HUMAN IN USE TEST UNDER DERMATOLOGICAL CONTROL

Study final report - version n° 2.0 of 30/03/2023

(this version cancels and replaces the version 1 of 14/12/2022)

STUDY REFERENCES

EUROFINS EVIC Romania – ER 22/235
EUROFINS EVIC France – OP0000762212B6B

INVESTIGATIONAL PRODUCT	
Denomination	**F3320**
Reference	**F3320/RD0224E17**
Batch Number	**0224E017221012H**

SPONSOR	**SODEL** 190 RUE RENE BARTELEMY 14100 LISIEUX France
STUDY MONITOR	**Mr Romain Boissonnot**
COORDINATING CENTRE	**EUROFINS EVIC Product Testing France SAS** 122, rue Croix de Seguey 33000 BORDEAUX – France Tel: +33 5 56 95 59 95 Fax: +33 5 56 95 05 22 *e-mail: evic-blanquefort@eurofins.com*
INVESTIGATING CENTRE	**EUROFINS EVIC PRODUCT TESTING ROMANIA S.R.L** 64-66, Marasesti Avenue 040256 - Bucharest - Romania Tel.: +40 21 335 70 90 ; Fax: +40 21 335 70 91
INVESTIGATOR	**Dr Rozalia Olsavszky** (dermatologist) Registered N° (Romanian ministry of health): 461524 (specialist in dermato-venerology doctor, doctor in medical science) Tel: +4 021 335 70 90; Fax: +4 021 335 70 91 *e-mail: RO02_Medical@eurofins.com*
SUB-INVESTIGATOR	**Dr. Duta Andra Daiana** (resident dermatologist) Tel: +40 21 335 70 90 Fax: +40 21 335 70 91 *e-mail: RO02_Medical@eurofins.com*

Date of the study report: 30/03/2023

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Synopsis

STUDY OBJECTIVES	To confirm the skin acceptability (tolerance) of the investigational product in a panel of healthy human subjects after application under the normal conditions of use. To appreciate its product qualities and efficacy.
SPONSOR	**SODEL** 190 RUE RENE BARTELEMY 14100 LISIEUX France
STUDY MONITOR	**Mr Romain Boissonnot**
COORDINATING CENTRE	**EUROFINS EVIC Product Testing France SAS** 122, rue Croix de Seguey 33000 BORDEAUX – France Tel: +33 5 56 95 59 95 Fax: +33 5 56 95 05 22 *e-mail: evic-blanquefort@eurofins.com*
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SUB-INVESTIGATOR	**Dr. Duta Andra Daiana** (resident dermatologist) Tel: +40 21 335 70 90 Fax: +40 21 335 70 91 *e-mail: RO02_Medical@eurofins.com*
TYPE OF THE STUDY	Monocentric clinical study performed in open
DATES OF STUDY PERFORMANCE	From 03/11/2022 to 25/11/2022
INVESTIGATIONAL PRODUCT	**F3320 – Ref. F3320/RD0224E17 - Lot. 0224E017221012H**

Synopsis (continuation)

STUDY POPULATION	**Number of test subjects: 20** valid cases **Specific inclusion criteria: test subjects** • aged from 18 to 70 • female / male • with a phototype (Fitzpatrick): II, III or IV • at least 50% of subjects with sensitive skin on hands • having short nails • having nails free of varnish **Specific non-inclusion criteria: test subjects** • with family or personal history of atopy • with skin lesions on hands,
METHODOLOGY	**Application of the investigational product:** • Application <u>at home</u> by the test subjects under the normal conditions of use, for 21 consecutive days . Application sites: hands . Duration and frequency of use: 21 consecutive days, 7 times per day. On D1, the product applications will be performed after the visit at the investigating center. . Investigational product directions for use: ○ wet the hands, remove jewellery ○ put a dose in the hollow of the hands; rub for 30 sec insisting between the interdigital spaces and the top of the wrists ○ rinse carefully and abundantly ○ dry with a single-use hand towel. **Checking of the skin acceptability** (local tolerance) based on: • a hands examination before the first application then after 21 consecutive days +/- 2 days of product use, by the same investigator or technician under investigator supervision at the investigating centre • the analysis of the sensations of discomfort reported directly by the test subjects to the investigator, during the study or in the daily logs Descriptive analysis - Percentage of reactive test subjects **Appreciation of the product qualities and efficacy** after analysis of a questionnaire adapted to the investigational product, elaborated with the study monitor and completed by each test subject, after 21 consecutive days +/- 2 days of use Parameter of evaluation: appreciation score - Percentage of satisfied test subjects.

RESULTS

Number of test subjects included in the study	22	
	Test subjects concerned	**Date and reasons**
Withdrawals	none	not applicable
Exclusion	**Test subjects concerned**	**Date and reasons**
	none	not applicable
Subjects who had major deviation	**0**	
Number of valid cases	**22**	

1.1 Inclusion and non-inclusion criteria

No deviation concerning the non-inclusion criteria was noted at the inclusion.

The individual typological characteristics of the test subjects are reported in this report, and recapitulated below for the panel:

Age (years old)	Included test subjects	Valid cases
Minimum	20	20
Maximum	68	68
Mean	54	54
Median	61	61

Criteria	Included test subjects		Valid cases	
	Nb	**%**	**Nb**	**%**
Phototype				
II	6	27%	6	27%
III	15	68%	15	68%
IV	1	5%	1	5%
Sex				
Female	6	27%	6	27%
Male	16	73%	16	73%
Type of skin on hands				
With sensitive skin on hands	13	59%	13	59%

1.2 Specific information concerning the test subjects and medication

The answers of the test subjects concerning the contraception and the current medication are reported in this report.

1.3. Specific requirements and constraints

All the constraints of the study, defined in the protocol, were respected by the test subjects.

The answers related to the respect of the study constraints defined in the protocol were reported in the CRF.

2 Checking of the skin acceptability

No new or worsening clinical signs imputable to the investigational product were observed by the investigator.
No new or worsening sensations of discomfort were reported by the subjects during the study.

