

Safety data sheet

according to Regulation (EC) No 1907/2006, (EU) No 2015/830

Printing date: 23.04.2017

Version number: 1

Revision: 23.04.2017

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

- **1.1 Product identifier**
- **Trade name: Colloidal Silver ARGENA**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture:**
Cleaning and protection of external parts of the human body (epidermis, hair system, nails, lips and external genital organs) teeth and mucous membranes of the oral cavity.
- **Uses advised against:** Any other than the above mentioned.
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier:**
PaedDr. Miroslav Coufal
Drahy 1424, 763 31 Brumov-Bylnice, Česká republika
IČ: 621 04 616
Tel.: +420 728 280 627 / E-mail: kinetfyz@email.cz
- **Further information obtainable from:** Ing. Karel Královec, Studio2K, E-mail: bl@studio2k.cz
- **1.4 Emergency telephone number**
Phone: +420 224 919 293 or +420 224 915 402; E-mail: tis@vfn.cz
Toxicology Information Centre in Prague (TIS), Na Bojišti 1, 120 00 Prague 2
Permanent medical information service for cases of acute poisoning of humans and animals.
National helpdesks contact details - <http://echa.europa.eu/cs/support/helpdesks/national-helpdesks/list-of-national-helpdesks>.

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is classified as dangerous in the terms of the Regulation (EC) No 1272/2008 (CLP).
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008:**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms:** Void.
- **Signal word:** Void.
- **Hazard-determining components of labelling:** Void.
- **Hazard statements:**
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements:**
P102 Keep out of reach of children.
P273 Avoid release to the environment.
P501 Dispose of contents/container in accordance with local regulations.
- **Additional information:** Void.
- **Regulation (EC) No 1223/2009 on cosmetic products:**
Cosmetic product conforming to the Regulation (EC) No 1223/2009 of the European Parliament and of the Council.
On the product packaging, list the ingredients (INCI) from section 3.2. The list shall be preceded by the term "ingredients".
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:**
The mixture does not contain substances classified as of the date of preparation of the safety data sheet as PBT pursuant to Regulation (EC) No 1907/2006 (REACH).
- **vPvB:**
The mixture does not contain substances classified as of the date of preparation of the safety data sheet as vPvB pursuant to Regulation (EC) No 1907/2006 (REACH).

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:**
Water dispersion of spherical nanoparticles of silver with an average diameter of 6 - 7 nm, with an Ag 35 ± 5 ppm (mg/l) concentration, after deionization with a reduced content of silver cations Ag⁺ < 10 %.
Contains: Aqua, Argentum Colloidal, Gummi Arabicum, Gelatin, Lactosium, (Acidum Lacticum).

- **Dangerous components:**

CAS: 7440-22-4	silver in nano form (median particle size <100 nm)	0.0035%
EINECS: 231-131-3	⚠ Aquatic Acute 1, H400 (M=1000); Aquatic Chronic 1, H410 (M=100)	
Reg.-No:01-2119555669-21-XXXX		

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CAS: 9000-01-5 EINECS: 232-519-5	Gum arabic Eye Irrit. 2, H319	0.0010%
· Non dangerous components:		
CAS: 7732-18-5 EINECS: 231-791-2	water, distilled, conductivity or of similar purity	< 100%
CAS: 63-42-3 EINECS: 200-559-2	lactose	0.0100%

· SVHC:

The product does not contain substances classified as of the date of preparation of the safety data sheet as PBT or vPvB and stated in the Candidate list of substances producing very high concerns for Appendix XIV of Regulation (EC) No 1907/2006 (REACH).

· **Regulation (EC) No 648/2004 on detergents / Labelling for contents:** Not apply.

· Additional information:

The substances named in this section are given with their actual, appropriate classification!
For substances that are listed in appendix VI, table 3.1/3.2 of the Regulation (EC) No 1272/2008 (CLP Regulation) this means that all notes that may be given here for the named classification have been taken into account.
For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· 4.1 Description of first aid measures**· General information:**

In case of doubt, appearance of symptoms or upon any problems, seek medical help and present this safety data sheet or the product label.

· **After inhalation:** This product has no generally irritating effect.

· **After skin contact:** This product has no generally irritating effect.

· **After eye contact:** This product has no generally irritating effect.

· After swallowing:

Thoroughly drink water.

If symptoms persist consult doctor.

