

HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL

Study report – version n° 1 of 20/08/2019

STUDY REFERENCE

EUROFINS EVIC france – I19 0473

INVESTIGATIONAL PRODUCT

Denomination

Snow Panda Extra Care "Aroma"

Reference / Formula number

P12/19

Cosmetic category

Hygiene

Galenic form and organoleptic characteristics

White / pink paper

SPONSOR	Eurofins Agro Testing Ukraine LLC Perspektyvnaya St 7a (Ihoria Branovytskoho St 7a) 01042 KYIV - Ukraine
STUDY MONITOR	Rakhmetov Anar Tel.: +38 044 594 90 04 e-mail: AnarRakhmetov@eurofins.com
INVESTIGATING CENTRE	EUROFINS EVIC france - Idec department 57, rue Ulysse Gayon 33000 - Bordeaux - France Tel: +33 5 57 14 00 80 Fax: +33 5 56 48 72 49 e-mail: evic-idec@eurofins.com
MAIN INVESTIGATOR	Dr MAGNE Françoise (Dermatologist)

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EUROFINS EVIC PRODUCT TESTING FRANCE SAS au capital de 475 000 € - RC 70870 Bordeaux -
SIREN 470 200 700 - FR79470200700



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HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL

Synopsis

STUDY OBJECTIVE	To evaluate the ability of the investigational product to keep in good condition the human body (skin compatibility) in a panel of healthy adult subjects after single application under maximising and controlled experimental conditions.
TYPE OF THE STUDY	Monocentric randomised study performed in open, not considered as a "Research in Human Beings" as it does not intend "to develop medical or biological knowledges" as described in the French Decree n° 2017-884 of May 9th 2017. The test subject was used as own control.
DATES OF STUDY PERFORMANCE	Initiation date: 16/07/2019 Completion date: 18/07/2019
STUDY POPULATION	Number of test subjects: 10 valid cases Inclusion criteria: test subjects <ul style="list-style-type: none"> • suitable to participate in the study and corresponding to the quality of "healthy subject" • declaring to have a health coverage • signing an "informed consent form" for this study • certifying not to take part simultaneously in another clinical study which could interfere • certifying the truth of the personal information declared to the investigator • capable of following directions and reliable to respect the constraints of the protocol • free to ensure the visits to the investigating centre • aged from 18 to 70 • female/male • with all types of skin on back • with a phototype (Fitzpatrick): I to IV • declaring not to have exposed themselves to a risk of pregnancy for at least 3 months before the beginning of the study and committing themselves to use effective contraceptive method throughout the study (for the women of childbearing potential)

