

**REPORT No. 714541/24/INT/S**

|                                                          |            |                                                                                                                                                               |
|----------------------------------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sponsor:                                                 |            | Investigational product (according to declaration of the Sponsor)<br><br><b>R24-34395; R24112635 - PROLOM ANTI-AGE FACE CREAM, 50ml (ID NUMBER: DS170501)</b> |
| <b>SP Laboratorija A.D., 21220 BECEJ, INDUSTRIJSKA 3</b> |            |                                                                                                                                                               |
| Sample reception date:                                   | 14.11.2024 |                                                                                                                                                               |
| Start of study:                                          | 03.12.2024 |                                                                                                                                                               |
| End of study:                                            | 06.12.2024 |                                                                                                                                                               |
| Report date:                                             | 09.12.2024 | Sample status: no objections<br>Sample received from the Sponsor                                                                                              |

**DERMATOLOGICAL TEST - PRESENCE OF AN ALLERGIC  
REACTION/CONTACT ECZEMA. IN VIVO SKIN IRRITATION METHOD -  
SEMI-OPEN TEST (25 SUBJECTS WITH ALLERGOLOGICAL HISTORY,  
25 SUBJECTS WITHOUT ALLERGOLOGICAL HISTORY)**

**REPORT No. 714541/24/INT/S****THE STUDY IS COMPLIANT WITH:**

- Regulation of the European Parliament and of the Council (EC) No. 1223/2009 of 30 November 2009 on Cosmetic Products.
- Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines Product Test Guidelines for the Assessment of Human Skin Compatibility 1997.
- Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.

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**REPORT No. 714541/24/INT/S****1. BASIS OF THE STUDY**

The test sample was delivered by the Client.

The qualitative composition of the product was delivered by the Client.

The results of microbiological purity of the product provided by the Client (or the Client's declaration concerning microbiological purity) do not apply to low microbiological risk products.

The Client is responsible for compliance with the declared qualitative composition and microbiological purity of the product sample sent for testing.

**2. OBJECT OF THE STUDY**

| Parameter    | Description                                                             |
|--------------|-------------------------------------------------------------------------|
| Intended use | Cosmetic                                                                |
| Packaging    | Replacement packaging containing the name and sample number for testing |

**3. QUALITATIVE COMPOSITION OF THE PRODUCT**

The qualitative composition was delivered to the Laboratory by the Client before the start of the study.

**4. PURPOSE OF THE STUDY**

The purpose of the study was to assess irritating properties (skin tolerance) of the product on a healthy adult skin, with applied patch test.

**REPORT No. 714541/24/INT/S****5. DESCRIPTION OF VOLUNTEERS**

The volunteers (50 people) were healthy, 25 people with negative and 25 people with positive history of allergies. The selection of the group included the criteria of inclusion and exclusion. General inclusion criteria: healthy men and women over 18 years old, phototype: I-IV on Fitzpatrick scale, Caucasians, skin without irritations or changes requiring pharmacological treatment. General exclusion criteria: volunteers who use any treatment on the skin area subject to the study, volunteers exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the study, pregnant or breastfeeding women or women planning a pregnancy during the study. None of the volunteers reported documented oversensitivity or history of adverse reactions to individual ingredients of the product tested. All the volunteers fulfilled the requirements of inclusion for tests and signed the Informed Consent Form (ICF). Additionally, they were informed on the purpose, methodology of the study and possible adverse effects. The skin at the application spot (arms or interscapular area) was healthy, without lesions. The volunteers were advised to exercise caution in handling the applied contact tests.

**6. TESTING METHODOLOGY**

The preparation in an appropriate concentration is applied onto filter paper discs of 12 mm diameter, manufactured by SmartPractice® and then fixed to the arm or interscapular area with the use of a sticking patch. At the same time, in order to guarantee objective results of the study and to exclude possible reading errors connected with dermal irritations, two control samples (control sample called "blind" and control sample containing water) are used. The dermatologist removes the patch 48 hours after the application and examines the skin reaction 30 minutes after the removal. 72 hours after the application, the dermatologist examines the skin again for a reaction. If irritations appear or persist 72 hours after the application, an additional examination takes place after 96 hours. While determining the skin reaction, the dermatologist assesses the irritating and sensitising effects of the tested product. The study results may be influenced by factors such as lifestyle, stress, diet and environmental conditions, etc.

