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INSTYTUT BADAŃ KOSMETYKÓW

COSMETIC PRODUCT SAFETY REPORT
No OB/663/12/2016/ENG

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

Product	**Formulation for personal hygiene and skin care (H_2O Au Ag Cu) containing non-chemical gold, silver and nanocolloid copper**
Responsible person	GOLDEX Nowicki Piotr Mazurska 10 42-202 Częstochowa

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PART A

COSMETIC PRODUCT SAFETY INFORMATION

Product	**Formulation for personal hygiene and skin care (H_2O Au Ag Cu) containing non-chemical gold, silver and nanocolloid copper**
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	Material Description	INCI	CAS*	%	Function
1	SENA	Demineralized water	Aqua	7732-18-5	99,9985	SOLVENT
2	GOLDEX	Colloidal gold 50 ppm	Gold	7440-57-5	0,0015	SKIN CONDITIONING
3	GOLDEX	Colloidal silver 50 ppm	Silver	7440-22-4	0,0015	ANTIMICROBAL
4	GOLDEX	Colloidal copper 50 ppm	Copper	7440-50-8	0,0015	COLORANT

Metal concentration is cited in % in 1000 ml of demineralized water.
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	Gold Silver Copper
Substances qualified as CMR	Not present
Substances listed in annexes I-VI	Colloidal Silver Colloidal Copper

2. BRIEF DESCRIPTION OF THE TECHNOLOGICAL PROCESS

The improved dispersion-condensation method in electric micro voids in the dispersion medium (demineralized water) associated with the method of Svedberg.

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	Liquid with a slightly pink tint
Colour	Light pink
Fragrance	Odorless
pH	5,47-6,07
Viscosity	Does not concern
Density	Does not concern
3.3. Stability of the cosmetic product	
Test type	Does not concern
Report No.	Does not concern
Measured parameters	Does not concern
Range of temperatures	Does not concern
Test result	Does not concern

4. MICROBIOLOGICAL QUALITY

Microbiological quality of the substances or mixtures	
In compliance with the microbiological specifications	Purity of the finished product indicates the microbiological purity of raw materials
Microbiological quality of the product	
Test methodology	The Procedure PM-04, Issue 2 dated 12/05/2014
Report No.	PAZ16-002263-01
Tested microorganisms	Mesophilic aerobic microorganisms The number of yeasts and molds
Test results	Meet the requirements

5. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

5.1. Impurities, traces

Impurities, traces of prohibited substances	There are no impurities and traces of prohibited substances threaten to human health.

5.2. Information about the packaging material

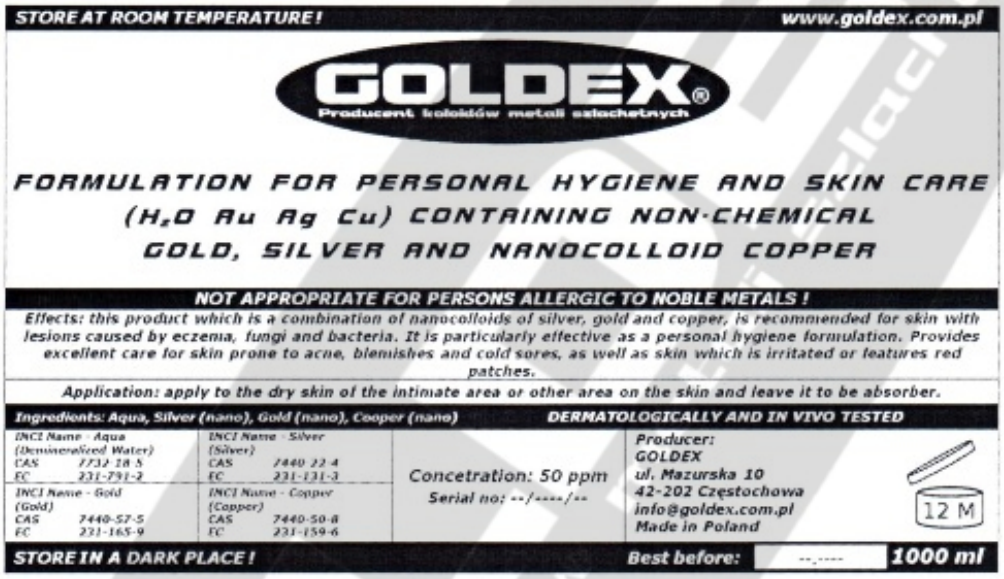
Manufacturer	PETPOWER, EASTAR
Material used to manufacture particular elements of packaging	PET, PETG
Declaration of packaging compatible with the requirements of the Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.	YES
Substances classified as CMR or skin irritants category 1A and 1B or 2, pursuant to Annex VI to the 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.	Not applicable because the packaging has the declaration of compatibility with the requirements on materials and articles intended to come into contact with food
Substances prohibited or allowed for use with restrictions under the annexes ii or iii to the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.	Not applicable because the packaging has the declaration of compatibility with the requirements on materials and articles intended to come into contact with food
Presence of heavy metals	Not applicable because the packaging has the declaration of compatibility with the requirements on materials and articles intended to come into contact with food
SVHC (Substances of Very High Concern) Substances pursuant to REACH Regulation 1907/2006 (Art.33)	Not applicable because the packaging has the declaration of compatibility with the requirements on materials and articles intended to come into contact with food
Potential migration of substances contained in the packaging to the cosmetic mass.	Not applicable because the packaging has the declaration of compatibility with the requirements on materials and articles intended to come into contact with food
Possible interactions between the mass and packaging	Not applicable because the packaging has the declaration of compatibility with the requirements on materials and articles intended to come into contact with food
Compatibility of the packaging with the mass	Does not concern
Packaging stability	Does not concern