<p>STUDY POPULATION (continuation)</p>	<p>Non inclusion criteria: test subjects</p> <ul style="list-style-type: none"> • being in exclusion period • deprived of freedom by administrative or legal decision or under guardianship • who cannot be contacted in case of emergency • admitted in a residential care • planning an hospitalisation during the study • belonging to the staff of the investigating centre • being of age but protected by law • having received vaccination within the 3 weeks prior to the study or intending to be vaccinated during the course of the study • with personal history of adverse reactions to the same type of product as the investigational product • with personal history of adverse reaction to colophony, rubber, patch materials, adhesive plaster, • with documented history of contact allergy • exhibiting skin marks and/or moles and/or freckles in too great quantity and/or hyperpilosity on the experimental area able to interfere with the assessment of the possible skin reactions • with still visible eczematous reaction, scar or pigmentary after-effects of previous tests on the experimental area • under treatment, prior to the study, able to interfere with the study results, • foreseeing, during the study, a treatment able to interfere with the interpretation of the study results (systemic or topical anti-acne medication, topical or systemic medication with anti-inflammatory or antihistamine, antibiotics, desensitisation treatment, ...) • having had a fever lasting more than 24 hours, within the 8 days prior to the study • having had any invasive aesthetic cares on chest and back (peeling, laser...) by a dermatologist within the 2 months prior to the study or foreseeing it for the duration of the study • having had any non invasive aesthetic cares on chest and back by an aesthetician within the month prior to the study or foreseeing it for the duration of the study • having received excessive or intensive exposure to sunlight (natural or artificial) within the month prior to the study or foreseeing UV exposures for the duration of the study • under treatment with PUVA or UVB within the month prior to the study • having participated in a human repeated insult patch test with challenge with or without sun exposure within the 4 months prior to the study • having participated in a cumulative irritability test within the 2 months prior to the study or in a single patch test within the month prior to the study • having already participated in 5 clinical studies involving patch test, including 3 human repeated patch tests maximum with or without challenge within the year prior to the study • foreseeing bath (in bathtub, sea or swimming pool), sauna or Turkish bath during the study period • regularly practicing intensive sport causing sweating and requiring frequent showers • with personal history of adverse reaction to aluminium • with personal history of adverse reaction to nickel • breastfeeding or pregnant or planning a pregnancy during the study (for the women of childbearing potential) • having started or changed oestrogen-progesterone contraception or hormonal treatment, within the 3 months prior to the study or foreseeing it for the duration of the study
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<p>METHODOLOGY</p>	<p>Definition and preparation of the experimental areas:</p> <ul style="list-style-type: none"> - Skin areas defined by the technician in charge of the study on the back of the test subjects, taking into account the skin appearance and avoiding the areas of friction with clothes - Before patching, wiping of the skin with a cotton pad <p>Application of the investigational product, by the technician in charge of the study at the investigating centre:</p> <ul style="list-style-type: none"> - once (on D1), - under maximising conditions of exposure (under Occlusive patch - Finn Chamber Standard® : aluminium cupula kept in position by an hypoallergenic adhesive: Scanpor® (inner diameter: 8 mm, surface: 50 mm²) - quantity applied= 1 square of 0.5x0.5cm put into the patch) - humidified with water for injection - during a defined time (48h ± 4h) <p>Application in parallel of water for injection (20 µl) to a skin area on back, under Occlusive - Finn Chamber Standard® patch and during a defined time (48h ± 4h) - (control area, to take into account the possible effects not directly related to the investigational product but due to the patch material)</p> <p>Checking of the investigational product ability to keep in good condition the human body (skin compatibility), based on:</p> <ul style="list-style-type: none"> • a skin examination of the treated and control areas, visually, by the same investigator with the appropriate experience, under standard "daylight" source, on: <ul style="list-style-type: none"> ⬇ D1/T0, before application ⬇ D3/T15-30 minutes, after patches removal • the analysis of the sensations of discomfort reported directly by the test subjects to the investigator during the study <p>Descriptive analysis – Percentage of reactive test subjects (erythema and other visible signs of reactivity)</p> <p><u>Expression of the results:</u></p> <ul style="list-style-type: none"> • Percentage of reactive test subjects: calculated taking into account only the following signs of reactivity: erythema, dryness, oedema, papula, vesicle, bulla, scab, soap effect, pruritus <p>Description of the other reactivity clinical signs or sensations of discomfort and calculation of the corresponding percentage of test subjects if justified by the appearance frequency</p> <ul style="list-style-type: none"> • Individual daily irritation score (IDIS) calculated for each test subject : IDIS = sum of the marks obtained for all the signs observed • Mean daily irritation score (MDIS) calculated for the panel : MDIS = Σ (IDIS) / nb of valid cases <p>Classification of the reaction according to ICDRG scale in case of reaction of allergy</p> <p>Descriptive analysis of the data</p>
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RESULTS

Characteristics of the included panel

Number of included subjects: 11

Number of exclusions: 0

Number of withdrawals: 1 (Ref. 11) for personal reasons independent of the study

Number of valid cases: 10

- Age: 21 to 68 (Mean= 45 years old)
- Sex: 8 women and 2 men
- Phototype: II to IV
- With all types of skin on back

Checking of the investigational product ability to keep in good condition the human body (skin compatibility)

For the investigational product:

Control time after patch removal	Type of reaction	Number of reactive test subjects	% of reactive test subjects	Mean daily irritation score MDIS	Skin compatibility of the product
T15-30 minutes (D3)	/	0	0%	0	Very good skin compatibility

Legend: / = none

For the control site:

No reaction was noted on the control site.

OVERALL CONCLUSION

Under the experimental conditions adopted:

single application of the product, under patch, on a panel of 8 women and 2 men, aged between 21 and 68 years old, with phototype II to IV and with all types of skin on back,

the product **Snow Panda Extra Care "Aroma" - Ref. P12/19** has a **very good compatibility with skin**. The product did not cause irritation during testing.



HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL

Signatures and dates

Investigator: Dr MAGNE Françoise (Dermatologist)

I the undersigned, Dr MAGNE Françoise (Dermatologist), declare that the overall conduct of the study was carried out under my responsibility in accordance with the protocol and the internal procedures and in the spirit of the principles of Good Clinical Practices (International recommendations ICH E6(R1) of 10/06/1996, Directive of the European Parliament and Council 2001/20/EC.

I assume the responsibility of the validity of all the raw data obtained during the study which are reported in the present study report.

Date:
Signature:

200819
F. Magne

Quality Assurance Personnel: MIMIAGUE Joëlle

I the undersigned, MIMIAGUE Joëlle, declare that:

- this type of study audit was carried out according to the procedures of the investigating centre:

Reference of the audited "Patch test"	Audited phase	Date of audit performance	Date of audit report transmission to	
			the investigator	the management of the Investigating centre
I19 0184	D1	16/05/19	16/05/19	16/05/19

- this report was examined on August 20th, 2019,
- the reported results accurately and completely reflected the raw data of the study.

Date: 20.08.19
Signature:

Po F. Prod'Homme

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APPENDICES



Appendix 1

TYPOLOGICAL CHARACTERISTICS OF THE TEST SUBJECTS

Test subjects reference	age (years)	sex F=female M=male	Type of skin on back ⁽¹⁾	phototype ⁽²⁾
1	48	F	N	IV
2	21	M	N	III
3	44	F	N	IV
4	59	F	N	III
5	23	F	N	III
6	60	F	N	III
7	68	F	N	III
8	41	M	N	II
9	51	F	N	II
10	34	F	D	III
11	53	F	N	II

Legends:

 Withdrawal

⁽¹⁾ types of skin on back: N= normal, D= dry, O= oily

⁽²⁾ phototype: Type I: Always burns easily, never tans, Type II: Always burns easily, tans minimally, Type III: Burns moderately, tans gradually, Type IV: Burns slightly, always tans easily, Type V: Burns rarely, tans intensely, Type VI: Never burns, strongly pigmented

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Appendix 2

SPECIFIC INFORMATION CONCERNING THE TEST SUBJECTS					
Test subjects reference	Skin sensitivity / reactivity	Atopy	Current medication		Contraception
			If yes (commercial denomination)		If yes (Type to be specified)
			At the inclusion	During the study	
1	/	/	/	Vogalène® 2 tablets on D3	Condom
2	/	/	/	/	NC
3	x	/	/	/	Coil
4	/	/	/	/	NC
5	x	/	/	/	Condom
6	x	/	/	/	NC
7	/	/	/	/	NC
8	/	/	/	/	NC
9	x	/	/	/	NC
10	x	/	/	/	Condom
11	/	/	/		Coil

Legends: / = no x = yes



Withdrawal

NC = Not concerned

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Appendix 3/1

SKIN COMPATIBILITY - SKIN EXAMINATION AND QUESTIONING
INVESTIGATIONAL PRODUCT

REACTIONS :

Clinical signs

E = Erythema: E0,5 = very very slight, E1 = very slight, E2 = slight, E3 = moderate, E4 = severe

D = Dryness: D1 = very slight, D2 = slight, D3 = moderate, D4 = severe

Oe = Homogeneous infiltration/Oedema

Pa = Papules : Pa1 = few (≤ 3), Pa2 = numerous (> 3)

V = Vésicules : V1 = few (≤ 3), V2 = numerous (> 3)

Bu = Bullae

Cr = Scab – Exsudation and/or surface encrustation

Sv = Soap effect (shiny skin with possibly wrinkles)

Hypo = Hypo-pigmentation

Hyper = Hyper-pigmentation

C = Skin coloration

Sensations of discomfort

Pr = Pruritus: Pr1 = very slight, Pr2 = slight, Pr3 = moderate, Pr4 = severe

B = Burning

d: diffuse

p: punctuated

peri: peripheral

/: no reaction

Test subjects reference	Experimental times	
	D3	
	Reactions + intensity	IDIS
1	/	0
2	/	0
3	/	0
4	/	0
5	/	0
6	/	0
7	/	0
8	/	0
9	/	0
10	/	0
11		
MDIS	0	

