

COSMETIC PRODUCT SAFETY REPORT

No 275a/06/2015/ENG

This document has been prepared in compliance with European legislation (Regulation (EC) 1223/2009 regarding cosmetic products.

Product **NANOCOLLOIDAL SILVER (H₂O Ag) NON-CHEMICAL**
The fluid to daily care of the skin and entire body, containing nanocolloidal silver non- chemical

Responsible person **GOLDEX Nowicki Piotr**
Mazurska 10
42-202 Częstochowa

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PART A

COSMETIC PRODUCT SAFETY INFORMATION

Product **NANOCOLLOIDAL SILVER (H₂O Ag) NON-CHEMICAL**
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1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE PRODUCT

1.1. Qualitative and quantitative formulation

	Supplier/code number	Chemical name	INCI	CAS*	Concentration %	Function
1.	SENA	Demineralised water	Aqua	7732-18-5	-	SOLVENT
2.	GOLDEX	Colloidal silver	Silver	7440-22-4	0.015 /wag	ANTIMICROB AL

* Chemical names of raw materials and supplier details are included in raw materials specification charts in the possession of the manufacturer.

	Name of the substance
Nanomaterials	Colloidal silver
Substances qualified as CMR	-
Substances listed in annexes I-VI	-

2. BRIEF DESCRIPTION OF THE TECHNOLOGICAL PROCESS

Improved dispersion-condensation method in the micro-electric arc when the dispersion medium is demineralised water; combined with the Svedberg's method.

3. PHYSICAL/CHEMICAL CHARACTERISTICS OF THE COSMETIC PRODUCT

3.1. Physical and chemical characteristics of the substances or mixtures	
In compliance with the respective MSDS	Physical and chemical properties of the raw materials give no cause for concern. Inconsistencies not detected.
3.2. Physical and chemical characteristics of the cosmetic product	
Appearance	Transparent liquid
Colour	Colourless

Fragrance	Odourless
pH	5,5-7
Viscosity	n/a
Density	n/a
Supplementary characteristics	Absence
3.3. Stability of the cosmetic product	
Test type	n/a
Report No.	n/a
Measured parameters	n/a
Range of temperatures	n/a
Test result	n/a

4. MICROBIOLOGICAL QUALITY

4.1. Microbiological quality of the substances or mixtures	
In compliance with the microbiological specifications	The purity of the finished product indicates the microbiological purity of the raw materials.
4.2. Microbiological quality of the product	
Test methodology	The procedure PM-04 Issue 2 dated 12.05.2014
Report No.	02/03/15/CK/K
Tested microorganisms	Aerobic mesophilic microorganisms
4.3. Test results	Consistent with requirements

5. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

5.1. Impurities, traces

Impurities, traces	Impurities endangering the human health not identified.
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5.2. Information about the packaging material

Producer	PETPOWER, EASTAR
Packaging type/material	Bottle, PET
Microbiological purity	Microbiologically pure
Impurity	Absence
Stability	Stable at temperatures: 0 – 40 °C
Packaging compatibility	Compatible
Possible interactions	Absence


6. NORMAL AND REASONABLY FORSEEABLE USE

Normal use	Skin care
Potential use	Absence

Target population(s)	Persons at age 20 - 60
Site(s) of application	Skin of face, neck and lowerneck, partly

7. PACKAGING DESIGN/LABELLING

STORE AT ROOM TEMPERATURE ! www.goldex.com.pl



**NON-CHEMICAL NANOCOLLOIDAL
SILVER (H₂O Ag)**

Daily face and body cleansing solution with non-chemical nanocolloidal silver


NOT APPROPRIATE FOR PERSONS ALLERGIC TO NOBLE METALS!

Effect: Perfectly cleansed and moistened face skin. The product facilitates daily regimen for problematic skin, prone to the appearance of pimples, cold sores, acne, irritation or redness. Due to its antibacterial properties, the solution reduces the unpleasant odor and increased production of sweat. Perfect as an after shave. Leaves your skin comfortably fresh.

Application: Apply on dry skin of the face or body. Leave to absorb.

Ingredients: Aqua, Silver (nano) **DERMATOLOGICALLY AND IN VIVO TESTED**

<p>INCI Name - Aqua (Water) CAS 7732-18-5 EC 232-791-2</p>	<p>Concentration: 50 ppm Serial no.: --/---/--</p>	<p>Producer: GOLDEX ul. Mazurska 10 42-202 Częstochowa info@goldex.com.pl Made in Poland</p>
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STORE IN A DARK PLACE ! **Best before: ---/---/--- 1000 ml**

INFORMATION:

Content of the packaging material is an integral part of the safety assessment, however the responsible person is obliged to provide it for the regulatory compliance.