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

Possible toxicological effects resulting from the classification are stated in Section 11.

No further relevant information is available.

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

Usually immediate medical help is not necessary.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media**· Suitable extinguishing agents:**

No extinguishing substances are determined, the mixture is not flammable. Use fire extinguishing methods suitable to surrounding conditions.

· **For safety reasons unsuitable extinguishing agents:** No extinguishing substances are determined.

· **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.

· **Additional information:** Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Respect the instructions set forth in Sections 7 and 8 of the safety data sheet.

No safety measures are necessary.

· **6.2 Environmental precautions** Do not allow product to enter sewers, surface and ground water and soil.

· 6.3 Methods and material for containment and cleaning up

Wipe off the leaked product with a paper towel and place it in the waste container.

· 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.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet. Observe directions on label and instructions for use.
- **Information about fire - and explosion protection:**
The product is not flammable.
No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Reliably prevent leakage into the soil.
Store only in unopened original receptacles.
- **Information about storage in one common storage facility:**
Store separately from chemical products containing sulphide sulfur.
- **Further information about storage conditions:**
Protect from frost.
Protect from direct sunlight and warming.
Keep out of reach of children.
Usability time: 1 month.
- **Recommended storage temperature:** Store at room temperature.
- **7.3 Specific end use(s)**
Specific use is stated in the manual for use on the product packaging label or in the product documentation.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**

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

7440-22-4 silver in nano form (median particle size <100 nm)

WEL (Great Britain)	Long-term value: 0.1 mg/m ³
IOELV (EU)	Long-term value: 0.1 mg/m ³
AGW (Germany)	Long-term value: 0.1 E mg/m ³ 8(I);DFG, EU

- **Regulatory information:**
WEL (Great Britain): EH40/2011
AGW (Germany): TRGS 900
- **DNELs:** No values available.
- **PNECs:** No values available.
- **Ingredients with biological limit values:**
The product does not contain any relevant quantities of materials with biological limit values.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures:** Not apply.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Material of gloves:** Not determined.
- **Penetration time of glove material:** Not determined.
- **Eye protection:** Not required.
- **Body protection:** Not required.
- **Thermal hazards:** Not applicable.
- **Limitation and supervision of exposure into the environment:**
Adhere to usual measures for environmental protection, see Section 6.

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance

Form: Fluid.
Colour: Orange yellow.

· Odour: Odourless.
· Odour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/freezing point: Not determined.
Initial boiling point and boiling range: Not determined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Ignition temperature: Not determined.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits

Lower: Not determined.
Upper: Not determined.

· Oxidising properties: No.

· Vapour pressure: Not determined.

· Density: Not determined.

· Vapour density: Not determined.

· Evaporation rate: Not determined.

· Solubility in / Miscibility with water: Fully miscible.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity

Dynamic: Not determined.
Kinematic: Not determined.

· Solvent content

VOC (2010/75/EC): Not apply.

· 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity: No relevant information is available.

· 10.2 Chemical stability:

Upon adhering to the determined regulations of storage and use, the product is stable (see Section 7).

· 10.3 Possibility of hazardous reactions: It reacts with substances containing sulphide sulfur.

· 10.4 Conditions to avoid:

Protect against frost.
Protect against extreme temperature and direct sunlight.

· 10.5 Incompatible materials: No incompatible materials are known.

· 10.6 Hazardous decomposition products: No decomposition when used as directed.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity: Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

7440-22-4 silver in nano form (median particle size <100 nm)

Oral LD50 > 10000 mg/kg (rat)

· Primary irritant effect

· Skin corrosion/irritation: Based on available data, the classification criteria are not met.

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- **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.
- **Additional toxicological information:** No relevant information is available.
- **Acute effects:** No acute effects are known.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):** No CMR effects are known.
- **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.
- **Other information:** No further information is available.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** Hazardous to the aquatic environment - Aquatic Chronic 3.
- **12.2 Persistence and degradability** No further relevant information available.
- **Behaviour in waste water treatment plants:** No relevant information is available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects**
- **Remark:** Harmful to fish
- **Additional ecological information**
- **General notes:**
Harmful to aquatic organisms
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:**
The mixture does not contain substances classified as of the date of preparation of the safety data sheet as the PBT pursuant to Regulation (EC) No 1907/2006 (REACH).
- **vPvB:**
The mixture does not contain substances classified as of the date of preparation of the safety data sheet as the vPvB pursuant to Regulation (EC) No 1907/2006 (REACH).
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**
Must not be disposed together with household waste. Do not allow product to reach sewage system.
Remove the remains of the product according to corresponding local directives in appropriate facilities, e.g. depositing on suitable landfills or burning in a waste incinerator.
- **Waste disposal key:**
The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances. (2001/118/EC, 2001/119/EC, 2001/573/EC).
The catalogue numbers with the asterisk (*) mark hazardous waste (N), numbers without the asterisk mark other waste (O).