Comments: none

Legends: / = no



Withdrawal

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Appendix 3/2

SKIN COMPATIBILITY - SKIN EXAMINATION AND QUESTIONING CONTROL AREA

REACTIONS :
Clinical signs

E = Erythema: **E0.5** = very very slight, **E1** = very slight, **E2** = slight, **E3** = moderate, **E4** = severe

D = Dryness: **D1** = very slight, **D2** = slight, **D3** = moderate, **D4** = severe

Oe = Homogeneous infiltration/Oedema

Pa = Papules : **Pa1** = few (≤ 3), **Pa2** = numerous (> 3)

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Hypo = Hypo-pigmentation

Hyper = Hyper-pigmentation

C = Skin coloration

Sensations of discomfort

Pr = Pruritus: **Pr1** = very slight, **Pr2** = slight, **Pr3** = moderate, **Pr4** = severe

B = Burning

d: diffuse

p: punctuated

peri: peripheral

/: no reaction

Test subjects reference	Experimental times	
	D3	
	Reactions + intensity	IDIS
1	/	0
2	/	0
3	/	0
4	/	0
5	/	0
6	/	0
7	/	0
8	/	0
9	/	0
10	/	0
11		
MDIS	0	

Comments: none

Legends: / = no



Withdrawal

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HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL

Study report – version n° 1 of 20/08/2019

STUDY REFERENCE

EUROFINS EVIC france – I19 0473

INVESTIGATIONAL PRODUCT

Denomination

Snow Panda Extra Care "Superior"

Reference / Formula number

P11/19

Cosmetic category

Hygiene

Galenic form and organoleptic characteristics

White paper

SPONSOR	Eurofins Agro Testing Ukraine LLC Perspektyvnaya St 7a (Ihoria Branovytskoho St 7a) 01042 KYIV - Ukraine
STUDY MONITOR	Rakhmetov Anar Tel.: +38 044 594 90 04 <i>e-mail: AnarRakhmetov@eurofins.com</i>
INVESTIGATING CENTRE	EUROFINS EVIC france - Idec department 57, rue Ulysse Gayon 33000 - Bordeaux - France Tel: +33 5 57 14 00 80 Fax: +33 5 56 48 72 49 <i>e-mail: evic-idec@eurofins.com</i>
MAIN INVESTIGATOR	Dr MAGNE Françoise (Dermatologist)

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505 rue Louis Berton CS 50550 - F13594 AIX EN PROVENCE Cedex 3 - Tél. 33 (0)4 42 37 16 28 - E-mail : FR03_EVIC_TOX@eurofins.com

EUROFINS EVIC PRODUCT TESTING FRANCE SAS au capital de 475 000 € - RC 70870 Bordeaux -
SIREN 470 200 700 - FR79470200700



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HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL

Synopsis

STUDY OBJECTIVE	To evaluate the ability of the investigational product to keep in good condition the human body (skin compatibility) in a panel of healthy adult subjects after single application under maximising and controlled experimental conditions.
TYPE OF THE STUDY	Monocentric randomised study performed in open, not considered as a "Research in Human Beings" as it does not intend "to develop medical or biological knowledges" as described in the French Decree n° 2017-884 of May 9th 2017. The test subject was used as own control.
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	Completion date: 18/07/2019
STUDY POPULATION	<p>Number of test subjects: 10 valid cases</p> <p>Inclusion criteria: test subjects</p> <ul style="list-style-type: none"> • suitable to participate in the study and corresponding to the quality of "healthy subject" • declaring to have a health coverage • signing an "informed consent form" for this study • certifying not to take part simultaneously in another clinical study which could interfere • certifying the truth of the personal information declared to the investigator • capable of following directions and reliable to respect the constraints of the protocol • free to ensure the visits to the investigating centre • aged from 18 to 70 • female/male • with all types of skin on back • with a phototype (Fitzpatrick): I to IV • declaring not to have exposed themselves to a risk of pregnancy for at least 3 months before the beginning of the study and committing themselves to use effective contraceptive method throughout the study (for the women of childbearing potential)