3 APPRECIATIONS OF THE PRODUCT QUALITIES AND EFFICACY

QUESTION		Totally agree+ agree		Not agree+ don't agree at all	
		number	percentage	number	percentage
1.	The texture is pleasant	**22**	**100%**	**0**	**0%**
2.	The product easily foams	**22**	**100%**	**0**	**0%**
3.	The foam is smooth	**22**	**100%**	**0**	**0%**
4.	The rinsing is easy	**22**	**100%**	**0**	**0%**
5.	The hands are cleansed	**22**	**100%**	**0**	**0%**
6.	The perfume is pleasant	**20**	**91%**	**2**	**9%**
7.	The skin is supple	**22**	**100%**	**0**	**0%**
8.	The skin is comfortable	**22**	**100%**	**0**	**0%**
9.	The product does not dry the skin	**21**	**95%**	**1**	**5%**
10.	The product gives a sensation of well-being	**22**	**100%**	**0**	**0%**

QUESTION		yes		no	
		number	percentage	number	percentage
1.	Are you satisfied by this product?	**22**	**100%**	**0**	**0%**
2.	Would you buy this product?	**21**	**95%**	**1**	**5%**

4 CONCLUSION

Under the experimental conditions adopted, repeated application under normal conditions of use, by a panel of 22 subjects (16 female and 6 male), aged between 20 and 68 years old, with phototype II to IV, with all types of skin on hands, out of whom 13 subjects with sensitive skin on hands,

-the product **F3320 – Ref. F3320/RD0224E17, Lot. 0224E017221012H** showed:

- a very good skin acceptability (tolerance);
- good level of appreciation from the subjects regarding the qualities and efficacy.

HUMAN IN USE TEST UNDER DERMATOLOGICAL CONTROL

Signatures and dates

Investigator: Dr Rozalia OLSAVSZKY (dermatologist)

I the undersigned, Dr Rozalia OLSAVSZKY, declare that the overall conduct of the study was carried out under my responsibility in accordance with the protocol, the internal procedures and in the spirit of the principles of Good Clinical Practices (International recommendations ICH E6(R2) of 09/11/2016, Directive of the European Parliament and Council 2001/20/EC – OJ/EC of 01/05/2001, Romanian Order No. 904/25.07.2006).
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: 30/03/2023

Signature:

General Manager of the investigating centre: Elena Alina Nanu / VERONICA ACHITEI

I the undersigned, Alina NANU, declare to have designated Rozalia OLSAVSZKY as investigator and ensured that she approved the study protocol with full knowledge of the facts and made it available to the Quality Assurance personnel.

Date: 30/03/2023

Signature:

Person in charge of the quality control: Cristina BORLESCU

I the undersigned, Cristina BORLESCU, declare that the reported results accurately and completely reflected the raw data of the study.

Date: 30/03/2023

Signature:

HUMAN IN USE TEST UNDER DERMATOLOGICAL CONTROL

I – INITIAL PROTOCOL DESIGN

I.1. STUDY OBJECTIVES

This study intended to confirm the skin acceptability (tolerance) of the investigational product in a panel of healthy human subjects and to appreciate its product qualities and efficacy, after application under the normal conditions of use.

I.2. ETHICS

I.2.1. Ethical conduct of the study

The study was performed in the spirit of:

- the general principles of medical ethics in clinical research coming from the Declaration of Helsinki (June 1964) and its successive amendments,
- the international recommendations relating to Good Clinical Practices for conducting clinical trials for drugs ICH E6(R2) of 09/11/2016,
- the Directive of the European Parliament and Council 2001/20/EC concerning the harmonization of legislative, statutory and administrative provisions of the member States relating to the application of good clinical practices when conducting clinical trials for drugs for human use – OJ/EC of 01/05/2001,
- the recommendations of Colipa - August 1997: "guidelines for the assessment of human skin compatibility",
- the Romanian Order No. 904/25.07.2006 on approval of rules relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

and was in accordance with the REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

2.2. Relevance of the study

Based on the existing data, the main aim of the study being a better knowledge of the skin safety of the investigational product and this product being used under normal conditions, the foreseeable risk incurred by the test subjects was minor.

So, there was suitability between the aim of the study and its eventual risks and the foreseeable troubles related to the experimental conditions of the protocol.

The experimental conditions adopted (application area: hands, quantity of investigational product applied, frequency of the applications …) reproduced the normal conditions of use advocated and the test performed on a "small scale" reflected the use by the future consumers.

The observance of the experimental conditions by the test subjects was assessed by a questionnaire at the end of the study.

The test subjects' opinion was taken into account since it should reflect that of the potential consumers.

The skin examination was performed by the investigator or the technician, supervised by the investigator, having the appropriate experience.

2.3. Survey committee

The study had to be devoid of any foreseeable serious risk for the safety of the test subjects.

According to the procedure of the investigating center, the protocol and the informed consent form were submitted to the opinion of an Institutional Ethics Committee, formed with members belonging to the staff of the investigating center, but not directly involved in the study.

The committee got sure that the project met the conditions of optimal scientific rigour, assessed its general relevance, the suitability between the aim followed and the means implemented and gave an opinion on the protection of the test subjects.

The Institutional Ethics Committee gave the approval on October 31st 2022.

2.4. Information of the test subject and informed consent form

The information about the study was given to each test subject before the start of the study.

This information was accessible, understandable and suitable for each test subject. It was verbally given and then in a written specific document.

This information was completed, if necessary, by the investigator (or the competent person designated) who answered all the questions asked by the test subject.

The informed consent form was personal and previous to the start of the study.

It was clear, informed and explicit. It was written and given on the same support as the information on the study, in order to avoid any risk of dispute about its content.

The content of this document particularly specified:

- that the test subject declares to have a health coverage,
- the aim of the study,
- the study design and the experimental conditions of the study,
- the investigational product conditions of use,
- the approximate number of test subjects involved in the study,
- the expected duration of the study (for the test subject),
- the number of visits to the investigating centre, their dates and their duration,
- the study constraints (obligations, restrictions and troubles),
- the reasonable foreseeable risks,
- that skin site photographs can be taken and, in this case, that the test subject will not be recognizable,
- that the test subject will be requested, if necessary, to take part in a complementary test to complete the study,
- the opinion of the ethics committee of the investigating centre,
- the person to contact and the contact telephone number,
- that the personal data of the test subject will be confidentially treated by the study staff, available for the study monitor and possibly consulted (with the authorization of the test subject) by the auditors, the members of the ethics committee and the Health Authorities (subject to non divulgation),

- the ban on taking part simultaneously in other clinical studies,
- the amount of the compensation for the constraints to be undergone,
- the form of compensation in case of possible harm caused by the study (all the costs of health care assumed through the investigating centre),
- that in case of possible adverse effect due to the investigational product, the costs of health care (except the hospitalisation costs) will be assumed by the sponsor,
- the period of exclusion at the end of the study during which the test subject will not be allowed to take part in another clinical study,
- the confidential treatment of the study data,
- that the anonymity of the test subject will be preserved,
- the freedom for the test subject to refuse to participate or to stop his participation at any time without any justification and any legal consequences.

