EVALUATION OF PRIMARY SKIN IRRITATION POTENTIAL
(48 HOUR PATCH TEST)

PROTOCOL N°: 1110
TEST CODE: TO0405
SUBMITTED TO: DERMOGYN S.r.l.

Viale Umbria n° 63
20135 Milano

PRODUCT: EMULGEL GINECOLOGICO LINDT 1418
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FINAL REPORT
EVALUATION OF PRIMARY SKIN IRRITATION POTENTIAL
(48 HOUR PATCH TEST)

TEST CODE: TO0405
DATE: 15/07/05

SUBMITTED TO: DERMOGYN S.r.l.
Viale Umbria n° 63
20135 Milano

PRODUCT: EMULGEL GINECOLOGICO LINDT 1418

PROTOCOL: 1110
PACKING CHARACTERISTICS:
-MATERIAL: plastic
-TYPE: tube
-COLOUR: white

PRODUCT:
-QUANTITY: 50 gr
-PHYSICAL ASPECT: gel
-COLOUR: beige

SAMPLES RECEIVING DATE: 16/05/05
TEST START DATE: 04/07/05

RESPONSIBLE FOR THE STUDY: Dr. Adele Sparavigna
Clinical Research Director
Dermatologist

DermIng, Institute of Clinical Research and Bioengineering
Viale Cesare Battisti, 38 20052 Monza (MI)
Tel: 039/329666 Fax: 039/5964228

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TEST CONDUCTED BY: DermIng, Institute of Clinical Research and Bioengineering, Viale Cesare Battisti 38, 20052 Monza, Milan.

1. SUMMARY OF THE PROTOCOL

1.1 Study objective and definitions
Aim of the study is to evaluate primary skin irritation potential of the product on volunteers' healthy skin by a 48-hour patch test.
The 48 hours patch test corresponds to the application of the product under occlusive conditions for 48 hours.

1.2 Characteristics of the population at inclusion
21 healthy volunteers, whose written informed consent had been obtained, were included in the study.
1.2.1 Sex: 22 females
1.2.2 Age range: 23 – 66 years

1.3 Summary of the study methodology
The test product was applied undiluted and remained for 48 hours under occlusive conditions on the back skin of 22 healthy volunteers.
Results were collected at the following times: 15 minutes, 24h, 48h and 72h after the removing of the patch test.

2. RESULTS
Under the reported experimental conditions, the irritation index resulted 0 at all considered times.
No irritant or allergic reaction was observed for the study product.
3. CONCLUSIONS

The "EMULGEL GINECOLOGICO LINDT 1418" resulted as not irritant when in contact with human skin. In the group of the examined volunteers no allergic reaction to the product occurred.

These results concern exclusively tested product and experimental conditions adopted.

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### EMULGEL GINECOLOGICO LINDT 1418

#### PRODUCT:  
**1110**

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### LEGEND:

**ERYTHEMA**

0 = no erythema  
1 = very slight erythema (barely perceptible)  
2 = well-defined erythema  
3 = moderate to severe erythema  
4 = severe erythema (beet redness)  
   to slight eschar formation (injuries in depth)

**OEDEMA**

0 = no oedema  
1 = very slight oedema (barely perceptible)  
2 = slight oedema  
3 = moderate oedema  
4 = severe oedema

**OTHER SYMPTOMS**

0 = no vesiculation  
1 = slight vesiculation  
2 = evident vesiculation  
3 = severe vesiculation

### IRRITATION INDEX:

0 at all considered times

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Test code: TO0405

Total pages n°: 0190066
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STUDY PROCEDURE
STUDY PROCEDURE
EVALUATION OF PRIMARY SKIN IRRITATION POTENTIAL
(48 HOUR PATCH TEST)

1. PURPOSE AND DEFINITIONS
Aim of the study is to evaluate primary skin irritation potential of the product on volunteers’ healthy skin by a 48 hour patch test.