<p>STUDY POPULATION (continuation)</p>	<p>Non inclusion criteria: test subjects</p> <ul style="list-style-type: none"> • being in exclusion period • deprived of freedom by administrative or legal decision or under guardianship • who cannot be contacted in case of emergency • admitted in a residential care • planning an hospitalisation during the study • belonging to the staff of the investigating centre • being of age but protected by law • having received vaccination within the 3 weeks prior to the study or intending to be vaccinated during the course of the study • with personal history of adverse reactions to the same type of product as the investigational product • with personal history of adverse reaction to colophony, rubber, patch materials, adhesive plaster, • with documented history of contact allergy • exhibiting skin marks and/or moles and/or freckles in too great quantity and/or hyperpilosity on the experimental area able to interfere with the assessment of the possible skin reactions • with still visible eczematous reaction, scar or pigmentary after-effects of previous tests on the experimental area • under treatment, prior to the study, able to interfere with the study results, • foreseeing, during the study, a treatment able to interfere with the interpretation of the study results (systemic or topical anti-acne medication, topical or systemic medication with anti-inflammatory or antihistamine, antibiotics, desensitisation treatment, ...) • having had a fever lasting more than 24 hours, within the 8 days prior to the study • having had any invasive aesthetic cares on chest and back (peeling, laser...) by a dermatologist within the 2 months prior to the study or foreseeing it for the duration of the study • having had any non invasive aesthetic cares on chest and back by an aesthetician within the month prior to the study or foreseeing it for the duration of the study • having received excessive or intensive exposure to sunlight (natural or artificial) within the month prior to the study or foreseeing UV exposures for the duration of the study • under treatment with PUVA or UVB within the month prior to the study • having participated in a human repeated insult patch test with challenge with or without sun exposure within the 4 months prior to the study • having participated in a cumulative irritability test within the 2 months prior to the study or in a single patch test within the month prior to the study • having already participated in 5 clinical studies involving patch test, including 3 human repeated patch tests maximum with or without challenge within the year prior to the study • foreseeing bath (in bathtub, sea or swimming pool), sauna or Turkish bath during the study period • regularly practicing intensive sport causing sweating and requiring frequent showers • with personal history of adverse reaction to aluminium • with personal history of adverse reaction to nickel • breastfeeding or pregnant or planning a pregnancy during the study (for the women of childbearing potential) • having started or changed oestrogen-progesterone contraception or hormonal treatment, within the 3 months prior to the study or foreseeing it for the duration of the study
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<p>METHODOLOGY</p>	<p>Definition and preparation of the experimental areas:</p> <ul style="list-style-type: none"> - Skin areas defined by the technician in charge of the study on the back of the test subjects, taking into account the skin appearance and avoiding the areas of friction with clothes - Before patching, wiping of the skin with a cotton pad <p>Application of the investigational product, by the technician in charge of the study at the investigating centre:</p> <ul style="list-style-type: none"> - once (on D1), - under maximising conditions of exposure (under Occlusive patch - Finn Chamber Standard® : aluminium cupula kept in position by an hypoallergenic adhesive: Scanpor® (inner diameter: 8 mm, surface: 50 mm²) - quantity applied= 1 square of 0.5x0.5cm put into the patch) - humidified with water for injection - during a defined time (48h ± 4h) <p>Application in parallel of water for injection (20 µl) to a skin area on back, under Occlusive - Finn Chamber Standard® patch and during a defined time (48h ± 4h) - (control area, to take into account the possible effects not directly related to the investigational product but due to the patch material)</p> <p>Checking of the investigational product ability to keep in good condition the human body (skin compatibility), based on:</p> <ul style="list-style-type: none"> • a skin examination of the treated and control areas, visually, by the same investigator with the appropriate experience, under standard "daylight" source, on: <ul style="list-style-type: none"> ⬇ D1/T0, before application ⬇ D3/T15-30 minutes, after patches removal • the analysis of the sensations of discomfort reported directly by the test subjects to the investigator during the study <p>Descriptive analysis – Percentage of reactive test subjects (erythema and other visible signs of reactivity)</p> <p><u>Expression of the results:</u></p> <ul style="list-style-type: none"> • Percentage of reactive test subjects: calculated taking into account only the following signs of reactivity: erythema, dryness, oedema, papula, vesicle, bulla, scab, soap effect, pruritus <p>Description of the other reactivity clinical signs or sensations of discomfort and calculation of the corresponding percentage of test subjects if justified by the appearance frequency</p> <ul style="list-style-type: none"> • Individual daily irritation score (IDIS) calculated for each test subject : IDIS = sum of the marks obtained for all the signs observed • Mean daily irritation score (MDIS) calculated for the panel : MDIS = Σ (IDIS) / nb of valid cases <p>Classification of the reaction according to ICDRG scale in case of reaction of allergy</p> <p>Descriptive analysis of the data</p>
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RESULTS

