

**REPORT OF ANALYSIS No. 137227/19/JSHR**

Client: <b>PHARMAID/CHRYSOVERGI-STAMATIOU OE COSMETICS-PHARMACEUTICALS, 85101 RHODES, KANARI 182 PASTIDA</b>		Sample description ( <i>according to declaration of the Client</i> ) C01 Oil 6PH SUNSCREEN OIL SPF 6 LOT 180618
Sample received on:	21.03.2019	
Report issued on:	02.04.2019	

**Dermatological test SEMI-OPEN TEST (NOT EXPANDED)**

Prepared by: Kinga Roman, Technician  
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
Katrzyzna Cięszczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

## **REPORT OF ANALYSIS No. 137227/19/JSHR**

### **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 (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

Prepared by: Kinga Roman, Technician  
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
Katrzyzna Cięszczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

**REPORT OF ANALYSIS No. 137227/19/JSHR****LIST OF CONTENTS**

1. Basis of the study
2. Object of the study
3. Qualitative composition of the product
4. Purpose of the study
5. Description of volunteers
6. Testing methodology
7. Date of the study
8. Evaluation parameters
9. Results
  - 9.1. Characteristics of volunteers
  - 9.2. Table of skin response
10. Calculated values
11. Interpretation
12. Conclusion
13. Signatures

Prepared by: Kinga Roman, Technician  
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
Katrzyzna Ciężczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

## REPORT OF ANALYSIS No. 137227/19/JSHR

### 1. BASIS OF THE STUDY

Test sample delivered by the Client.

The qualitative composition of the product delivered by the Client.

The results of microbiological purity of the product provided by the Client (or declaration from the Client about microbiological purity) does 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
Appearance	Liquid
Color	Yellow
Fragrance	Characteristic for raw materials (or fragrance composition)
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.

Prepared by: Kinga Roman, Technician  
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
Katrzyzna Cięszczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

## **REPORT OF ANALYSIS No. 137227/19/JSHR**

### **5. DESCRIPTION OF VOLUNTEERS**

The volunteers (25 people) were healthy, with negative allergy history. 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 and 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 the 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. Simultaneously, to objectify the results of the study and in order to exclude possible reading errors connected with dermal irritations two control samples (control sample called "blind" and control sample with water) are used. The purpose of this study is to exclude possible reading errors connected with dermal irritations. The results of the study are presented in section 10 of this report. The dermatologist removes the patch 48h after the application and examines the skin response 30 minutes after removal. 72h after the application, the dermatologist examines the skin again for a response. If irritations appear or persist 72h after the application, an additional examination takes place after 96 hours. Determining the response of the skin, 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.

### **7. DATE OF THE STUDY**

25.03.2019 – 29.03.2019

Prepared by: Kinga Roman, Technician  
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
Katrzyzna Ciężczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

**REPORT OF ANALYSIS No. 137227/19/JSHR**
**8. EVALUATION PARAMETERS**

<b>EVALUATION PARAMETERS OF SKIN REACTION</b>	
<b>Erythema</b>	<b>Classification point</b>
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
<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 beyond the application area)	4

Prepared by: Kinga Roman, Technician  
 Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
 Katarzyna Ciężczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

**REPORT OF ANALYSIS No. 137227/19/JSHR**
**9. RESULTS**
**9.1. CHARACTERISTICS OF VOLUNTEERS**
**Table 1**

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype
1	NYK.EW	25.03.2019	35	F	II
2	BIE.IZ	25.03.2019	30	F	III
3	ROS.WI	25.03.2019	42	F	II
4	RYD.AN	25.03.2019	64	M	II
5	RYD.WI	25.03.2019	59	F	II
6	SUT.GR	25.03.2019	65	F	II
7	RON.AG	25.03.2019	31	F	II
8	KRZ.KL	25.03.2019	23	F	II
9	RUT.MI	25.03.2019	33	M	II
10	KAR.JO	25.03.2019	25	F	III
11	BIE.VI	25.03.2019	58	F	II
12	BIE.AL	25.03.2019	36	F	II
13	WYS.ZA	25.03.2019	40	F	II
14	CZA.HA	25.03.2019	44	F	III
15	OBA.KA	25.03.2019	40	F	II
16	SMI.MA	25.03.2019	29	F	II
17	SMI.DO	25.03.2019	51	F	II
18	MIK.RE	25.03.2019	68	F	II
19	WIE.MA	25.03.2019	50	F	II
20	MLY.MI	25.03.2019	60	F	II
21	CHE.ZO	25.03.2019	64	F	II
22	KAL.EW	25.03.2019	58	F	II
23	PAT.AN	25.03.2019	48	F	II
24	KAP.YU	25.03.2019	21	F	II
25	KOP.AN	25.03.2019	67	M	II
			<b>Min</b>	21	<b>No. F phototype I</b>
			<b>Max</b>	68	22
			<b>Average</b>	46	<b>No. M phototype II</b>
				3	22
					<b>phototype III</b>
					3
					<b>phototype IV</b>
					0

Table 1. Characteristics of volunteers with a negative history of allergy

Prepared by: Kinga Roman, Technician  
 Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
 Katarzyna Ciężczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

**REPORT OF ANALYSIS No. 137227/19/JSHR**
**9.2. TABLE OF SKIN RESPONSE**
**Table 2**

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 2. Results for volunteers with a negative history of allergy

Prepared by: Kinga Roman, Technician  
 Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
 Katarzyna Ciężczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)



## REPORT OF ANALYSIS No. 137227/19/JSHR

### 10. 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	
$X_{av}$	0.00					

### 11. 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
$X_{av} < 0.50$	Not 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

Prepared by: Kinga Roman, Technician  
 Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
 Katarzyna Ciężczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

**REPORT OF ANALYSIS No. 137227/19/JSHR****12. CONCLUSION**

The patch test study was performed under dermatological control on a group of 25 volunteers. The study allows to conclude that product C01 OIL 6PH used by volunteers, that 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 NOT IRRITATING.

Prepared by: Kinga Roman, Technician  
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
Katrzyzna Ciężczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)

**REPORT OF ANALYSIS No. 137227/19/JSHR****13. SIGNATURES**

<b>Technician</b>	<b>Kinga Roman</b>	
<b>Dermatologist - venereologist</b>	<b>Karolina Osiecka (2487308)</b>	
<b>Project Manager Senior Assistant</b>	<b>Katarzyna Ciężczyk</b>	

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

Prepared by: Kinga Roman, Technician  
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)  
Katarzyna Ciężczyk, Project Manager Senior Assistant (qualified electronic signature)

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

The results relate to the analysed samples only. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on [www.hamilton.com.pl](http://www.hamilton.com.pl)