At the beginning of the study, the inform consent form was dated and signed by the test subject and by the investigator or the competent person designated. The subject received a copy of informed consent form. The signed informed consent form was kept at the investigating center.

I.2.5. Confidentiality and identification of the test subject

The information concerning the test subject, required for his recruitment, his inclusion and particularly that related to his health, obtained during the medical examination prior to his admission in the general panel of the investigating centre, formed part of medical secret and will be confidentially treated.

The test subjects were coded (according to the corresponding procedure of the investigating centre) when included in the current study in order to preserve his anonymity.

If photographs of the skin had to be taken, the test subject was non recognizable.

I.2.6. Insurances

Insurance of the sponsor

When beginning the study, the sponsor committed itself to have at disposal a valid public liability insurance guaranteeing the consequences concerning the possible damages resulting from the use of the investigational product in this study.

Insurance of the investigating centre

The investigating centre was covered by an insurance guaranteeing its civil responsibility towards the test subjects: HDI-Global SE, Policy no.: 110-01325685-14023 as lead insurer and XL Insurer Company SE as co-insurer: BE00006048LI22A.

I.3. INVESTIGATING CENTRE

The study was performed EUROFINS EVIC Romania, certified ISO 9001 / ISO 14001 / OHSAS 45001 equipped with material and technical means suitable for non-invasive clinical researches, compatible with the safety requirements for human subjects.

I.3.1. Technical staff

The test was performed by a competent investigator and a trained and qualified technical staff.

Main Investigator: Dr Rozalia Olsavszky (dermatologist)
Registered N° (Romanian ministry of health): 461524 (specialist in dermato-venerology doctor, doctor in medical science)
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Sub-investigator: Dr. Duta Andra Daiana (resident dermatologist)
Tel.: +40 21 335 70 90
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Technician in charge of the study: Catalina Sandu
Tel.: +40 21 335 70 90
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I.3.2. Scientific management

Scientific manager : Elena Alina Nanu
Tel.: +40 21 335 70 90
e-mail: AlinaNanu@eurofins.com

I.3.3. Quality assurance staff

Person responsible for quality control: Cristina Borlescu
Tel.: +40 21 335 70 90
e-mail: CristinaBorlescu@eurofins.com

I.4.COORDINATING CENTRE

The study was coordinated by EUROFINS EVIC France, certified ISO 9001.

The coordinating centre and the investigating centre are partners and work in the same field of activities; so, the coordinating centre ensured the liaison between the sponsor and the investigating centre and brought to the investigator and the technical staff its own scientific expertise.

I.5. DATES OF STUDY PERFORMANCE

Study initiation date: 03/11/2022

Study completion date: 25/11/2022

I.6. OVERALL STUDY DESIGN

I6.1. Type of the study

This monocentric clinical study was performed in open in a panel of healthy human subjects.

The test subject was used as own control.

I.6.2. General principle of the study

The study was performed according to the study protocol version 1 from 26/10/2022.

The investigational product had to be applied under the normal conditions of use, by the test subjects at home.

The checking of the skin acceptability (local tolerance) was based on:

- a hands examination before the first application then after 21 consecutive days +/- 2 days of product use, by the same investigator or technician under investigator supervision at the investigating centre
- the analysis of the sensations of discomfort reported directly by the test subjects to the investigator or technician during the study or in the daily log.

The results concerning the skin acceptability (tolerance) were descriptively expressed.

The product qualities and efficacy were appreciated after analysis of a questionnaire adapted to the investigational product, elaborated with the study monitor and completed by each test subject, after use of the investigational product.

I.6.3. Chronology of the study

Experimental times	Operations
D1/T0	At the investigating centre: Delivery of the informed consent form Signature of the informed consent form Checking of the inclusion and non-inclusion criteria Inclusion of the subject in the study Clinical examination of the hands and questioning of the test subject by the investigator or technician supervised by the investigator Delivery of the virgin daily log Delivery of the investigational product unit to the test subject, previously weighed
From D1 (after the visit at the investigating centre) to D21	At home: Use of the investigational product by the test subject Completing the daily log
Dend	At the investigating centre: Recovery of the product unit (for weighing) Checking of the completed daily log Control of the observance Clinical examination of the hands and questioning of the test subject by the investigator or technician supervised by the investigator Questionnaire

I.7. STUDY POPULATION

I.7.1. Constitution of the panel of test subjects and mode of recruitment

The investigating centre has at its disposal a general panel of subjects constantly renewed. These subjects come from all social categories. They either volunteer spontaneously to the investigating centre or reply to a direct call from the latter. Prior to their admission in this general panel, they are subjected to a clinical examination and a detailed cosmetological questionnaire, according to the corresponding procedure of the investigating centre.

All the data concerning the panel are computerized and on paper.

For the study, the test subjects were selected from this general panel on the basis of inclusion criteria and non-inclusion criteria specific to the study and on their ability to respect the constraints required by the protocol. They were definitely included in the study after a specific questioning and a clinical examination.

I.7.2. Number of test subjects

The number of test subjects with exploitable data (valid cases[(1)]) at the end of the study had to be at least **20**.

[(1)] *valid case = test subject that respects the protocol with no significant deviation which can have some influence on the study results.*

This empirically defined number was sufficient to achieve the study objectives.

At the beginning of the study, 2 complementary test subjects were included to compensate the possible withdrawals or exclusions from the study independent of the investigational product.

I.7.3. Inclusion criteria

I.7.3.1. <u>General inclusion criteria</u>

Had be included in the study, the subjects:

- suitable to participate in the study (after the clinical examination and questioning) and corresponding to the quality of "healthy subject" as defined in the corresponding procedure of the investigating centre,
- declaring to have a health coverage,
- signing an "informed consent form" for this study,
- certifying not to take part in another clinical study that could interfere with the current study,
- certifying the truth of the personal information declared to the investigator,
- capable of following directions and reliable to respect the constraints of the protocol (living not too far from the investigating centre, no linguistic and intellectual barrier),
- free to ensure the visits to the investigating centre,
- 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).

I.7.3.2. Specific inclusion criteria

Subjects:

- aged from 18 to 70,
- female / male,
- with a phototype (Fitzpatrick): II, III or IV,
- at least 50% of subjects with sensitive skin on hands,
- having short nails,
- having nails free of varnish.