8. EXPOSURE TO THE COSMETIC PRODUCT

8.1. Exposure to the cosmetic product

Type of the product	Left on skin
Surface area(s) of application	15670 cm ²
Amount of product applied	7,82 g
Duration and frequency of use	Twice a day
SED	123,20 mg/kg/day
Possible secondary exposure	Possibility eye irritation

8.2. Exposure to the substances

INCI	SED	MoS
Silver	0,0185	Impossible to calculate

SED = Systemic exposure dose expressed in mg/kg/day

MoS = Margin of Safety

Due to the ban on animal testing for finished cosmetic products, cosmetic ingredients and their combinations, which has been in force in the European Union since 2009, the NOAEL value is unknown, so that the Margin of Safety cannot be calculated. This applies to the components of the product for which the value of the MoS has not been calculated.

Literature data concerning the subject of the tests in the possession of the Safety Assessor.

9. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

Silver- (Ag)- has been known to be a potent antibacterial, antifungal and antiviral agent, but in recent years, the use of silver as a biocide in solution, suspension, and especially in nano-particulate form has experienced a dramatic revival. Due to the properties of silver at the nano level, nanosilver is currently used in an increasing number of consumer and medical products. The remarkably strong antimicrobial activity is a major reason for the recent increase in the development of products that contain nanosilver.

Researchers have shown that while exposure to nanosilver is toxic under certain experimental conditions, other researchers have shown that nanosilver is non-toxic under similar experimental conditions. From a review of the toxicological studies being conducted in the literature, it is becoming increasingly apparent that the main difference in the outcome of the toxicity studies is due to variations in physicochemical features of the nanosilver being used in various studies. The physicochemical features of the nanoparticles must be characterized under the experimental setting so that definitive associations between these parameters and any biological responses observed may be identified. There are difficulties in monitoring nanomaterial behavior when dispersed in physiological solutions as the latter often contain particulate and charged materials that will mask the true size distribution and charge measurements of the nanomaterials themselves. Agglomeration can also be temperature dependent and so measurements should be made at a constant temperature, which requires temperature- controlled equipment. Many of the techniques currently available to assess surface area, morphology and composition are reliant on dry samples and are difficult to apply to nanomaterials in solution. In a porcine model of wound healing, nanosilver wound dressing promoted rapid wound healing of full-thickness wounds on the back of pigs. (EPA/600/R-10/084 August 2010).

The results of tests in volunteers have shown no sensitisation nor allergenicity. The toxicological profile of silver is appropriate for a cosmetic component. The lethal dose given orally to mice is over 10g/kg. The lethal dose given orally to Guinea pigs is over 5g/kg.

NOTE

Physical and chemical characteristics of individual raw materials are contained in the Safety Data Sheets and Raw Material Specifications. The manufacturer shall be responsible for their accuracy.

9.1. Information on the adverse effects of the cosmetic product

No data on the undesirable effects from the competent authority. The responsible person shall monitor these activities.

10. INFORMATION ON THE COSMETIC PRODUCT

10.1. Tests results

Tests	Report No., results
Microbiological tests	182/14/Gold/TK- pure
Dermatological tests	B – 170/15, negative result
Assessment of the product claims	B - 0300/15, confirmed
Usage/Instrument tests	n/a
UV protection tests	n/a

10.2. Responsible persons

Contact person (coordinator)

Name	Nowicki Piotr
Address	Mazurska 10, 42-202 Częstochowa
Phone	601-500-565
E-mail	info@goldex.com.pl

Manufacturing, packaging and quality control

Name	Nowicki Piotr
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PART B

COSMETIC PRODUCT SAFETY ASSESSMENT

Product	NANOCOLLOIDAL SILVER (H₂O Ag) NON-CHEMICAL The fluid to daily care of the skin and entire body, containing nanocolloidal silver non- chemical
Responsible person	GOLDEX Nowicki Piotr Mazurska 10 42-202 Częstochowa

1. ASSESSMENT CONCLUSION

Cosmetic product listed below of the domestic production of the declared by the manufacturer chemical composition used for the intended purpose and method of use, do not pose a risk to the human health and is prepared in accordance with the Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products (Official Journal of the European Union L 342, 22.12.2009).

