HAMILTON INTERNATIONAL

REPORT No. 253843/17/JSHS

Client:		Sample *(according to declaration of the Client):*
KOŽELJ d.o.o. Dob **Vegova ulica 12** **1233 Dob**		**RIBODERMIN MAZILO** Ribodermin mazilo, 35 g Batch number: 186 Expiration date: 07.2019
Received on:	27.06.2017	
Analysis completed on:	28.07.2017	
Report date:	31.07.2017	

DERMATOLOGICAL TEST REPORT

SEMI-OCCLUSIVE PATCH TEST

EXPANDED GROUP OF VOLUNTEERS

Prepared by: Helena Barańska, Project Manager Assistant
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Marta Rosińska, Cosmetic Laboratory Manager (qualified electronic signature)

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SCOPE OF TESTS 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 (previously COLIPA) Guidelines Product Test Guidelines for the Assessment of Human Skin Compatibility 1997.
- Cosmetics Europe – The Personal Care Association (previously COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.
- Research Procedure applicable at the J.S. Hamilton Poland S.A. PB-242 - semi-occlusive patch test.
- Technical Instruction applicable at the J.S. Hamilton Poland S.A. IT-01/PK - Scope and organization of the tests in the Cosmetic Laboratory.
- Technical Instruction applicable at the J.S. Hamilton Poland S.A. IT-02/PK – Dilution form of tested product used in semi-open patch test.
- Technical Instruction applicable at the J.S. Hamilton Poland S.A. IT-16/PK - Proceeding in positive skin reactions and side effects presence.

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CONTENT OF THE REPORT:

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1. THE BASIS OF THE STUDY

- Test sample delivered by the Client.
- The qualitative composition of the product delivered by the Client.
- The result of microbiology purity performed in J.S. Hamilton (Report no. 253843/17/JSHS).

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

2. REQUIREMENTS FOR PRODUCTS CALLED "HYPOALLERGENIC"

- Does not contain fragrance composition or the composition does not contain allergens in the INCI composition (verification IFRA certificate, list of allergens, MSDS).
- Does not contain Color Index in the INCI composition.
- pH similar to the natural pH of the skin.
- Does not contain irritating raw materials in the INCI composition.

3. OBJECT OF STUDY:

No.	Parameter	Description
1.	Appearance	Ointment
2.	Color	Yellow
3.	Fragrance	Characteristic for used raw ingredients
4.	Packaging	Repackaging containing the name and the number of sample

4. QUALITATIVE COMPOSITION OF THE PRODUCT*:

PETROLATUM, FISH LIVER OIL, LANOLIN, CERA ALBA, CETEARYL ALCOHOL, VANILLIN, RETINOL, CHOLECALCIFEROL

5. DECLARED INTENDED USE OF THE PRODUCT:

The product is intended for use as an ointment.

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6. OBJECTIVE OF THE TEST:

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

7. DESCRIPTION OF VOLUNTEERS:

50 volunteers at the age of 22 to 65 were selected for the test. The selection of the group included the criteria of inclusion and exclusion. In this group: 25 of the volunteers didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product. The others 25 volunteers had dry, atopic, particular sensitive skin and reported documented oversensitivity or a history of adverse reactions to individual ingredients of the tested cosmetic or detergent product. All volunteers fulfilled the requirements of inclusion for tests and signed an informed consent form. Additionally they were advised of the purpose, methodology of the test and possible adverse effects. The skin at the application spot (arms or interscapular area) was healthy, without lesions. The participants were advised to use caution in handling the applied contact tests.

8. TESTING METHODOLOGY:

Patch (skin) tests according to Jadassohn-Bloch as modified by Rudzki are performed under the supervision of a dermatologist. The semi-occlusive test is the basic kind of test confirming contact skin irritation. The assessment of sensitising and irritating properties of the product is performed on a group of 50% healthy volunteers with positive history of allergy/atopy.

The preparation in the useful concentration is applied into a filter paper discs of 12 mm diameter, manufactured by SmartPractice® and then fixed to the arm or interscapular area using sticking plaster. In a parallel time to objectify the results of studies two control samples: control sample name: "blind" and control sample with water are carried out. The purpose of this test is to exclude possible reading errors connected with the dermal irritation. The results of the studies are presented in section 10. The dermatologist removes the patch after 48h since the application and checks the skin response 30 minutes after removal. After 24h from last verification the dermatologist checks again for a skin response. If it is necessary, the skin response is observed also after 72 hours. Reading the response of the skin, the dermatologist assesses the irritating and sensitising effects of the tested product. The test results may be influenced by such factors as: the lifestyle, stress, diet and environmental conditions etc.