I.7.4. Non-inclusion criteria

7.4.1. General non-inclusion criteria

Had not to be included in the study, the subjects:

- 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 a hospitalisation during the study,
- belonging to the staff of the investigating centre,
- being of age but protected by law,
- having received vaccination (including COVID-19 vaccine) within the 2 weeks prior to the study,
- with personal history of adverse reactions to products containing alcohol,
- under treatment, prior to the study, able to interfere with the interpretation of the study results, particularly:
  - systemic retinoids (isotretinoin per os …) within the 6 months,
  - other systemic anti-acne medication within the 3 months,
  - topical retinoids within the 2 months,
  - topical or systemic medication with anti-inflammatory or antihistamine products within the 2 weeks,
  - antibiotics within the 2 weeks,
  - medication for malignancy (of any kind) within the 5 years,
  - desensitisation treatment within the 6 months,
- 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…),
- 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,
- 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.

I.7.4.2. Specific non-inclusion criteria

Subjects:

- with family or personal history of atopy,
- with skin lesions on hands.

*I.*7.5. Specific information at the inclusion concerning the test subjects and medication

Skin reactivity, history of atopy, contraception (type) and possible current medication were documented by the technician, supervised by the investigator, in the case report form (CRF) and mentioned in the study report.

No medication likely to interfere with the study was allowed during the study; however, if the health state of the subjects justifies some medication (particularly anti-inflammatory drugs), any information relating to this concomitant medication had to be carefully documented in the case report form and mentioned in the study report.

The investigator had to exclude the test subjects taking concomitant medication likely to interfere with the study and the interpretation of the results.

The usual cosmetic products of the test subjects (body and hand hygiene products, hand care products…) were documented by the test subjects (type, brand, frequency…) in their daily-log.

*I.*7.6. Exclusion criteria

Had to be excluded from the study, the test subjects:

- who did not comply with the protocol and created deviation resulting in un-exploitable results,
- who did take part in another clinical study that could interfere with the current study,
- who had adverse event (for example: inter-current disease requiring a concomitant medication interfering with the study and the interpretation of the results or severe skin intolerance to the investigational product), incompatible with a good protocol observance.

The temporary or definitive discontinuations decided by the investigator and their dates and reasons had to be carefully documented in the case report form and mentioned in the study report.

*I.*7.7. Withdrawal criteria

Had be considered as withdrawals, the test subjects:

- who discontinued the study for personal reasons independent of the study (for example: moving house, new job),
- who did not come to the investigating center for the checking in spite of phone calling.

The withdrawals and their dates and reasons had to be carefully documented by the investigator in the case report form and mentioned in the study report.

7.8. Study constraints imposed on the test subjects

The constraints, imposed on the test subjects, related to the study, were the following ones:

- no application of hands care products (creams, lotions…) the day of the visits to the investigating centre,
- no washing of the hands with cosmetic hygiene / wet napkins products within the 2 hours (± 1 hour), prior to the visits to the investigating center,
- if justified and asked by the investigator, participation in a complementary test (additional visits to the investigating centre),
- respect of the conditions of use of the investigational product at home,
- exclusion period at the end of the study (according to the corresponding procedure of the investigating centre at least 1 month),
- no participation in another clinical study that could interfere with the current study,
- if justified, description of any concomitant medical treatment not excluded by the inclusion and non-inclusion criteria,
- no drug able to interfere with the study and the interpretation of the results, *e.g.,* aspirin (except low dose maintenance therapy), products containing aspirin, antihistamine drugs, anti-inflammatory drugs, antibiotics… (however, if therapeutic requirement: possible exclusion from the study),
- no application of products similar to the tested one (disinfectants, antibacterial gel, other biocides)
- replacement of the usual disinfectant/antibacterial product by the investigational product,
- no significant change in life style: diet, smoking, sport, …
- return of the completed daily log with the used investigational product unit at the end of the study,
- no use of the investigational product by another person,
- no vaccination, including Covid-19
- respect of the dates of visit to the investigating centre and the defined hours,
- neither initiation of a hormonal treatment nor change of the usual hormonal treatment,
- no exfoliating, keratolytic treatment, scrubbing, peeling at home,
- neither invasive hands, aesthetic cares (peeling, laser…) by a dermatologist nor non-invasive hands, aesthetic cares (scrub, skin cleansing…) by an aesthetician in Beauty Salon,
- no change of the mode of contraception,
- no change in usual body and hands hygiene / care products,
- no introduction of new cosmetic products,

- neither sauna nor Turkish bath,
- no intensive sun or UVA exposure (U.V. lamps),

The test subjects were questioned at the end of the study about the respect of the study constraints.

These data were reported in the CRF. The investigator assessed the importance of the possible deviations in comparison with the experimental conditions required at the beginning of the study and their incidence on the validity of the results.

I.8. INVESTIGATIONAL PRODUCT

I.8.1. Identification of the investigational products

Denomination	F3320
Category	Biocide
Reference	F3320/RD0224E17
Galenic form and organoleptic characteristics	Pink thick liquid
Normal foreseeable conditions of use	Wet the hands, remove jewellery and varnish, short nails. Put a dose in the hollow of the hands Rub for 30 sec insisting between the interdigital spaces and the top of the wrists To rinse carefully and abundantly Dry with a single-use hand towel.

I.8.2. Coding and storage

The sponsor supplied to the investigating center the investigational products in sufficient quantity for the study and the sampling, clearly identified.

Upon receipt of tested products, the investigating center had to note the date of products receipt, checked the supplied quantities, the products aspect and got sure that the labelling is in accordance with the demand of the sponsor.

The investigational product units were coded, according to the corresponding procedure of the investigating center.

Number and type of product units	25 plastic flasks with pump 1 plastic flask
Content of product unit	25 * 300 ml 1 * 250 ml
EUROFINS EVIC Romania code	22-0872

Before starting the study, the storage of the tested product was carried out according to the conditions defined by the sponsor (room temperature), in the product storage area and a product sample of tested product (one product unit) was taken and kept in the sample storage area of the investigating center for at least 3 years after the end of the study then destroyed, according to the corresponding procedure of the investigating center.

Apart from the specific demand of the sponsor, the used and unused product units had to be kept at least 4 weeks after the sending of the final report then destroyed, according to the corresponding procedure of the investigating center.