Characteristics of the included panel

Number of included subjects: 11

Number of exclusions: 0

Number of withdrawals: 1 (Ref. 11) for personal reasons independent of the study

Number of valid cases: 10

- Age: 21 to 68 (Mean= 45 years old)
- Sex: 8 women and 2 men
- Phototype: II to IV
- With all types of skin on back

Checking of the investigational product ability to keep in good condition the human body (skin compatibility)

For the investigational product:

Control time after patch removal	Type of reaction	Number of reactive test subjects	% of reactive test subjects	Mean daily irritation score MDIS	Skin compatibility of the product
T15-30 minutes (D3)	/	0	0%	0	Very good skin compatibility

Legend: / = none

For the control site:

No reaction was noted on the control site.

OVERALL CONCLUSION

Under the experimental conditions adopted:

single application of the product , under patch, on a panel of 8 women and 2 men, aged between 21 and 68 years old, with phototype II to IV and with all types of skin on back,

the product **Snow Panda Extra Care "Superior" - Ref. P11/19** has a **very good compatibility with skin**. The product did not cause irritation during testing.



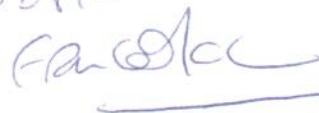
HUMAN PATCH TEST UNDER DERMATOLOGICAL CONTROL

Signatures and dates

Investigator: Dr MAGNE Françoise (Dermatologist)

I the undersigned, Dr MAGNE Françoise (Dermatologist), declare that the overall conduct of the study was carried out under my responsibility in accordance with the protocol and the internal procedures and in the spirit of the principles of Good Clinical Practices (International recommendations ICH E6(R1) of 10/06/1996, Directive of the European Parliament and Council 2001/20/EC.

I assume the responsibility of the validity of all the raw data obtained during the study which are reported in the present study report.

Date: 20.08.19
Signature: 

Quality Assurance Personnel: MIMIAGUE Joëlle

I the undersigned, MIMIAGUE Joëlle, declare that:

- this type of study audit was carried out according to the procedures of the investigating centre:

Reference of the audited "Patch test"	Audited phase	Date of audit performance	Date of audit report transmission to	
			the investigator	the management of the investigating centre
I19 0184	D1	16/05/19	16/05/19	16/05/19

- this report was examined on August 20th, 2019,
- the reported results accurately and completely reflected the raw data of the study.

Date: 20.08.19
Signature: 

Pa F. Prad'Homme

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APPENDICES



Appendix 1

TYPOLOGICAL CHARACTERISTICS OF THE TEST SUBJECTS

Test subjects reference	age (years)	sex F=female M=male	Type of skin on back ⁽¹⁾	phototype ⁽²⁾
1	48	F	N	IV
2	21	M	N	III
3	44	F	N	IV
4	59	F	N	III
5	23	F	N	III
6	60	F	N	III
7	68	F	N	III
8	41	M	N	II
9	51	F	N	II
10	34	F	D	III
11	53	F	N	II

Legends:

Withdrawal

⁽¹⁾ types of skin on back: N= normal, D= dry, O= oily

⁽²⁾ phototype: Type I: Always burns easily, never tans, Type II: Always burns easily, tans minimally, Type III: Burns moderately, tans gradually, Type IV: Burns slightly, always tans easily, Type V: Burns rarely, tans intensely, Type VI: Never burns, strongly pigmented