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9. DATE OF PERFORMANCE OF THE STUDY:

17.07.2017 – 21.07.2017

24.07.2017 – 28.07.2017

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10. EVALUATION PARAMETERS:

Table 1

EVALUATION PARAMETERS OF SKIN REACTION	
Erythema	**Classification point**
No erythema	0
Light erythema	0,5
Erythema and/or papules	1
Erythema and/or papules and/or vesicles	2
Erythema and/or papules and/or vesicles and/or blisters	3
Erythema Bullous and/or ulcerative reaction and/or papules and/or vesicles and/or blisters	4
Edema	**Classification point**
No edema	0
Very light edema (hardy visible)	1
Light edema	2
Moderate edema (about 1mm raised skin)	3
Strong edema (extended swelling even beyond the application area)	4

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11. RESULTS:

Table 2 Results for 25 volunteers with a negative history of allergy.

No.	Characteristics of the volunteers		History of allergy	Application spot	Test result 48 hours after application		Test result 72 hours after application		Test result 96 hours after application	
	Age	Sex			Erythema	Edema	Erythema	Edema	Erythema	Edema
1	65	F	negative	Arm	0	0	0	0	0	0
2	36	F	negative	Arm	0	0	0	0	0	0
3	31	F	negative	Arm	0	0	0	0	0	0
4	29	F	negative	Arm	0	0	0	0	0	0
5	26	F	negative	Arm	0	0	0	0	0	0
6	27	F	negative	Arm	0	0	0	0	0	0
7	25	F	negative	Arm	0	0	0	0	0	0
8	23	F	negative	Arm	0	0	0	0	0	0
9	28	F	negative	Arm	0	0	0	0	0	0
10	33	F	negative	Arm	0	0	0	0	0	0
11	45	F	negative	Arm	0	0	0	0	0	0
12	49	F	negative	Arm	0	0	0	0	0	0
13	30	F	negative	Arm	0	0	0	0	0	0
14	59	F	negative	Arm	0	0	0	0	0	0
15	27	F	negative	Arm	0	0	0	0	0	0
16	25	F	negative	Arm	0	0	0	0	0	0
17	25	F	negative	Arm	0	0	0	0	0	0
18	24	F	negative	Arm	0	0	0	0	0	0
19	30	F	negative	Arm	0	0	0	0	0	0
20	48	F	negative	Arm	0	0	0	0	0	0
21	25	M	negative	Arm	0	0	0	0	0	0
22	59	F	negative	Arm	0	0	0	0	0	0
23	23	F	negative	Arm	0	0	0	0	0	0
24	31	M	negative	Arm	0	0	0	0	0	0
25	40	F	negative	Arm	0	0	0	0	0	0

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Table 3 Results for 25 volunteers with a positive history of allergy.

No.	Characteristics of the volunteers		History of allergy	Application spot	Test result 48 hours after application		Test result 72 hours after application		Test result 96 hours after application	
	Age	Sex			Erythema	Edema	Erythema	Edema	Erythema	Edema
1	37	F	positive	Arm	0	0	0	0	0	0
2	24	M	positive	Arm	0	0	0	0	0	0
3	26	F	positive	Arm	0	0	0	0	0	0
4	22	F	positive	Arm	0	0	0	0	0	0
5	59	F	positive	Arm	0	0	0	0	0	0
6	26	F	positive	Arm	0	0	0	0	0	0
7	60	F	positive	Arm	0	0	0	0	0	0
8	24	F	positive	Arm	0	0	0	0	0	0
9	26	F	positive	Arm	0	0	0	0	0	0
10	25	F	positive	Arm	0	0	0	0	0	0
11	47	F	positive	Arm	0	0	0	0	0	0
12	25	F	positive	Arm	0	0	0	0	0	0
13	30	F	positive	Arm	0	0	0	0	0	0
14	39	F	positive	Arm	0	0	0	0	0	0
15	45	F	positive	Arm	0	0	0	0	0	0
16	26	F	positive	Arm	0	0	0	0	0	0
17	27	M	positive	Arm	0	0	0	0	0	0
18	26	F	positive	Arm	0	0	0	0	0	0
19	27	F	positive	Arm	0	0	0	0	0	0
20	27	F	positive	Arm	0	0	0	0	0	0
21	32	F	positive	Arm	0	0	0	0	0	0
22	29	F	positive	Arm	0	0	0	0	0	0
23	42	F	positive	Arm	0	0	0	0	0	0
24	27	F	positive	Arm	0	0	0	0	0	0
25	30	F	positive	Arm	0	0	0	0	0	0