\*Dermatological test - Presence of an allergic reaction/contact eczema. In vivo skin irritation method - semi-open and closed test PB-561 ed. 3 of 15.01.2024

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**7. EVALUATION PARAMETERS**

| <b>EVALUATION PARAMETERS OF SKIN REACTION</b>                                                          |                             |
|--------------------------------------------------------------------------------------------------------|-----------------------------|
| <b>Erythema</b>                                                                                        | <b>Classification point</b> |
| No erythema                                                                                            | 0                           |
| Light erythema                                                                                         | 0.5                         |
| Erythema<br>and/or papules                                                                             | 1                           |
| Erythema<br>and/or papules<br>and/or vesicles                                                          | 2                           |
| Erythema<br>and/or papules<br>and/or vesicles<br>and/or blisters                                       | 3                           |
| Erythema<br>Bullous and/or ulcerative reaction<br>and/or papules<br>and/or vesicles<br>and/or blisters | 4                           |
| <b>Edema</b>                                                                                           | <b>Classification point</b> |
| No edema                                                                                               | 0                           |
| Very light edema (hardly visible)                                                                      | 1                           |
| Light edema                                                                                            | 2                           |
| Moderate edema (about 1mm raised skin)                                                                 | 3                           |
| Strong edema (extended swelling even<br>beyond the application area)                                   | 4                           |

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**8. RESULTS**
**8.1. CHARACTERISTICS OF VOLUNTEERS**
**Table 1**

| No. of subject | Identification of subject | Beginning of the study | Age            | Sex | Phototype                 |
|----------------|---------------------------|------------------------|----------------|-----|---------------------------|
| 1              | MOK.PA                    | 03.12.2024             | 24             | F   | II                        |
| 2              | BOC.AL                    | 03.12.2024             | 46             | F   | II                        |
| 3              | WOZ.MA                    | 03.12.2024             | 26             | F   | II                        |
| 4              | ZAW.AG                    | 03.12.2024             | 42             | F   | II                        |
| 5              | WEN.MO                    | 03.12.2024             | 27             | F   | II                        |
| 6              | ROK.BA                    | 03.12.2024             | 62             | F   | II                        |
| 7              | GAS.ZE                    | 03.12.2024             | 55             | F   | II                        |
| 8              | KLI.JA                    | 03.12.2024             | 56             | M   | II                        |
| 9              | JAW.LU                    | 03.12.2024             | 51             | F   | II                        |
| 10             | KUB.KL                    | 03.12.2024             | 48             | F   | II                        |
| 11             | GAN.AG                    | 03.12.2024             | 27             | F   | II                        |
| 12             | DAW.NA                    | 03.12.2024             | 25             | F   | II                        |
| 13             | BIE.IZ                    | 03.12.2024             | 36             | F   | II                        |
| 14             | ADA.AN                    | 03.12.2024             | 40             | F   | II                        |
| 15             | GOL.DA                    | 03.12.2024             | 21             | M   | II                        |
| 16             | WOJ.JU                    | 03.12.2024             | 25             | F   | II                        |
| 17             | FAN.AL                    | 03.12.2024             | 27             | F   | II                        |
| 18             | KRZ.EW                    | 03.12.2024             | 38             | F   | II                        |
| 19             | ROS.WI                    | 03.12.2024             | 48             | F   | II                        |
| 20             | ZAM.PA                    | 03.12.2024             | 33             | F   | II                        |
| 21             | JUR.ED                    | 03.12.2024             | 40             | F   | II                        |
| 22             | UFN.DO                    | 03.12.2024             | 24             | F   | II                        |
| 23             | DOB.MI                    | 03.12.2024             | 65             | M   | II                        |
| 24             | KOT.AN                    | 03.12.2024             | 64             | M   | II                        |
| 25             | DIE.BE                    | 03.12.2024             | 50             | F   | II                        |
|                |                           |                        | <b>Min</b>     | 21  | <b>No. F phototype I</b>  |
|                |                           |                        | <b>Max</b>     | 65  | 4                         |
|                |                           |                        | <b>Average</b> | 40  | <b>No. M phototype II</b> |
|                |                           |                        |                | 21  | 25                        |
|                |                           |                        |                |     | <b>phototype III</b>      |
|                |                           |                        |                |     | 0                         |
|                |                           |                        |                |     | <b>phototype IV</b>       |
|                |                           |                        |                |     | 0                         |