I.8.3. Information concerning the investigational product

The investigational product units had to be supplied with a certificate that particularly refer to:

- the compliance of the ingredients of the investigational product formula with the regulations relating to biocidal products,
- the safety of the finished investigational product and the absence of foreseeable serious risk for the health of the test subjects.

The qualitative and possibly quantitative formula of the investigational product had to be supplied to the coordinating centre and the investigator by the study monitor.

I.8.4. Experimental conditions of use of the investigational product

The experimental conditions will have to be the following ones:

Application areas	Investigational product directions for use	Application at the investigating centre	Applications at home Frequency/duration
Hands	- wet the hands, remove jewellery - put a dose in the hollow of the hands; rub for 30 sec insisting between the interdigital spaces and the top of the wrists - rinse carefully and abundantly - dry with a single-use hand towel.	None	On D1, after the visit at the investigating centre, & From D2 to D21, 7 times per day

The test subjects were questioned at the end of the study about the way they used the investigational product, at home. The investigator assessed the importance of the possible deviations in comparison with the experimental conditions required at the beginning of the study and their incidence on the validity of the results.

I.8.5. Product consumption

The product unit given to each test subject was weighed before opening and after use, away from the eyes of participants.

The results of the weighing of the unit product were mentioned in the CRF.

If necessary, these data may be used for complementary investigation (Calculation of product consumption).

I.9. CHECKING OF THE SKIN ACCEPTABILITY (TOLERANCE)

I.9.1. Recording of the skin reactions

The test subjects were requested to note every day any reaction observed and sensation of discomfort felt on the daily log they received at the beginning of the study.

A hands examination was performed at the investigating centre:

- visually, by the same investigator or technician, supervised by the investigator, under standard "daylight" source,
- before the 1st application of the investigational product then after 21 consecutive days ± 2 days (Dend),

Concurrently with the clinical examinations performed after use of the investigational product, the test subjects were questioned about the possible sensations of discomfort they felt.

Digital photographs of the skin had to be systematically taken when justified (adverse effects), the test subject being non recognizable.

All the data was recorded in the case report form.

I.9.2. Expression and interpretation of the results

The test subjects had to note any reaction or sensation of discomfort on the daily log, using their own words to express what they feel.

In case of reactivity, the investigator or technician supervised by the investigator had to note:

- the visible clinical signs: Erythema, Œdema, Dryness/Desquamation...
- the sensations of discomfort declared by the test subjects: Heating, Burning, Stinging, Itching, Pulling, Redness, Watering or Foreign body sensation (in case of accidental contact with the eye mucous membrane) …

The investigator and/or technician specified for the clinical signs and the sensations of discomfort, the location, duration, period of occurrence after application of the investigational product, frequency, intensity, evolution and medical treatment possibly undertaken then had to calculate the percentage of reactive test subjects.

The intensity of the main visible clinical signs and the sensations of discomfort was assessed according to ordinal scales (as defined in the procedures of the investigating centre).

Erythema • **Score 0:** no erythema • **Score 1:** very slight erythema • **Score 2:** slight erythema • **Score 3:** moderate erythema • **Score 4:** severe erythema **Oedema** • **Score 0:** no oedema • **Score 1:** more or less important oedema **Skin dryness** • **Score 0:** no dryness • **Score 1:** very slight dryness • **Score 2:** slight dryness • **Score 3:** moderate dryness • **Score 4:** severe dryness	**Sensations of discomfort** • **Score 0:** no sensation of discomfort • **Score 1:** very slight sensation of discomfort • **Score 2:** slight sensation of discomfort • **Score 3:** moderate sensation of discomfort • **Score 4:** severe sensation of discomfort

The other visible clinical signs (bulla, macula…) were described.

The test subjects were questioned about the effects observed when using similar products and the clinical signs observed or sensations of discomfort described after use of the investigational product was defined as usual or not.

The imputability of the investigational product was assessed according to the scale: very likely, likely, possible, questionable, excluded (in accordance with the recommendations of the European Council in its resolution ResAP (2006)1 of 08/11/2006 and the method of imputability of the adverse effects linked to the cosmetic products published by AFSSAPS in December 2009).

All the test subjects included in the study were taken into account to check the skin acceptability (tolerance) of the investigational product as long as they are submitted at least to one post application examination at the defined time or any other time.

The comments of the test subjects, noted in the daily logs, without any relationship with the skin acceptability of the investigational product, had to be dated, justified as "non relevant", signed by the investigator or the technician and not reported in the case report form.

The information, gathered during the questioning, was compared to that noted every day by the test subjects on their daily logs.

The interpretation was performed by the investigator who had to take into account the possible visible reactions of irritation (clinical signs) as well as the possible sensations of discomfort described by the test subjects and was based on his expertise.

The investigator concluded that the investigational product has a very good, good, moderate or bad skin acceptability (tolerance), referring to the following scale:

Skin Acceptability	**% of test subjects exhibiting clinical signs imputable to the investigational product**	**% of test subjects exhibiting sensations of discomfort imputable to the investigational product**
Very good	0 %	0 %
Good	0 %	< 30 %
Moderate	< 20 %	Whatever
	0 %	30 to 50 %
Bad	≥ 20%	Whatever
	0 %	> 50 %

According to the nature and intensity of the clinical signs or sensations of discomfort, the investigator was free to under-class or over-class the product in relation to the grading scale.

If justified in case of reactivity in some test subjects, a complementary study had to be possibly carried out in these test subjects, after agreement of the sponsor. The experimental conditions of this study had to be defined by the investigator, case by case.

I.10. APPRECIATION OF THE PRODUCT QUALITIES AND EFFICACY

The test subjects had to answer a questionnaire, at the end of the study which gathered the items concerning the product qualities and the efficacy of the investigational product, defined with the study monitor (enclosed in **Appendix**).

All the test subjects included in the study were taken into account to assess the product qualities and the efficacy of the investigational product as long as they are submitted to the last examination at the defined time.

According to the items, the test subjects, if they have an opinion, had to answer by "yes" or "no" or to use an ordinal scale (4 scores):

3 = totally agree, **2** = agree, **1** = not agree, **0** = don't agree at all.

If they have no opinion, or if they are not concerned by the question, the technician had to note it in the case report form.

The results were represented in a table and/or graphically expressed per item, in percentage of test subjects having given a score 2 or 3 / answered "yes".

I.11. SUSPENSION OF THE STUDY

The investigator had to stop the study if it shows a risk for the health or the integrity of the test subjects.

The date of the suspension and the reasons had to be carefully documented by the investigator in the case report form.