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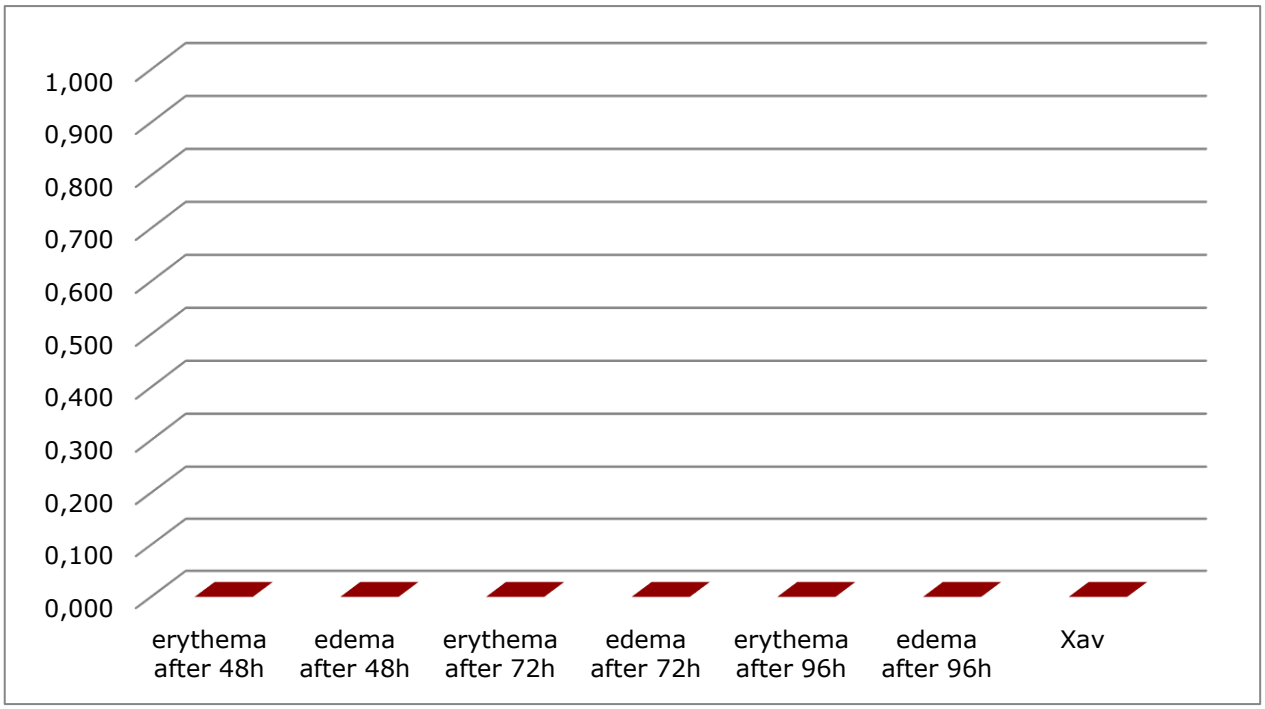
12. CALCULATED VALUES:

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

Table 4	Result 48 hours after product application	Result 72 hours after product application	Result 96 hours after product application
Erythema	0,00	0,00	0,00
Edema	0,00	0,00	0,00
X_{av}	0,00		

13. GRAPHICAL REPRESENTATION OF THE RESULTS:



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14. INTERPRETATION:

The average irritation index (x_{av}) of the 50 tests was calculated. The product was then classified according to the following table no 5:

Table 5

Average irritation index (xav)	Class
$\mathbf{x_{av}} < 0,5$	Not irritating
$0,5 \leq \mathbf{x_{av}} < 2,0$	Slightly irritating
$2,0 \leq \mathbf{x_{av}} < 5,0$	Moderately irritating
$5,0 \leq \mathbf{x_{av}}$	Highly irritating

15. CONCLUSION:

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers with positive history of allergy/atopy (sensitive skin). The study allows to conclude, that product **RIBODERMIN MAZILO** used by persons, for whom allergy to any of its ingredients hasn't been documented, is good tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements for products called "hypoallergenic" and requirements of compatibility test with atopic and sensitive skin (Skin Compatibility Test) and can be classified as **NOT IRRITATING**.

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16. SIGNATURES:

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Authorized by:	**Cosmetic Laboratory Manager** **Marta Rosińska**	
Prepared by:	**Project Manager Assistant** **Helena Barańska**	

*The Client is responsible for conformity with the declared quality composition as well as microbiological cleanliness of the delivered samples.
Attention: Released opinion of dermatological safety does not apply people who are allergic to any ingredient of the tested product.

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