On the basis of the guide for the safety assessment of a packaging in accordance with Regulation 1223/2009

6. NORMAL AND REASONABLY FORSEEBLE USE

Normal use	Skin care
Potential use	n/a
Target population(s)	20-60 years old
Site(s) of application	Skin on the face, neck, intimate areas; topically

7. PACKAGING DESIGN/LABELLING



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	Leave-on
Surface area(s) of application	17 500 cm^2
Amount of product applied	18,67 g
Duration and frequency of use	Twice a day
SED	**311,17 mg/kg/doba**
Possible secondary exposure	Not occur

8.2. Exposure to the substances

INCI	SED	MoS
Colloidal Gold	0,0046	Lack of absorption. Not calculated
Colloidal Silver	0,0046	Lack of absorption. Not calculated
Colloidal Copper	0,0046	Lack of absorption. Not calculated

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 (NOAEL, LOAEL, NOEL, LOEL, BMD, VSD) in the possession of the Safety Assessor.

9. TOXICOLOGIACAL PROFILE OF THE SUBSTANCES

Colloidal Gold – colloidal gold. Gold, precious element, present in nature primarily in the native state, is chemically resistant to different chemical compounds. It occurs in the human body, bones, of less than 10 mg. It is used in medicine and dentistry. Oral administration does not have any toxic effects. Under current legislation it is listed as dyes (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 human health.

Colloidal Silver – Silver (Ag) – a metal of group I of the Periodic Table. It is counted among the precious metals. It has antibacterial properties, known since antiquity. The results showed 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 dermatological study conducted in volunteers showed no irritation and sensitization. The toxicological profile of silver is suitable for a cosmetic ingredient. A lethal dose orally administered to mice is more than 10 g/kg; lethal dose orally administered to guinea pigs is more than 5 g/kg. Accordingly, the use of the preparation with a concentration of 50 ppm of silver as an ingredient in cosmetics does not present a health hazard.

Colloidal Copper – copper – an element present in the human body. It is essential for blood formation. Daily demand for copper in the human body is 8 mg. Therefore, the use of the "Formulation for personal hygiene and skin care (H_2O Ag Au Cu), containing non-chemical gold, silver and noncolloidal copper", as an ingredient in cosmetics 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.
Monitoring for undesirable effects is carried out according to the guidelines of the European Commission.
The confirmed reported side effects: None.
Confirmed notifications of serious adverse reactions: None.

10. INFORMATION ON THE COSMETIC PRODUCT

10.1. Tests results

Tests	Report No., results
Challenge test	PAZ16-002263-02, positive
Dermatological tests	B – (517a/09/2016), negative
Assessment of the product claims	B – 517b/09/2016, confirmed
UV protection tests	n/a

10.2. Responsible persons

Contact person (coordinator)

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Manufacturing

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Packaging

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Quality Control

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PART B

COSMETIC PRODUCT SAFETY ASSESSMENT

Product	**Formulation for personal hygiene and skin care (H_2O Au Ag Cu) containing non-chemical gold, silver and nanocolloid copper**
Responsible person	GOLDEX Nowicki Piotr Mazurska 10 42-202 Częstochowa

1. ASSESSMENT CONCLUSION

Cosmetic product listed below 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. ECHA Database.
13. 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 final product

Badań stabilności nie wykonywano ze względu na rodzaj masy i skład produktu.

Microbiological quality of the raw materials

Microbiological specifications of the particular raw materials are in the possession of the manufacturer. However, the purity of the finished product indicates the absence of microbial contamination.

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

There is no impurities threaten to human health.

The material that has been used for packaging making does not have any negative influence on the product safety. Completeed tests do not indicate any migration of the substance contained in the package to the product.

The packaging is devoid of technical and microbiological impurities.

Labelling does not give rise to any concerns.

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

The look of the product and its labelling 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:

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

Product **Formulation for personal hygiene and skin care (H_2O Au Ag Cu) containing non-chemical gold, silver and nanocolloid copper** 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; Court-certified expert at the District Court in Warsaw
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27.12.2016

Signature

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2. The results relate only to the product of the prescription composition provided by the Principal.