2. MATERIALS
- Non-occlusive porous sticking plasters Luxor Pore (large: 5 cm) - (Salvadori S.p.a.).
- Filter paper IQ Chambers – (Chemotechnique Diagnostics)
- Inert plastic material IQ Chambers - (Chemotechnique Diagnostics)
- Sterile disposable syringes

3. VOLUNTEERS
3.1 Source
Volunteers are selected from the general volunteer panel belonging to the centre

3.2 Age and sex
Volunteers of both sexes are between the age of 18 and 70.

3.3 Number of volunteers
At least 20 subjects

3.4 Volunteers’ consent
All volunteers must sign a standard consent form which includes the following elements:
1) An explanation of the purposes of research, the expected duration of the test and a brief description of the procedures to be followed.
2) Information about any foreseeable risks to the subject
3) A description of the benefits of the test
4) A statement describing the confidentiality of records
5) Name and telephone number of the dermatologist to be contacted for additional information about the research and in case of a research-related injury to the subject
6) A statement that participation in the study is completely voluntary and free of charge
7) A statement that the treatment of obtained data is made according to Italian Law n.675 of 31.12.96

3.5 Recruitment of the volunteers
3.5.1 Inclusion criteria
- Volunteers of both sexes
- Age 18 to 70 years
- Healthy volunteer not taking drugs or undergoing surgical interventions

3.5.2 Non inclusion criteria
- Persons who do not fulfil the above-mentioned criteria
- Volunteers having participated to a similar study during the previous three months
- Volunteers with visible dermatosis on test area
- Volunteers reporting allergies to cosmetic products or toiletries
- Volunteers anticipating significant exposure to the sun or to UV light during the study

3.6 Case report form
A record card is filled in for each volunteer, reporting name, address, telephone number, assignation of the products, clinical evaluations made in basal and at the end of the treatment, and any information concerning test results.

4. SAMPLES ACCEPTANCE
4.1 Samples record
The products to be tested are recorded, with a reference number, in the Human Studies Record Book together with additional information such as the arrival date, the test
requested, Sponsor's name, the product code, the order number and any other information reported on the container.

4.2 Analytical control investigation
It is the responsibility of the Study Sponsor to determine identity and physicochemical characteristics of the product, and all other criteria permitting identification of the product batch.

4.3 Storage
The sample is stored under ambient conditions unless the Sponsor issues special instructions. After testing, a sample of each product is retained and stored under ambient conditions for at least 12 months from the date of report issue.

5. PROCEDURE
5.1 Preliminary examination
Volunteers are examined by the dermatologist who ensures that the skin areas to treat are free from dermatitis and that each volunteer has understood the test, the consent form being completed and signed.

5.2 Test recording
The dermatologist fills in the case report card, recording basal and final measurements.

5.3 Test products concentration
The test product concentration to be used will be determined as described: most product are applied undiluted. Products containing surface active agents are tested at dilutions of 1% and 10% in deionised water. In the case of soaps, dissolution is achieved by immersing the vessel containing the required amount of soap and deionised water in hot water. In the case of aerosol products these are sprayed onto filter paper, allowing the propellant to evaporate so that only the concentrate is applied to the skin. All sample dilutions are freshly prepared on the day of the test.
5.4 Test products application
Product application may be either occlusive or non-occlusive as agreed with the Sponsor. In general products containing surface active agents or a high proportion of organic solvent are tested without occlusion since these materials are highly irritant under occlusive conditions.

5.5 IQ Chambers removal
After 48 hours since products application, the volunteers will go back to the Centre to remove the IQ Chambers.
The cutaneous areas tested will be cleaned with water and marked by dermographic pencil. All the cutaneous areas where the occlusive conditions are not maintained for 48 hours, will be excluded from the evaluation of irritation index.

5.6 Examination of skin reactions
Skin reactions are scored and recorded according to the grades in the following table. In addition to the observation of irritation any serious lesion and other toxic effect are fully examined.

A) Erythema:

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<tr>
<td>0</td>
<td>no erythema</td>
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<tr>
<td>1</td>
<td>very slight erythema (barely perceptible)</td>
</tr>
<tr>
<td>2</td>
<td>well-defined erythema</td>
</tr>
<tr>
<td>3</td>
<td>moderate to severe erythema</td>
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<tr>
<td>4</td>
<td>severe erythema (beet redness) to slight eschar formation (injuries in depth)</td>
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B) Oedema formation:

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<td>very slight oedema (barely perceptible)</td>
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<tr>
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<td>moderate oedema</td>
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<tr>
<td>4</td>
<td>severe oedema</td>
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</table>
Other symptoms like vesicles, blistering, etc. are also investigated. The reaction is considered allergic in the following cases:

+: erythema, oedema, slight vesiculation
++: erythema, oedema, evident vesiculation
+++: erythema, oedema, severe vesiculation

5.7 Results calculation
The individual scores for erythema and oedema at each time are summed. The mean irritation index at 15 minutes, 24, 48 and 72 hours are calculated by summing up total individual scores and dividing for the number of volunteers. In this way the medium erythema index for each product and for each the evaluation times is obtained.