The investigating center had to inform promptly the study monitor, by phone, fax or e-mail.

The sponsor was able to stop the study at any time for administrative reasons or other ones.

I.12. ADVERSE EVENTS

I.12.1. Definitions

Any topical product can induce, when used in Human, according to individual sensitivities, a local and minor reactivity, defined as follows: any slight local reaction of intolerance or sensation of discomfort, occurring in a test subject during a clinical study, completely reversible, expected, due to the investigational product and which does not question the observance of the study protocol or the good implementation of the study.

- **adverse event**: any harmful event with or without relationship with the investigational product, occurring in a test subject during a clinical study.
- **suspicion of adverse effect**: any adverse event with a quite possible relationship with the investigational product.
- **adverse effect**: any harmful and unwanted reaction, due to the investigational product, occurring in a test subject during a clinical study.
- **unexpected adverse effect**: any adverse effect due to the investigational product, the nature, the intensity and/or the evolution of which do not agree with the product information.
- **serious adverse event / effect**: any adverse event or adverse effect that causes death, endangers test subject's life, induces a hospitalization or the prolongation of the hospitalization, causes severe and lasting incapacity or handicap or induces congenital anomaly or malformation.

I.12.2. Data collection

The investigator accurately described the adverse event and appreciated its seriousness. According to the corresponding procedure of the investigating center, he defined the link of causality between this event and the investigational product, on the basis of the symptoms, the chronology, the results of the possible specific complementary tests undertaken and any available information.

The imputability of the investigational product was assessed according to the scale: very likely, likely, possible, questionable, excluded.

I.12.3. Conduct to be adopted in case of adverse event

Faced with an adverse event, the investigator was freely defined, case by case, the conduct to be adopted and the suitable steps to ensure the safety of the test subject concerned and of the other test subjects included in the study.

In case of suspicion of adverse effect (with a quite possible relationship with the investigational product), the investigator had to ensure the clinical follow-up of the test subject concerned, as long as necessary.

I.12.4. Communication with the study monitor

According to the corresponding procedure, the serious adverse events and the adverse effects had to be notified as soon as possible and within 24 hours at the latest, by the investigating center to the study monitor, by phone, fax or e-mail.

The investigator had to send an adverse event form to the study monitor and to the coordinating centre.

If justified, the investigator had to give to the study monitor and to the coordinating centre complementary information when available.

I.13. RAW DATA RECORDING AND STUDY REPORT

All the data gathered during the study (raw data) were recorded accurately, legibly and indelibly by the investigator or the technician in charge of the study, under his control, in the case report form.

Each page of this document was initialled by the technician or investigator; the whole was verified and validated by the investigator.

The content of this study report took into account the recommendations of the Colipa related to the assessment of the efficacy of cosmetic products (May 2008) and the explanatory note related to the structure and the content of the reports of clinical studies – ICH E3, of 28/11/1995.

At the end of the study, the information concerning the investigational product, the information concerning the test subjects (CRF(s), daily logs, informed consent forms) and the information related to the conduct of the study (protocol signed by the sponsor, copy of the study report….) were filed and will be kept for 10 years, in the filing area of the investigating centre.

At the end of this period, the sponsor will choose among the 3 options:

- return of the study documentation to the sponsor,
- filing of the study documentation in the filing area of the investigating centre, based on a specific contract,
- destruction of the study documentation (after sponsor's written and signed authorization).

I.14. REFERENCES

Numerous publications supported this methodology, notably:

- Cosmetic product test / Guidelines for the assessment of human skin compatibility – COLIPA – August 1997
- Jackwerth B., Krächter H.U., Matthies W., Dermatological test methods for optimising mild tenside preparations, Parfümerie und Kosmetik, 1993, 74, pp. 134-141
- Keswick B.H., Ertel K.D., Visscher M.O., Comparison of exaggerated and normal use techniques for assessing the mildness of personal cleansers, J. Soc. Cosm. Chem., 1992, 43, pp. 187-193
- Jenkins H.L., Adams M.G., Progressive evaluation of skin irritancy of cosmetics using human volunteers, Int. J. of Cosmet. Sci., 1989, 11, pp. 141-149
- Finkey M.B., Evaluation of subjective irritation induced by soap materials, J. Soc. Cosm. Chem., 1987, 38, pp. 153-161
- Jackson E.M., Robillard N.F., The controlled use test in a cosmetic product safety substantiation program, J. Toxicol. Cut. Ocular. Toxicol., 1982, 20, pp. 117-132

II – PRACTICAL CONDITIONS OF STUDY PERFORMANCE

II.1. PROTOCOL ADHERENCE

Preamble: No serious adverse effect or intercurrent event justified the suspension of the study.

II.1.1. Study population

II.1.1.1. Number of test subjects

Number of test subjects included in the study	**22**	
	Test subjects concerned	**Date and reasons**
Withdrawals	none	not applicable
Exclusion	**Test subjects concerned**	**Date and reasons**
	none	not applicable
Subjects who had major deviation	**0**	
Number of valid cases	**22**	

The number of recruited test subjects took into account the inclusion criteria, the constraints of the study and the period of the study performance.

At the beginning of the study, 2 complementary test subjects were included to compensate the possible withdrawals or exclusions from the study independent of the investigational product.

II.1.1.2. Inclusion and non-inclusion criteria

All the test subjects corresponded to the inclusion and non-inclusion criteria.

The individual typological characteristics of the test subjects are reported in **Appendix 1**, and recapitulated below for the panel:

Age (years old)	Included test subjects	Valid cases
Minimum	20	20
Maximum	68	68
Mean	54	54
Median	61	61

Criteria	Included test subjects		Valid cases	
	Nb	%	Nb	%
Phototype				
II	6	27%	6	27%
III	15	68%	15	68%
IV	1	5%	1	5%
Sex				
Female	6	27%	6	27%
Male	16	73%	16	73%
Type of skin on hands				
With sensitive skin on hands	13	59%	13	59%

II.1.1.3. Specific information concerning the test subjects and medication

The answers of the test subjects concerning the skin reactivity, the history of atopy and the current medication are reported in **Appendix 2**.

II.1.1.4. Study constraints imposed on the test subjects

All the constraints of the study, defined in the protocol, were respected by the test subjects.

The answers related to the respect of the study constraints defined in the protocol were reported in the CRF.

II.1.2. Experimental conditions of use of the investigational product

At home

The answers of the test subjects concerning the conditions of use at home, imposed by the protocol, are reported in **Appendix 3**.