Table 1. Characteristics of volunteers with negative history of allergies

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**Table 2**

| No. of subject | Identification of subject | Beginning of the study | Age | Sex          | Phototype            |
|----------------|---------------------------|------------------------|-----|--------------|----------------------|
| 1              | CIE.MA                    | 03.12.2024             | 63  | F            | II                   |
| 2              | PIO.AN                    | 03.12.2024             | 52  | F            | II                   |
| 3              | ZAL.IZ                    | 03.12.2024             | 46  | F            | II                   |
| 4              | WEN.EL                    | 03.12.2024             | 37  | F            | II                   |
| 5              | SZR.MA                    | 03.12.2024             | 49  | F            | II                   |
| 6              | MAZ.HA                    | 03.12.2024             | 21  | F            | II                   |
| 7              | SZY.MA                    | 03.12.2024             | 53  | F            | II                   |
| 8              | KWI.BO                    | 03.12.2024             | 69  | F            | II                   |
| 9              | SOS.AG                    | 03.12.2024             | 36  | F            | II                   |
| 10             | GAN.MA                    | 03.12.2024             | 60  | F            | II                   |
| 11             | ROM.KA                    | 03.12.2024             | 50  | F            | II                   |
| 12             | PIA.DA                    | 03.12.2024             | 60  | F            | II                   |
| 13             | MAN.MA                    | 03.12.2024             | 49  | F            | II                   |
| 14             | STR.MA                    | 03.12.2024             | 38  | F            | II                   |
| 15             | ZYL.AN                    | 03.12.2024             | 64  | F            | II                   |
| 16             | BAR.KA                    | 03.12.2024             | 45  | F            | II                   |
| 17             | SAD.MA                    | 03.12.2024             | 27  | F            | II                   |
| 18             | KIE.OL                    | 03.12.2024             | 44  | F            | II                   |
| 19             | TRO.MA                    | 03.12.2024             | 45  | F            | II                   |
| 20             | SRE.DO                    | 03.12.2024             | 52  | F            | II                   |
| 21             | DRO.KR                    | 03.12.2024             | 61  | F            | II                   |
| 22             | ROZ.AG                    | 03.12.2024             | 42  | F            | II                   |
| 23             | WEN.JU                    | 03.12.2024             | 23  | F            | II                   |
| 24             | WIE.MO                    | 03.12.2024             | 44  | F            | II                   |
| 25             | BOV.TE                    | 03.12.2024             | 55  | F            | II                   |
|                |                           | <b>Min</b>             | 21  | <b>No. F</b> | <b>phototype I</b>   |
|                |                           | <b>Max</b>             | 69  | 25           | 0                    |
|                |                           | <b>Average</b>         | 47  | <b>No. M</b> | <b>phototype II</b>  |
|                |                           |                        |     | 0            | 25                   |
|                |                           |                        |     |              | <b>phototype III</b> |
|                |                           |                        |     |              | 0                    |
|                |                           |                        |     |              | <b>phototype IV</b>  |
|                |                           |                        |     |              | 0                    |