2. LABELLED WARNINGS AND INSTRUCTIONS OF USE

The label of the product does not give rise to concern.

3. REASONING

Toxicological assessment of the components included in the product has been made on the basis of data collected in part A of the safety assessment report and::

1. Material Safety Data Sheets of the individual substances.
2. Raw Material Specifications of the individual substances.
3. CIR Toxicological database.
4. GRASS Database.
5. The existing opinions of SCCS.
6. CCRIS Database.
7. GENETOX Database.
8. DART Database.
9. HSDB Database.
10. CPDP Database.
11. IRIS Database.
12. Available scientific publications.

Qualitative and quantitative composition of the product

Substances contained in the product comply with the requirements laid down in the Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of 30 November 2009. On cosmetic products (Official Journal of the European Union L 342, 22.12.2009

Physical and chemical properties of the raw materials and the finished product

The physicochemical properties of the individual components do not raise objections, and do not adversely affect the safety and toxicological profile of the finished product. No evidence of non-compliance prescription.

Stability of the finished product

Tests not performed due to the nature of the mass.

Microbiological quality of the raw materials

The microbiological specifications of the raw materials indicate their purity, none of the individual raw materials do not pose a risk to the human health in terms of microbiology.

Microbiological quality of the finished product and the effectiveness of the preservative system

Conducted microbiological test indicates appropriate quality of the finished product. The results of preservation challenge test confirm the effectiveness of the preservative system.

Impurities, traces, material of packaging

Impurities that threaten the human health have not been found.

The material from which the package was done does not adversely affect the safety of the product

The packaging is devoid of technical and microbiological impurities.

Labeling of the product is satisfactory.

Normal and reasonably foreseeable use, exposure to the individual substances, and the finished cosmetic product.

The look of the product and its labeling clearly indicate the manner of use. Therefore, the risk of misuse of the product is low. The margin of safety calculated for the individual substances is above the 100, so it is assumed that these substances are safe for the human health. A full assessment of the risk associated with the operation of the other ingredients and the finished product is based on the available literature data, databases and toxicological research, as well as the own experience and knowledge. The product as the subject of the normal and reasonably foreseeable use does not pose a threat to the human health.

Toxicological profile of the substance

Toxicological profiles of raw materials do not raise objections. Safety assessment of substances or mixtures was done on the basis of molecular weight, the LogPo / w and a long history of safe use in cosmetic and food industries

While assessing the individual components the following criteria were taken into account: acute toxicity via the relevant routes of exposure, skin, mucous membranes and eyes irritation and corrosion, skin sensitization, skin absorption, repeated dose toxicity, mutagenicity, carcinogenicity and reproductive toxicity, and also toxicokinetics and phototoxicity.

The tests performed

There were dermatological tests carried out - with the participation of carefully selected volunteers, under the supervision of dermatologists – with the use of the dermatological patch test method according to the semi-open Declaration of Helsinki with the later subsequent additions, the EU and the Republic of Poland rules and the guidelines of the Cosmetics Europe. The above indicate a lack of irritation and allergy effects of the finished product.

NOTES:

The product should be reported to the portal CPNP portal as the product containing nanomaterials.

Any change in the chemical composition, scope and method of use or trade name of the product should be re-examined by an assessor safety of the product.

Safety assessment is not authoritative for people who are allergic to any component of the product being evaluated.

4. APPROVAL PART B AND QUALIFICATIONS OF THE EXPERT

4.1. Approval of part B

The product **NANOCOLLOIDAL SILVER (H₂O Ag) NON-CHEMICAL** The fluid to daily care of the skin and entire body, containing nanocolloidal silver non- chemical is considered to be safe for the human health under normal or reasonably foreseeable conditions of use.

4.2. Expert qualifications

Name and surname of the Safety Assessor

Piotr Koziej

Qualifications of the Safety Assessor:

Doctor of pharmaceutical sciences

Safety Assessment of Cosmetics in the EU, Vrije Universiteit Brussels Brussels iPAVUB Certificate 2003
Safety Assessment of the Cosmetics in the EU, Brussels 2009
Intensive Course in Dermato-Cosmetic Sciences, Brussels, Belgium, 2004, 2005, 2007, 2008, 2009. Member: Safety Assessor Responsible Person European Association working groups of the Polish Association of Cosmetics Industry

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01.07.2015

Signature



1. The test report without the approval of the laboratory cannot be reproduced except by a whole. Another form of copying require the written approval of the Contractor.
2. The results relate only to the product of the prescription composition provided by the Principal.