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Appendix 2

SPECIFIC INFORMATION CONCERNING THE TEST SUBJECTS

Test subjects reference	Skin sensitivity / reactivity	Atopy	Current medication		Contraception
			If yes (commercial denomination)		If yes (Type to be specified)
			At the inclusion	During the study	
1	/	/	/	Vogalène® 2 tablets on D3	Condom
2	/	/	/	/	NC
3	x	/	/	/	Coil
4	/	/	/	/	NC
5	x	/	/	/	Condom
6	x	/	/	/	NC
7	/	/	/	/	NC
8	/	/	/	/	NC
9	x	/	/	/	NC
10	x	/	/	/	Condom
11	/	/	/		Coil

Legends: / = no x = yes



Withdrawal

NC = Not concerned

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Appendix 3/1

SKIN COMPATIBILITY - SKIN EXAMINATION AND QUESTIONING INVESTIGATIONAL PRODUCT

REACTIONS :
Clinical signs

E = Erythema: **E0.5** = very very slight, **E1** = very slight, **E2** = slight, **E3** = moderate, **E4** = severe

D = Dryness: **D1** = very slight, **D2** = slight, **D3** = moderate, **D4** = severe

Oe = Homogeneous infiltration/Oedema

Pa = Papules : **Pa1** = few (≤ 3), **Pa2** = numerous (> 3)

V = Vésicules : **V1** = few (≤ 3), **V2** = numerous (> 3)

Bu = Bullae

Cr = Scab – Exsudation and/or surface encrustation

Sv = Soap effect (shiny skin with possibly wrinkles)

Hypo = Hypo-pigmentation

Hyper = Hyper-pigmentation

C = Skin coloration

Sensations of discomfort

Pr = Pruritus: **Pr1** = very slight, **Pr2** = slight, **Pr3** = moderate, **Pr4** = severe

B = Burning

d: diffuse

p: punctuated

peri: peripheral

/: no reaction

Test subjects reference	Experimental times	
	D3	
	Reactions + intensity	IDIS
1	/	0
2	/	0
3	/	0
4	/	0
5	/	0
6	/	0
7	/	0
8	/	0
9	/	0
10	/	0
11		
MDIS	0	

Comments: none

Legends: / = no



Withdrawal

CONFIDENTIAL DOCUMENT

11/12



Appendix 3/2

SKIN COMPATIBILITY - SKIN EXAMINATION AND QUESTIONING CONTROL AREA

REACTIONS :
Clinical signs

E = Erythema: **E0.5** = very very slight, **E1** = very slight, **E2** = slight, **E3** = moderate, **E4** = severe

D = Dryness: **D1** = very slight, **D2** = slight, **D3** = moderate, **D4** = severe

Oe = Homogeneous infiltration/Cedema

Pa = Papules : **Pa1** = few (≤ 3), **Pa2** = numerous (> 3)

V = Vésicules : **V1** = few (≤ 3), **V2** = numerous (> 3)

Bu = Bullae

Cr = Scab – Exsudation and/or surface encrustation

Sv = Soap effect (shiny skin with possibly wrinkles)

Hypo = Hypo-pigmentation

Hyper = Hyper-pigmentation

C = Skin coloration

Sensations of discomfort

Pr = Pruritus: **Pr1** = very slight, **Pr2** = slight, **Pr3** = moderate, **Pr4** = severe

B = Burning

d: diffuse

p: punctuated

peri: peripheral

/: no reaction

Test subjects reference	Experimental times	
	D3	
	Reactions + intensity	IDIS
1	/	0
2	/	0
3	/	0
4	/	0
5	/	0
6	/	0
7	/	0
8	/	0
9	/	0
10	/	0
11		
MDIS	0	

Comments: none

Legends: / = no



Withdrawal

CONFIDENTIAL DOCUMENT



12/12



EVIC

Eurofins Agro Testing Ukraine LLC

Perspektyvnaya St 7a
(Ihoria Branovytskoho St 7a)
01042 KYIV - Ukraine

Bordeaux, September 17th 2019

For the attention of Mr Denis Ganshevsky

I, the undersigned, attests that the results from study **I19 0473** concerning the product **Snow Panda Extra Care "Superior"** - Ref. **P11/19** can also be extended to product **Toilet paper Snow Panda Extra Care "Sensitive", 3 ply**, as long as composition and manufacturing process are the same than those used for the product that has been tested in the original study.

Dr MAGNE Françoise (Dermatologist)



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