, powder or water spray. Fight larger fires with water spray.*

*Use fire extinguishing methods suitable to surrounding conditions.*

· **5.2 Special hazards arising from the substance or mixture** *No further relevant information available.*

· **5.3 Advice for firefighters**

· **Protective equipment:** *No special measures required.*

### SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**

*Wear protective equipment. Keep unprotected persons away.*

· **6.2 Environmental precautions:** *No special measures required.*

· **6.3 Methods and material for containment and cleaning up:** *No special measures required.*

· **6.4 Reference to other sections**

*See Section 7 for information on safe handling.*

*See Section 8 for information on personal protection equipment.*

*See Section 13 for disposal information.*

### SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** *No special precautions are necessary if used correctly.*

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:**

*Store in a dry and well-ventilated area in the closed original packaging.*

· **Information about storage in one common storage facility:**

*Do not store together with acids.*

*At contact with acids, highly poisonous gases can be produced.*

· **Further information about storage conditions:**

*Respect the expiry date and the additional instruction given in the package insert.*

· **7.3 Specific end use(s)** *Laboratory use.*

### SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

*The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.*

· **8.2 Exposure controls**

· **Appropriate engineering controls** *No further data; see item 7.*

(Contd. on page 3)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges**  
**Enzyme-Labeled Antibody Solution**

(Contd. of page 2)

- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Hand protection**  
Wear protective gloves in order to be protected against chemical risks according to EN 420 and EN 374.
- **Material of gloves:**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material:**  
As the product is a preparation consisting of different substances, no specific information can be given about breakthrough times.  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **As protection from splashes gloves made of the following materials are suitable:**  
Nitrile rubber, NBR  
Recommended thickness of the material: 0.11 mm
- **Eye/face protection**  
Wear safety glasses in order to protect your eyes against chemical splashes according to EN 166.
- **Body protection:**  
Wear a laboratory coat for your protection against chemical splashes according to EN 340 and EN 369.
- **Environmental exposure controls** Comply with the current local and national environmental regulations.

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** Slightly yellow
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Product is not flammable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** 6.0-8.0
- **Viscosity:**
- **Kinematic viscosity** Not determined.
- **Dynamic:** Not determined.
- **Solubility**
- **water:** Soluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not determined.
- **Density and/or relative density**
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not determined.

(Contd. on page 4)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

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**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges**  
**Enzyme-Labeled Antibody Solution**

(Contd. of page 3)

- **9.2 Other information**
- **Appearance:**
- **Form:** Liquid
- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.
- **Solvent separation test:**
- **Solids content:** 0.1 %
- **Change in condition**
- **Evaporation rate** Not determined.

- **Information with regard to physical hazard classes**
- **Explosives** void
- **Flammable gases** void
- **Aerosols** void
- **Oxidising gases** void
- **Gases under pressure** void
- **Flammable liquids** void
- **Flammable solids** void
- **Self-reactive substances and mixtures** void
- **Pyrophoric liquids** void
- **Pyrophoric solids** void
- **Self-heating substances and mixtures** void
- **Substances and mixtures, which emit flammable gases in contact with water** void
- **Oxidising liquids** void
- **Oxidising solids** void
- **Organic peroxides** void
- **Corrosive to metals** void
- **Desensitised explosives** void

### **SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**  
Production of highly poisonous gases/vapours in contact with acids.  
Reacts with various metals.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** Production of explosive azides in contact with lead, copper and zinc.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### **SECTION 11: Toxicological information**

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.

(Contd. on page 5)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

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**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges**  
**Enzyme-Labeled Antibody Solution**

(Contd. of page 4)

- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No data available for this product.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Dispose of contents in accordance with local / regional/ national/ international regulations.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of container in accordance with local/regional/national/international regulations.

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| · <b>14.1 UN number or ID number</b>                                  | -               |
| · <b>ADR, ADN, IMDG, IATA</b>   | void            |
| · <b>14.2 UN proper shipping name</b>                                 |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   | void            |
| · <b>14.3 Transport hazard class(es)</b>                              |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | void            |
| · <b>14.4 Packing group</b>   |                 |
| · <b>ADR, IMDG, IATA</b>  | void            |
| · <b>14.5 Environmental hazards:</b>                                  |                 |
| · <b>Marine pollutant:</b>  | No              |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | void            |

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(Contd. on page 6)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date: 20.11.2023

Version: 6 (replaces version 5)

Revision: 20.11.2023

**Trade name: Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges**  
**Enzyme-Labeled Antibody Solution**

(Contd. of page 5)

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **National regulations:**

- **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

The data indicated in these documents is provided in good faith and according to the current state of our knowledge. We will accept no liability for the consequences if the product is used for applications different to that intended. It is the responsibility of the consumer to ensure that all regulations concerning protection of human beings and environment are complied with during the handling, storage and use of the products.

· **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· **Classification according to Regulation (EC) No 1272/2008**

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· **Version number of previous version: 5**

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· **\* Data compared to the previous version altered.**