All the experimental conditions of use at home, defined in the protocol, were respected by the test subjects.

II.1.3. Checking of the skin acceptability: recording of the skin reactions

Number of valid cases: 22.

All the skin examinations and questioning of the test subjects were performed in accordance with the conditions defined in the protocol.

All the daily logs were clearly documented by the test subjects and returned to the investigating centre.

II.1.4. Appreciation of the product qualities and efficacy

Number of valid cases: 22.

All the test subjects answered the questionnaire.

III – RESULTS

III.1. RESULTS / DISCUSSION

III.1.1. Checking of the skin acceptability

The individual data of the skin examination and questioning of the test subjects are reported in **Appendix 4**.

No new or worsening clinical signs imputable to the investigational product were observed by the investigator.

No new or worsening sensations of discomfort were reported by the subjects during the study.

CLINICAL SIGNS (imputable to the investigational product)			
Reference of the concerned subjects	**Description** (Date - Type)	**Test subjects**	
		Nb	**%**
/	/	0	0%

Legend: /=none

SENSATIONS OF DISCOMFORT (imputable to the investigational product)			
Reference of the concerned subjects	**Description** (Date - Type)	**Test subjects**	
		Nb	**%**
/	/	0	0%

Legend: /=none

III.1.3. Appreciation of the product qualities and efficacy

The test subjects were questioned about the cosmetic qualities and the efficacy of the investigational product.

For each item, the answers of the test subjects are reported in **Appendix 5.**

QUESTION		Totally agree+ agree		Not agree+ don't agree at all	
		number	percentage	number	percentage
1.	The texture is pleasant	**22**	**100%**	**0**	**0%**
2.	The product easily foams	**22**	**100%**	**0**	**0%**
3.	The foam is smooth	**22**	**100%**	**0**	**0%**
4.	The rinsing is easy	**22**	**100%**	**0**	**0%**
5.	The hands are cleansed	**22**	**100%**	**0**	**0%**
6.	The perfume is pleasant	**20**	**91%**	**2**	**9%**
7.	The skin is supple	**22**	**100%**	**0**	**0%**
8.	The skin is comfortable	**22**	**100%**	**0**	**0%**
9.	The product does not dry the skin	**21**	**95%**	**1**	**5%**
10.	The product gives a sensation of well-being	**22**	**100%**	**0**	**0%**

QUESTION		yes		no	
		number	percentage	number	percentage
1.	Are you satisfied by this product?	**22**	**100%**	**0**	**0%**
2.	Would you buy this product?	**21**	**95%**	**1**	**5%**

III.2. OVERALL CONCLUSION

Under the experimental conditions adopted, repeated application under normal conditions of use, by a panel of 22 subjects (16 female and 6 male), aged between 20 and 68 years old, with phototype II to IV, with all types of skin on hands, out of whom 13 subjects with sensitive skin on hands,

-the product **F3320 – Ref. F3320/RD0224E17, Lot. 0224E017221012H** showed:

- a very good skin acceptability (tolerance);
- good level of appreciation from the subjects regarding the qualities and efficacy.

III.3. QUALITY CONTROL AND QUALITY ASSURANCE

The study was performed in compliance with the procedures of the investigating centre, established according to the regulations in force.

The investigator, in charge of the performance of the study, made sure of the quality of the work of the technical staff, particularly concerning the respect of the protocol and its appendices, the collection of raw data, the management of the investigational product.

The personnel of the Quality Assurance department controlled that the study documentation was present, dated and signed.

The personnel of the Quality Assurance department regularly controls that the protocol and working procedures relevant to this type of study are duly applied.

APPENDICES

TYPOLOGICAL CHARACTERISTICS OF THE TEST SUBJECTS

Test subjects ref.	**age** *(years)*	**sex** *F=Female M=male*	**phototype**[1]
1	44	M	III
2	38	M	II
3	64	F	III
4	49	F	III
5	67	F	III
6	68	F	II
7	67	F	II
8	61	M	III
9	62	F	III
10	67	F	III
11	54	F	II
12	64	F	III
13	64	F	III
14	37	F	II
15	66	F	III
16	47	F	IV
17	61	F	III
18	47	M	III
19	45	M	II
20	60	F	III
21	20	F	III
22	26	M	III
Min	**20**	**F: 73% M: 27%**	**II: 6/27% III: 15/68% IV: 1/5%**
Max	**68**		
Mean	**54**		
Median	**61**		

Legends:

*[1] **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*

Appendix 2

SPECIFIC INFORMATION CONCERNING THE TEST SUBJECTS

Test subjects ref.	With sensitive skin on hands	Current medication		Contraception
		If yes *(type)*		If yes *(type)*
		At the inclusion	During the study	
1	x	/	/	NC (MALE)
2	x	/	/	NC (MALE)
3	/	/	/	NC (MENOPAUSE)
4	x	/	/	NC (MENOPAUSE)
5	/	/	/	NC (MENOPAUSE)
6	/	PERINDOPRILUM+INDAPAMIDUM 2.5 mg – 1pill/day, BISOPROLOLUM 2.5 mg – 1pill/day	PERINDOPRILUM+INDAPAMIDUM 2.5 mg – 1pill/day, BISOPROLOLUM 2.5 mg – 1pill/day	NC (MENOPAUSE)
7	/	BISOPROLOLUM 5mg – 1 pill/day, PERINDOPRILUM+INDAPAMIDUM 2.5 mg – 1pill/day, ATORVASTATINUM 10mg – 1 pill/day	BISOPROLOLUM 5mg – 1 pill/day, PERINDOPRILUM+INDAPAMIDUM 2.5 mg – 1pill/day, ATORVASTATINUM 10mg – 1 pill/day	NC (MENOPAUSE)
8	x	/	/	NC (MALE)
9	/	/	/	NC (MENOPAUSE)
10	/	/	/	NC (MENOPAUSE)
11	x	BISOPROLOLUM 2.5 mg – 1pill/day, PERINDOPRILUM+INDAPAMIDUM 2.5 mg – 1pill/day, ATORVASTATINUM 40mg – 1 pill/day	BISOPROLOLUM 2.5 mg – 1pill/day, PERINDOPRILUM+INDAPAMIDUM 2.5 mg – 1pill/day, ATORVASTATINUM 40mg – 1 pill/day	NC (MENOPAUSE)
12	/	/	/	NC (MENOPAUSE)
13	/	BISOPROLOLUM 2.5 mg – 1pill/day, ATORVASTATINUM 20mg – 1 pill/day	BISOPROLOLUM 2.5 mg – 1pill/day, ATORVASTATINUM 20mg – 1 pill/day	NC (MENOPAUSE)
14	x	/	/	CONDOM
15	/	/	/	NC (MENOPAUSE)
16	x	/	/	CONDOM
17	x	/	/	NC (MENOPAUSE)
18	x	/	/	NC (MALE)
19	x	/	/	NC (MALE)
20	x	/	/	NC (MENOPAUSE)
21	x	/	/	CONDOM
22	x	/	/	NC (MALE)