5.8 Product classification
The product is classified according to the primary irritation index, applying the table below which represents a modification of the one originally proposed by Draize.

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<td>0,5-2</td>
<td>slightly irritant</td>
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<tr>
<td>2-5</td>
<td>moderately irritant</td>
</tr>
<tr>
<td>5-8</td>
<td>severely irritant</td>
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</table>

The classification considers a test substance as non-irritant if its index is less than 0.5. With this scale one can thus distinguish between a very slight reaction of unknown cause and a distinct visible irritation due to the product. Regarding allergic reactions, proved by the presence of the symptoms like vesiculation which accompany erythema and oedema, the product is classified on the basis of the percentage of positive reactions obtained. This percentage must be less than 0.1%.
5.9 Possible breaks in continuity
The dermatologist examines volunteers who complain any skin reaction as soon as possible, recording the examination on the case report form and can stop the volunteer's participation to the test, if judges it necessary. Namely, when a product is classified moderately-severe irritant or causes an allergic reaction during the first patch test, treatment has to be interrupted.
All breaks in a volunteer's participation in the trial have to be recorded in the report and the reasons for discontinuation mentioned.

5.10 Drop-out criteria
Any person who in the course of the trial:
- Contracts a serious illness
- presents a serious illness
- does not adhere to the protocol
has to be withdrawn from the trial

5.11 Quality assurance and quality control
DermIng is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that clinical trials are conducted and data are generated, documented (recorded), and reported in compliance with the study protocols, GCP and the applicable regulatory requirement(s).

6. TEST FILE
At the end of the study, all raw data forms enter in a file which must include:
1) completed consent forms
2) case report cards
3) tables of results
4) any other paper concerning the study
7. FINAL REPORT
The test report includes:
-Sponsor’s name
-Tested products reference numbers
-Summary of the methodology used
-Tables reporting raw data
-Statistical evaluation results
-Colour graphics
-Conclusions

8. DOCUMENTS TO BE SUBMITTED BEFORE THE BEGINNING OF THE STUDY
8.1 Qualitative composition of the test article
Precising that it is not used any substance which use is prohibited in cosmetic and body hygiene compounds to manufacture this product (E.E.C. legislation), that preservatives, dyestuffs and sun filters, possibly included in the formula, are included in the E.E.C. positive lists and that they are used at the concentrations and according to the use foreseen in these lists. Precising that the components do not present any serious foreseeable toxicological effects established at the concentrations used. Precising the good stability of the test article.

8.2 Normal conditions of use of the test article

8.3 Results of toxicology and tolerance studies for the finished test article

8.4 Commitment attestation of insurance
It ensures the risks for the persons using the test article, whose administration having to be stopped immediately as soon as the investigator judges it necessary.

9. ETHICS
It is understood that the treatment would be immediately interrupted as soon as the investigator judges it necessary.
Each volunteer is precisely informed about the study, a consent form being completed and signed (see annexed)

10. CONFIDENTIALITY
Everything concerning this study must be considered confidential. DermIng Institute and the Sponsor commit themselves to respect confidentiality and to divulgate the methods and the results of the research only on the basis of a written consent of the counterpart.
11. REFERENCES


10) The Cosmetic, Toiletry and Fragrance Association (1991) "CTFA safety testing guidelines".