- **European waste catalogue:**

18 01 07	chemicals other than those mentioned in 18 01 06
15 01 02	plastic packaging
HP 14	Ecotoxic

- **Uncleaned packaging**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Empty container completely.
Non contaminated packagings may be reused.
Non contaminated packagings may be recycled.
Cleaned packagings can be disposed as other waste.
Handover the emptied packaging to the authorised organisation, which has a licence for their disposal.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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Regulations:

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.
 Commission Regulation (EU) No 1357/2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.
 Commission Decision No 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council.

SECTION 14: Transport information

· 14.1 UN-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	Not applicable.
· 14.6 Special precautions for user	Unless specified otherwise, general measures for safe transport must be followed.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	Non-dangerous material according to Transport Regulations.
· UN "Model Regulation":	Void.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Named dangerous substances - ANNEX I:** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction for the group No 3.

Legal regulations of the European Community:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a 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 Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

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, Authorisation and Restriction of Chemicals (REACH), as amended.

Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances, as amended.

COMMISSION REGULATION (EU) 2016/918 of 19 May 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

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

SECTION 16: Other information**Warning:**

The safety data sheet contains data needed for securing safety and health protection during work and environmental protection. The stated data correspond to the current state of knowledge and experience and is in accordance with valid legal regulations. It cannot be deemed as a guarantee of the properties, suitability, and usefulness of the product for specific application and therefore no contractual legal relationships are hereby created.

The safety data sheet is the property of the physical or legal entity stated in Section 1 and is protected by copy-right. All copying, distribution or sales without the consent of the owner is forbidden.

This mixture is a cosmetic product according to Regulation (EC) No 1223/2009 and is therefore not covered by Title IV Regulation No 1907/2006 - Information in the supply chain, and also the whole Regulation (EC) No 1272/2008, both documents in the updated version.

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It follows, that he is not subject to the obligation to issue a safety data sheet.

· **Relevant phrases:**

- H319 Causes serious eye irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

· **Training hints:** Before using, read the information on the product's packaging carefully.

· **Recommended restriction of use:**

The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to adhere to the product usage conditions and to respect the safety instructions for health and environmental protection.

· **Further information:** This product must be stored, sold, and used in accordance with valid hygienic regulations.

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

Classification of the mixture was performed according to the methods given in Annex I to Regulation (EC) No 1272/2008 (CLP).

· **Department issuing SDS:** Studio2K, Ing. Karel Královec, Phone: +420 354 526 677, E-mail: info@studio2k.cz

· **First issue of SDS:** 23.04.2017

· **Internal code formula:** 1050.001

· **Documents used to prepare SDS:**

The original documents provided by the supplier or manufacturer related to the product (mixture), eventually to individual substances contained.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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)
 VOC: Volatile Organic Compounds (USA, EU)
 DNEL: Derived No-Effect Level (REACH)
 PNEC: Predicted No-Effect Concentration (REACH)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 SVHC: Substances of Very High Concern
 vPvB: very Persistent and very Bioaccumulative
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1
 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· **Sources:**

The safety data sheet was prepared in accordance with the European Parliament and Council Regulation (EC) No 1272/2008 (CLP) and according to the requirements of the European Parliament and Council Regulation (EC) No 1907/2006 about the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency - head IV, article 31, appendix II (instructions for safety data sheet compiling), as amended by the Commission Regulation (EU) No 2015/830 dated 28 May 2015.

The missing ecotoxicology and toxicology data was obtained from the ESIS (European chemical Substances Information System), specifically from the IUCLID (International Uniform Chemical Information Database). As needed, data from further available chemical databases was used.

The classification of the mixture was performed pursuant to the European Parliament and Council Regulation (EC) No 1272/2008 (CLP). The data provided by the manufacturers or importers of individual mixture components stated in their safety data sheets served as the basis.

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