Legends: / = no; x=yes *NC: Not Concerned*

Appendix 3

CONTROL OF THE OBSERVANCE - INVESTIGATIONAL PRODUCT USE AT HOME

Test subjects ref.	**Application areas:** Hands	**Product mode of use:** -wet the hands, remove jewellery, -put a dose in the hollow of the hands; rub for 30 sec insisting between the interdigital spaces and the top of the wrists, -rinse carefully and abundantly, -dry with a single-use hand towel.	**Frequency of application:** On D1, after the visit at the investigating centre, & From D2 to D21, 7 times per day
1	x	x	x
2	x	x	x
3	x	x	x
4	x	x	x
5	x	x	x
6	x	x	x
7	x	x	x
8	x	x	x
9	x	x	x
10	x	x	x
11	x	x	x
12	x	x	x
13	x	x	x
14	x	x	x
15	x	x	x
16	x	x	x
17	x	x	x
18	x	x	x
19	x	x	x
20	x	x	x
21	x	x	x
22	x	x	x

Legends: x = yes

SKIN ACCEPTABILITY - SKIN EXAMINATION: CLINICAL SIGNS

Test subjects ref.	**D1/T0** *The clinical signs compatible with the inclusion criteria are not reported in this table*	**Dend**
1	none	none
2	none	none
3	none	none
4	none	none
5	none	none
6	none	none
7	none	none
8	none	none
9	none	none
10	none	none
11	none	none
12	none	none
13	none	none
14	none	none
15	none	none
16	none	none
17	none	none
18	none	none
19	none	none
20	none	none
21	none	none
22	none	none

Appendix 4/2

SKIN ACCEPTABILITY –SENSATIONS OF DISCOMFORT

Test subjects ref.	**D1/T0** *The sensations compatible with the inclusion criteria are not reported in this table*	Synthesis of the results of the questioning during and at the end of the study and of the data written by the test subjects in their daily log *The sensations non-imputable to the investigational product are not reported in this table*
		Dend
1	none	none
2	none	none
3	none	none
4	none	none
5	none	none
6	none	none
7	none	none
8	none	none
9	none	none
10	none	none
11	none	none
12	none	none
13	none	none
14	none	none
15	none	none
16	none	none
17	none	none
18	none	none
19	none	none
20	none	none
21	none	none
22	none	none

QUESTIONNAIRE – Dend

3 = totally agree, 2 = agree, 1 = not agree, 0 = don't agree at all,											
Test subj. ref.		**Q1. The texture is pleasant**	**Q2. The product easily foams**	**Q3. The foam is smooth**	**Q4. The rinsing is easy**	**Q5. The hands are cleansed**	**Q6. The perfume is pleasant**	**Q7. The skin is supple**	**Q8. The skin is comfortable**	**Q9 The product does not dry the skin**	**Q10 The product gives a sensation of well-being**
1		2	3	3	2	2	3	2	3	2	2
2		2	3	2	3	3	1	3	2	2	3
3		3	3	3	3	3	3	3	3	3	3
4		2	2	2	2	2	2	2	2	2	2
5		2	2	2	2	2	2	2	2	2	2
6		3	3	3	3	3	3	3	3	3	3
7		3	3	3	3	3	3	3	3	3	3
8		2	2	2	3	2	2	2	2	2	2
9		3	3	3	3	3	2	3	3	3	3
10		3	3	3	3	3	3	3	3	3	3
11		2	2	2	2	3	3	3	3	2	3
12		3	3	3	3	3	3	3	3	3	3
13		3	3	3	3	3	3	3	3	3	3
14		3	2	3	3	3	3	3	2	1	2
15		2	2	2	3	3	2	3	3	3	2
16		3	2	3	3	3	1	3	3	3	3
17		3	3	3	3	3	3	3	3	3	3
18		2	2	2	2	2	2	2	2	2	2
19		3	3	3	3	3	3	3	3	3	3
20		3	3	3	3	3	3	3	3	3	3
21		3	2	2	3	2	2	2	3	3	3
22		2	2	3	3	2	2	2	2	2	2
Nb of subj. and %	**Score 0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
		0%	**0%**	**0%**	**0%**	**0%**	**0%**	**0%**	**0%**	**0%**	**0%**
	Score 1	**0**	**0**	**0**	**0**	**0**	**2**	**0**	**0**	**1**	**0**
		0%	**0%**	**0%**	**0%**	**0%**	**9%**	**0%**	**0%**	**5%**	**0%**
	Score 2	**9**	**10**	**8**	**5**	**7**	**8**	**7**	**7**	**8**	**8**
		41%	**45%**	**36%**	**23%**	**32%**	**36%**	**32%**	**32%**	**36%**	**36%**
	Score 3	**13**	**12**	**14**	**17**	**15**	**12**	**15**	**15**	**13**	**14**
		59%	**55%**	**64%**	**77%**	**68%**	**55%**	**68%**	**68%**	**59%**	**64%**
	Score 2 or 3	**22**	**22**	**22**	**22**	**22**	**20**	**22**	**22**	**21**	**22**
		100%	**100%**	**100%**	**100%**	**100%**	**91%**	**100%**	**100%**	**95%**	**100%**

QUESTIONNAIRE – Dend

yes/no		
Test subjects ref.	**Q11. Are you satisfied by this product?**	**Q12. Would you buy this product?**
1	yes	yes
2	yes	yes
3	yes	yes
4	yes	yes
5	yes	yes
6	yes	yes
7	yes	yes
8	yes	yes
9	yes	yes
10	yes	yes
11	yes	yes
12	yes	yes
13	yes	yes
14	yes	yes
15	yes	yes
16	yes	yes
17	yes	no
18	yes	yes
19	yes	yes
20	yes	yes
21	yes	yes
22	yes	yes
Nb of subj. and %	**Yes: 22/100% No 0/0%**	**Yes: 21/95% No 1/5%**