12. APPENDICES

1) Informed consent form
2) Information for the volunteers
APPENDICES
INFORMAZIONI
Sono stato invitato a partecipare ad uno studio che valuti la tollerabilità di una formulazione cosmetica, prodotta in conformità alla normativa vigente. Questo studio avrà la durata di una settimana. Il primo giorno applicherò il prodotto sulla cute del mio dorso o del mio braccio tramite cerotto. Il terzo giorno dovrò presentarmi per rimuovere il cerotto. Nei giorni successivi dovrò recarmi presso il Centro DermIng per la lettura delle eventuali reazioni cutanee.
Durante questo studio devo:
- non bagnare la sede cutanea su cui mi è stato applicato il cerotto;
- non esporre la zona cutanea interessata al sole o alla lampada solare;
- presentarmi alle visite previste durante l'esecuzione dello studio
- informare il dermatologo, reperibile all'indirizzo in fondo alla pagina, degli eventi indesiderati che potrebbero insorgere (la comparsa di fenomeni di intolerance al trattamento).
Accetto di partecipare alla prova sopraindicata, ossia:
- Patch test (test di tollerabilità)
Dichiaro di essere stato/a informato/a degli obiettivi, delle condizioni, della durata dello studio, della possibile comparsa di fenomeni di intolleranza al trattamento (ad es. irritazione, allergia ecc.)/art. 13 D.LGS 30 GIUGNO 2003 N°196.
Nulla mi sarà addebitato per la partecipazione al test (la prova è interamente a carico di DermIng) e non riceverò alcun compenso. Anche in caso di accettazione rimango libera di interrompere la prova in qualsiasi momento, senza fornire spiegazioni: mi impegno unicamente a comunicare la mia decisione al medico. Autorizzo espressamente DermIng ad elaborare sul computer le informazioni che mi riguardano. Avrò la possibilità di avere accesso a queste informazioni, di correggerle o di annullarle (se lo ritengo necessario) presso il Centro DermIng, viale Cesare Battisti, 38 a Monza (MI) (art. 7 D.L.GS 30 GIUGNO 2003 N°196). Accetto inoltre che i risultati di queste ricerche siano comunicati, rispettando l'anonimato, da DermIng alla Società Committente. I dati ottenuti saranno resi anonimi e utilizzati esclusivamente per scopi scientifici e statistici.
- certifico che sono maggiorenne e che non sono incinta;
(2 copie di cui una in mio possesso)
Luogo e data di nascita: ________________________________
Cognome: ____________________ Nome: ____________________
Indirizzo: ____________________ Città: ____________________
Tel.: ____________________
Firma del volontario: ____________________ Monza, li ____________
Firma del Responsabile della Prova: ____________________
Dott.ssa Adele Sparavigna

DermIng, Institute of Clinical Research and Bioengineering
Viale Cesare Battisti, 38 20052 Monza (MI)
Tel.: 039/329666 Fax: 039/5964228

Test code: TO0405

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MODULO DI ARRUOLAMENTO

DermIng, Istituto di Ricerche Cliniche e Bioingegneria

Per poter essere ammessi allo studio in corso il soggetto non deve presentare nessuna delle seguenti condizioni:

- Gravidanza;
- Allattamento;
- Previsione di una gravidanza nel corso del test;
- Psoriasi;
- Eczemi;
- Dermatite seborroica;
- Dermatite atopica;
- Orticaria;
- Vitiligine;
- Allergie a prodotti cosmetici;
- Presenza di alterazioni cutanee nell’area destinata all’esecuzione del saggio;
- Diabete;
- Disendocrinie;
- Alterazioni ormonali;
- Malattia epatica evolutiva;
- Insufficienza renale;
- Insufficienza cardiaca;
- Malattie neoplastiche evolutive;
- Tumori della pelle;

Inoltre, il soggetto non deve essersi sottoposto, nei tre mesi precedenti allo studio, a nessuno dei trattamenti sotto elencati:

- Terapia con farmaci topici;
- Terapia sistemica con corticosteroidi, aspirina, antinfiammatori non steroidei, retinoidi, psoralseni;
- Trattamenti farmacologici topici ed interventi di tipo medico e/o chirurgico a livello delle sedi di applicazione eseguite da meno di tre mesi antecedenti lo studio;
- Diuretici;
- Cicli di chemioterapia.

NOME: ____________________________________________

COGNOME: ____________________________________________

LUOGO DI NASCITA: _____________________ DATA DI NASCITA: _____________________

FIRMA (del volontario) : _____________________ DATA: _____________________

Rev. 04 del 10.10.05
CERTIFICATE OF SUBJECTS INFORMATION

Regarding the study:

**Evaluation of primary skin irritation potential (48 hour patch test)**
Test Code: TO0405     Prot: 1110

I, Dott. Adele Sparavigna, certify that all subjects were informed about the study protocol modalities and their relatives rights, and that I have obtained their informed consent form.

Date: 15/07/05

Signature