Table 2. Characteristics of volunteers with positive history of allergies

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**8.2. TABLE OF SKIN RESPONSE**
**Table 3**

| No. | Evaluation after 48 hours of product application |       | Evaluation after 72 hours of product application |       | Evaluation after 96 hours of product application |       |
|-----|--------------------------------------------------|-------|--------------------------------------------------|-------|--------------------------------------------------|-------|
|     | Erythema                                         | Edema | Erythema                                         | Edema | Erythema                                         | Edema |
| 1   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 2   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 3   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 4   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 5   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 6   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 7   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 8   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 9   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 10  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 11  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 12  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 13  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 14  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 15  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 16  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 17  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 18  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 19  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 20  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 21  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 22  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 23  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 24  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 25  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |

Table 3. Results for volunteers with negative history of allergies

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**Table 4**

| No. | Evaluation after 48 hours of product application |       | Evaluation after 72 hours of product application |       | Evaluation after 96 hours of product application |       |
|-----|--------------------------------------------------|-------|--------------------------------------------------|-------|--------------------------------------------------|-------|
|     | Erythema                                         | Edema | Erythema                                         | Edema | Erythema                                         | Edema |
| 1   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 2   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 3   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 4   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 5   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 6   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 7   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 8   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 9   | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 10  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 11  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 12  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 13  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 14  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 15  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 16  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 17  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 18  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 19  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 20  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 21  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 22  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 23  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 24  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |
| 25  | 0                                                | 0     | 0                                                | 0     | Examination skipped                              |       |

Table 4. Results for volunteers with positive history of allergies

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**9. CALCULATED VALUES**

The following calculated values present the sum of negative reaction (erythema and edema) defined as Average Irritation Index ( $X_{av}$ ).

|                                                                 | Evaluation after 48 hours of product application |       | Evaluation after 72 hours of product application |       | Evaluation after 96 hours of product application |       |
|-----------------------------------------------------------------|--------------------------------------------------|-------|--------------------------------------------------|-------|--------------------------------------------------|-------|
|                                                                 | Erythema                                         | Edema | Erythema                                         | Edema | Erythema                                         | Edema |
| The sum of negative reaction (the sum of classification points) | 0.00                                             | 0.00  | 0.00                                             | 0.00  | Examination skipped                              |       |
| X <sub>av</sub>                                                 | 0.00                                             |       |                                                  |       |                                                  |       |

**10. INTERPRETATION**

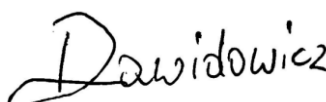
The average irritation index ( $X_{av}$ ) was calculated. The product was then classified according to the following table:

| Average irritation index ( $x_{av}$ ) | Class                 |
|---------------------------------------|-----------------------|
| $X_{av} < 0.50$                       | Non irritating        |
| $0.50 \leq X_{av} < 2.00$             | Slightly irritating   |
| $2.00 \leq X_{av} < 5.00$             | Moderately irritating |
| $5.00 \leq X_{av}$                    | Highly irritating     |

**REPORT No. 714541/24/INT/S****11. CONCLUSION**

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers with positive history of allergies/atopy (sensitive skin). The study allows to conclude that product **R24-34395; R24112635 - PROLOM ANTI-AGE FACE CREAM, 50ml (ID NUMBER: DS170501)** used by volunteers, who didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product, is well tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements of compatibility test with the skin (Skin Compatibility Test) and can be classified as **NON IRRITATING**.

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**12. SIGNATURES**

|                           |                                                                                                                                                        |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| PROJECT MANAGER           | Sign and date:<br><br>09.12.2024                                     |
| TECHNICIAN                | Sign and date:<br><br>09.12.2024                                     |
| QUALITY ASSURANCE AUDITOR | Sign and date:<br><br>09.12.2024                                    |
| DERMATOLOGIST             | Sign and date:<br><br>09.12.2024      Registered N° <b>2880077</b> |

**Attention:** The released opinion of dermatological compatibility does not apply to people who are allergic to any ingredient of the tested product.

Laboratory: ul. Bajana 3D, 80-463 Gdańsk, Poland

The results relate to the analysed samples only.

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\*Accredited study

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**THE END OF THE REPORT**