



Department of application and implementation research for cosmetics and chemical industries and specialized research for light industry



Cracow, August 03<sup>rd</sup> 2020 Copy 1 of 1

# REPORT FROM DERMATOLOGICAL RESEARCH (PATCH TEST)

Test number:

25/06/20/D/10

The Purest Solutions Intensive Hydration Serum

name and address of the Principal:

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We confirm the quality, efficacy and safety

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#### 1. BASIS OF TEST IMPLEMENTATION

- Order received on June 25<sup>th</sup>, 2020 with the assigned number 25/06/20/D/10
- Samples of the product delivered by the Principal
- Confirmation of positive results of microbiological researches attached by the Principal
- Quality composition of the product provided by the Principal:

INCI: Aqua, Ahnfeltia Concinna Extract, Sodium Hyaluronate Crosspolymer, Sodium Hyaluronate, Sodium Acetylated Hyaluronate, Hydrolyzed Sodium Hyaluronate, Hydroxyethylcellulose, Propylene Glycol, Panthenol, Inulin, Fructose, Hydrolysed Collagen, Triethanolamine.

## 2. PURPOSE OF THE RESEARCH

Dermatological safety assessment of the product – evaluation of the potential irritant and sensitizing properties.

### 3. LEGAL BASE OF THE RESEARCH:

- Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of November 30, 2009, relating to cosmetic products.
- Cosmetics Europe- The Personal Care Association Guidelines "Product test Guidelines for the Assessment of Human Skin Compatibility 1997"
- WMA Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects (1964r. and later changes)

## 4. PROBAND SELECTION

Probands taking part in the study were selected on the bases of:

- The current Polish and European law
- COLIPA Guidelines
- Declaration of Helsinki (1964) (with later additions)

10 women, aged 22 – 73 years were selected for the dermatological tests of the product. All of the probands selected for testing met the requirements for inclusion in the study, signed an agreement to participate in the study and were informed about: the purpose of the study, how it is carried out and what are the possible side effects. During the tests all the probands were under constant dermatological care.

## 5. METHODS AND DESCRIPTION OF RESEARCH

Dermatological tests were performed in accordance with the COLIPA Guideless for the Assessment of Human Skin Compatibility 1997". Test has been conducted on group of 10 individuals using Jodassohn-Bloch model (with Rudzki modifications). Reading the tests and results registration has been done in accordance with the recommendations of the International Contact Dermatitis Research Group (ICDRG).

Standard IQ chambers were used for patch testing. A small amount of product was applied to patients forearm for 48 hours and then removed. Baseline readings were recorded 30 minutes after removal of product from skin. Additional readings were performed after 72, 96 hours and one week after test application for product to show delayed reactions. Readings evaluation was done according to graphic scale which was consistent with generally accepted clinical dermatological scale.

## 6. **DURATION OF RESEARCH**

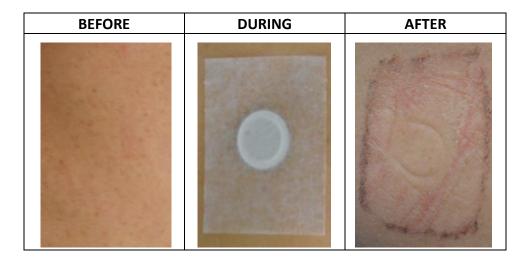
All the tests and analysis of their results were conducted from July 16<sup>th</sup>, 2020 to July 30<sup>th</sup>, 2020. Tests were completed by all enrolled people.

## **RESULTS**

NI -	Identification number	Sex	Age	Test result			
No.				48 h	72 h	96 h	one week
1	25/06/20/D/10-1	F	26	(-)	(-)	(-)	(-)
2	25/06/20/D/10-2	F	25	(-)	(-)	( - )	(-)
3	25/06/20/D/10-3	F	22	( - )	( - )	( - )	( - )
4	25/06/20/D/10-4	F	26	(-)	(-)	( - )	(-)
5	25/06/20/D/10-5	F	73	( - )	( - )	( - )	(-)
6	25/06/20/D/10-6	F	26	( - )	( - )	( - )	(-)
7	25/06/20/D/10-7	F	48	( - )	( - )	( - )	(-)
8	25/06/20/D/10-8	F	64	( - )	( - )	( - )	(-)
9	25/06/20/D/10-9	F	60	( - )	( - )	( - )	( - )
10	25/06/20/D/10-10	F	47	(-)	(-)	(-)	(-)

**F** – female

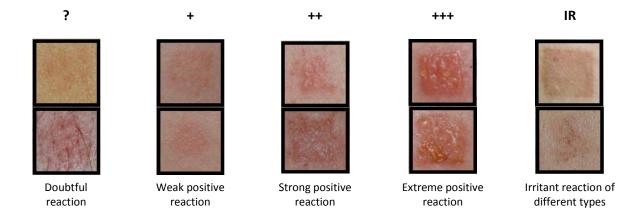
M – male



## **INTERPRETATION OF PATCH TEST**

Reading the test and writing their results have been done in accordance with the recommendations of the International Contact Dermatitis Research Group (ICDRG).

Record	Diagnosis	Interpretation		
-	Negative reaction	No skin lesions		
?	Doubtful reaction	Faint erythema only		
+	Weak positive reaction	Palpable erythema, infiltration, possibly papules		
++	Strong positive reaction	Erythema, infiltration, papules, vesicles		
+++	Extreme positive reaction	Intense erythema, infiltration and coalescing vesicles, bullous or ulcerative reaction		
IR	Irritant reaction of different types	Discrete patchy erythema without infiltration.		



#### **RESULT:**

None of 10 people, who were exposed to Patch Testing have shown positive reactions during the test reading.

## **CONCLUSION:**

## **Tested product**

## The Purest Solutions Intensive Hydration Serum

does not exhibit any allergic or/and irritating properties.

Published opinion does not concern people who are allergic to ingredients of the tested product.

Signature of the person responsible for the report

Signature of the person responsible for dermatological evaluation

Doctor of medicine Barbara Wnuk DERMATOLOGIST AND VENEROLOGIST KR 5562935 Signature of the approving person