

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## ARGENTUM COLLOIDALE AD USUM EXTERNUM

EN

FORM-06-14-01 (V00)

Page 1/12

Publication: 04/03/2022

Revision: 04/03/2022

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

#### 1.1 Product identifier

Product name:	Silver colloidal for external use Argentum colloidal ad usum externum Colloïdaal zilver voor uitwendig gebruik Argent colloïdal pour usage externe Kolloidales Silber zum äußerlichen Gebrauch
N° CAS:	9007-35-6
N° EC:	N/A

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Eye Irrit. 2	H319
Skin Irrit. 2	H315
STOT SE 3	H335

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning

Hazard statements:

H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.

Precautionary statements:

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



## ARGENTUM COLLOIDALE AD USUM EXTERNUM

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P501	Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Product fails to meet PBT/vPvB criteria.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Colloidal metallic silver containing protein.

Product name:	Silver colloidal for external use
IUPAC name:	Not available.
Synonyms:	Not available.
N° CAS:	9007-35-6
N° EC:	N/A
Molecular Formula:	Not available.
Content:	70.0 per cent to 80.0 per cent of Ag (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	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.
After inhalation:	Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.
After skin contact:	Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.
After eye contact:	Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 3/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



## ARGENTUM COLLOIDALE AD USUM EXTERNUM

After ingestion:

cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

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

Not applicable.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable 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.

Unsuitable extinguishing media:

IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

### 5.2 Special hazards arising from the substance/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

Surrounding fires:

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.

Protection against fire:

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.

Hazardous combustion products:

Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

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

#### For emergency responders

Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## ARGENTUM COLLOIDALE AD USUM EXTERNUM

EN

FORM-06-14-01 (V00)

Page 4/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



### 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

See sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:

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.

Personal protection:

Not available.

Technical protective measures:

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.

Technical recommendations to prevent ergonomic and toxicological risks: Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

Technical recommendations to prevent environmental risks: It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3).

Handling:

Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

In an airtight container.

Conditions for safe storage, including any incompatibilities:

Minimum temp.: 5 °C

Maximum temp.: 40 °C

Maximum time: 4 years

Storage – away from:

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

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## 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/m<sup>3</sup> // Respirable dust 4 mg/m<sup>3</sup>

DNEL (workers): Not applicable.

DNEL (general population): Not applicable.

PNEC: Not applicable.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



## ARGENTUM COLLOIDALE AD USUM EXTERNUM

### 8.2 Exposure controls

#### Appropriate engineering control

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.

Additional emergency measures:	<u>Emergency measure</u>	<u>Standards</u>
	Emergency shower	ANSI Z358-1 ISO 3864-1:2002
	Eyewash stations	DIN 12 899 ISO 3864-1:2002

#### Individual protection measures

Eye/face protection:	PPE:	Panoramic glasses against splash/projections.
	Labelling:	CE CAT II
	CEN Standard:	EN 166:2001 EN ISO 4007:2012
	Remarks:	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.
Skin protection:	PPE:	Work clothing.
	Labelling:	CE CAT I
	Remarks:	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2001, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	PPE:	Anti-slip work shoes.
	Labelling:	CE CAT II
	CEN Standard:	EN ISO 20347:2012
	Remarks:	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345 y EN 13832-1.
Hand protection:	PPE:	Protective gloves against minor risks.
	Labelling:	CE CAT I
	Remarks:	Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374.
Respiratory protection:	PPE:	Filter mask for gases and vapours.
	Labelling:	CE CAT III
	CEN Standard:	EN 405:2001+A1:2009

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



## ARGENTUM COLLOIDALE AD USUM EXTERNUM

Remarks: Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

Thermal hazards: Not determined.

### Environmental exposure control

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.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	Green or bluish-black metallic shiny flakes or powder, hygroscopic.
Odour:	Odourless.
Odour threshold:	Not applicable. *
pH:	Not applicable. *
Melting/freezing point:	Not applicable. *
Initial boiling point:	Not applicable. *
Boiling range:	Not applicable. *
Flash point:	Not applicable. *
Evaporation rate:	Not applicable. *
Flammability (solid/gas):	Not applicable. *
Upper/lower flammability or explosive limits:	Not applicable. *
Vapour pressure:	Vapour pressure at 50 °C: < 300,000 Pa (300 kPa)
Vapour density:	Not applicable. *
Relative density:	Not applicable. *
Solubility:	Practically insoluble in ethanol (96 per cent) and in methylene chloride.
Solubility in water:	Freely soluble or soluble in water.
Partition coefficient (n-octanol/water):	Not applicable. *
Auto-ignition temperature:	Not applicable. *
Decomposition temperature:	Not applicable. *
Viscosity:	Not applicable. *
Explosive properties:	Not applicable. *
Oxidising properties:	Not applicable. *

### 9.2 Other information

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

#### 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)

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 7/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



## ARGENTUM COLLOIDALE AD USUM EXTERNUM

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

Not applicable

Contact with air

Not applicable

Increase in temperature

Not applicable

Sunlight

Not applicable

Humidity

Not applicable

### 10.5 Incompatible materials

Acids

Avoid strong acids

Water

Not applicable

Combustive materials

Not applicable

Combustible materials

Not applicable

Others

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

Acute toxicity:

LD<sub>50</sub> oral: > 2000 mg/kg

LD<sub>50</sub> dermal: > 2000 mg/kg

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: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

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: Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.

Skin corrosion/irritation:

Produces skin inflammation.

Serious eye damage/irritation:

Produces eye damage after contact.

Respiratory/skin sensitisation:

- 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.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 8/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



## ARGENTUM COLLOIDALE AD USUM EXTERNUM

Germ cell 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.
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.
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.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.
STOT-repeated exposure:	<ul style="list-style-type: none"><li>- 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.</li><li>- 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.</li></ul>
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:	The experimental information related to the toxicological properties of the product itself is not available.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	Causes skin irritation.
Inhalation:	May cause respiratory irritation.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 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.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## ARGENTUM COLLOIDALE AD USUM EXTERNUM

EN

FORM-06-14-01 (V00)

Page 9/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Description: It is not possible to assign a specific code, as it depends on the intended use by the user.

Waste class (Regulation (EU) N° 1357/2014): Dangerous.

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

HP4 Irritant — skin irritation and eye damage, HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

#### 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 recommend 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 information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), No.  
IATA/ICAO (Air) :

##### 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

Not applicable.

##### 14.8 Additional transport information

Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## ARGENTUM COLLOIDALE AD USUM EXTERNUM

EN

FORM-06-14-01 (V00)

Page 10/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant

Risk phrases:

R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases:

S7/9 Keep container tightly closed and in a well-ventilated place.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 After contact with skin, wash immediately with plenty of water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

#### 15.2 Chemical safety assessment

The supplier has not carried out evaluation of chemical safety.

### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

#### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

#### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

#### 16.4 Method of classification in case of mixture

Not applicable.

#### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

#### 16.6 Training advisement

Not available

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## ARGENTUM COLLOIDALE AD USUM EXTERNUM

EN

FORM-06-14-01 (V00)

Page 11/12

Publication: 04/03/2022

Revision: 04/03/2022

Version: 00



### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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