

COSMETIC PRODUCT SAFETY REPORT
No 2637a/2015

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

Product **COLLOIDAL GOLD (H₂O Au) NON-CHEMICAL**
The unique skincare product containing colloidal gold to moisturise and regenerate the skin

Responsible person **GOLDEX Nowicki Piotr**
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PART A

COSMETIC PRODUCT SAFETY INFORMATION

Product **COLLOIDAL GOLD (H₂O Au) NON-CHEMICAL**
The unique skincare product containing colloidal gold to moisturise and regenerate the skin

Responsible person GOLDEX Nowicki Piotr
Mazurska 10
42-202 Częstochowa

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 gold	Gold	7440-57-5	0.015 /wag	SKIN CONDITIONING
3.	GOLDEX	Colloidal silver	Silver	7440-22-4	1	ANTIMICROBAL

	Name of the substance
Nanomaterials	Gold, 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	Pink
Fragrance	Odourless

pH	6-7
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 05/12/2014
Report No.	09/08/14/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, tests not performed due to the nature of the mass.
Possible interactions	Absence


6. NORMAL AND REASONABLY FORSEEABLE USE

Normal use	Skin care
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Potential use	Absence
Target population(s)	Persons at age 20 - 60
Site(s) of application	Skin of face, neck and lowerneck

7. PACKAGING DESIGN/LABELLING

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



***NON-CHEMICAL NANOCOLLOIDAL
GOLD (H₂O Au)***


Unique moisturizing, regenerative and nurturing formula with nanocolloidal gold

NOT APPROPRIATE FOR PERSONS ALLERGIC TO NOBLE METALS !

Effects: Moisturizes and regenerates your skin through stimulation of collagen synthesis, preventing appearance of wrinkles. Restores softness, firmness and radiance.

Application: Apply on dry skin of the face, neck and upper chest. Leave to absorb.

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

<small>INCI Name: Aqua (Water) CAS 7732-18-5 EC 231-791-2</small>	<small>INCI Name: Silver (Silver) CAS 7440-22-4 EC 231-131-3</small>	<small>Producer: GOLDEX ul. Mazurska 10 42-202 Częstochowa info@goldex.com.pl Made in Poland</small>
<small>Concentration: 50 ppm Serial no.: --/---/--</small>		

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	565 cm ²
Amount of product applied	1,54 g
Duration and frequency of use	Twice a day
SED	24,14 mg/kg/day
Possible secondary exposure	Possibility eye irritation

8.2. Exposure to the substances

INCI	SED	MoS
Gold	0,0036	Impossible to calculate
Silver	0,2414	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

Colloidal Gold- gold is a precious element which occurs in nature primarily in free elemental(native) form. It is chemically resistant to various chemicals. It occurs in the human body, in bones, in amount of less than 10 mg. It is used in medicine and dentistry. Orally administered shows no toxic effects. Under current legislation gold is listed on the list of colorants (as CI 77480) allowed for use in cosmetics. It is placed on the above list in the first column, which means that it can be used in all cosmetics without restrictions on use. Colloidal Gold is not a threat to the human health.

Silver- silver (Ag) -a metal from the group I of the periodic table of elements classified as a precious metal. It is the best conductor of heat and electricity of all the metals. In nature, it also occurs in the form of minerals, such as argentyd (silver sulfide) bromargiryt (AgBr), kerargiryt (AgCl). Silver is a component of the numerous metal alloys. Due to the physical and chemical properties of silver, its alloys and chemical compounds find the numerous applications in industry, electrical engineering and photography. Silver has also antibacterial properties, known since antiquity. Therefore, the antibacterial properties of silver may be also used for cosmetic purposes. The results have shown that the addition of colloidal silver in a concentration of 0.5 ppm inhibits the growth of microorganisms (*Enterococcus hirae*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus*, *Candida albicans*) after 15 minutes. The results of tests conducted in a group of volunteers showed lack of irritation and sensitization. The toxicological profile of silver is suitable for cosmetic ingredient. A lethal dose administered orally to mice is more than 10 g / kg; lethal dose administered orally to guinea pigs is more than 5 g / kg. Therefore, the silver does not present a health hazard.

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	127/14/Gold/TK- pure
Dermatological tests	B - 1101/14, negative result
Assessment of the product claims	B - 1101/14, 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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Phone	601-500-565
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PART B

COSMETIC PRODUCT SAFETY ASSESSMENT

Product	COLLOIDAL GOLD (H₂O Au) NON-CHEMICAL The unique skincare product containing colloidal gold to moisturise and regenerate the skin
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 GOLD (H2O Au) NON-CHEMICAL The unique non-chemical skincare product for moisturizing, regenerating and skin care containing colloidal gold** 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
Qualifications of the Safety Assessor:

Piotr Koziej
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

Adress:

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21.01.2015

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.