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TEST REPORT
17 24 01720

HUMAN REPEATED INSULT PATCH TEST (HRIPT) STUDY REPORT

FOCUS TOWEL

HAYAT KIMYA SAN. A.S

NOVEMBER 2017

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HUMAN REPEATED INSULT PATCH TEST (HRIPT) STUDY REPORT

PRODUCT MANUFACTURED BY	:	HAYAT KIMYA SAN. A.S
RECEIPT DATE	:	31/07/2017
STUDY PERIOD	:	02/10/2017 – 10/11/2017
LAB ID	:	5261 - 17 24 01720
PRODUCT NAME	:	FOCUS TOWEL
BRAND	:	FOCUS
LOT	:	NOT LISTED
STUDY SPONSOR	:	QACS Ltd
METHOD	:	Human Repeated Insult Patch Test

ASSESSMENT OF DERMAL SENSITIZATION POTENTIAL OF A PREPARATION HUMAN REPEATED INSULT PATCH TEST ON 50 VOLUNTEERS

TABLE OF CONTENTS

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REGULATORY, CONFIDENTALITY AND ARCHIVING

Regulatory
The study has been conducted by suitably trained, qualified and experienced personnel in accordance with the Declaration of Helsinki (1964) and subsequent revisions (World Medical Association, 1989, Council for International Organizations of Medical Sciences and the World Health Organization, 1993) and taking into consideration the requirements of Directives 2001/20/EC and 2005/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use and the COLIPA Guidelines edited on 1997 for the "Product Test Guidelines for the Assessment of Human Skin Compatibility".

Precautions have been taken to avoid the possibility that participants in the study might experience undesirable effects.

Ethical requirements which have been taken into consideration in the planning of the study include:
i) participants are informed volunteers, selected after application of inclusion/non inclusion criteria
ii) participants are aware of the purpose and nature of the study and of any foreseeable risks involved in participation in the study and have given written informed consent before the study starts
iii) a safety evaluation has been conducted on the product tested, before the study starts
iv) the test procedures conforms to national regulations
v) the Ethical Review Committee include medical, non-medical, appropriate experts and lay members; it has consider the general ethics of the test and verified that the safety and integrity of the participants in the test are protected, taking into account information on the ingredient(s)
vi) all reasonable care has been taken to avoid causing excessive skin reactions or other adverse health effects in the participants during the study
vii) safety procedures are in place in the event of any unexpected/adverse reactions, including appropriate medical cover
viii) volunteers are rewarded for their time, inconvenience, etc., but the reward is not so great that it would persuade them to participate.

Confidentiality
Requirements of Law 2472/1997 on the Protection of Individuals with regard to the processing of personal data are taken into consideration. Processing of volunteers personal data is carried out by doctors or other persons rendering medical services, provided that the Controller is bound by medical confidentiality or other obligation of professional secrecy, provided for in Law or code of practice, and data are neither transferred nor disclosed to third parties. Processing is carried out within the laboratory premises and relates to personal data of the volunteers, provided that the latter have given their consent and that such data are neither transferred nor disclosed to third parties. The anonymity of the volunteers is respected within all studies carried out in our laboratories. Each volunteer can be identified by the Investigator, the doctors and all the persons in charge of the study, thanks to his personal volunteer's code.

Archiving
The laboratory book which contains all the information (raw data and results) regarding the study and the study reports are kept in the laboratory archives during 2 years.

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TYPE AND OBJECTIVE OF THE STUDY

The purpose of this study is to determine the dermal sensitization potential of a product. The HRIPT is performed to confirm the safe use of potentially sensitizing substances in consumer products, preparations such as cosmetics or household products.

PANEL STUDIED, INCLUSION / NON INCLUSION CRITERIA.

Number of volunteers: A number of 50 volunteers has been recruited to satisfy the objectives of the test.

Panel characteristics
Volunteers are selected on the basis of inclusion and non-inclusion criteria. The volunteers satisfy all the inclusion criteria and are not in conflict with any of the non-inclusion criteria and had a medical examination (health certificate) and a dermatological examination. The volunteers are clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They give their written informed consent before participation in the study.

Inclusion criteria
- ✓ Informed volunteers who agree to follow the conditions specified
- ✓ where appropriate of relevant age : 18-70 years old
- ✓ where appropriate of relevant gender : female and/or male
- ✓ where appropriate of relevant origin and health
- ✓ free from any dermatological problems on the area studied
- ✓ meet the specific study criteria on skin type
- ✓ proof of home address & social security number
- ✓ able to understand the Greek languish and the study requirements

Non inclusion criteria
- ✓ volunteers who does not meet the inclusion criteria
- ✓ pregnancy or nursing condition
- ✓ irritated skin on test site(s)
- ✓ blemishes, marks (e.g. tattoos, scars, sunburn) on the test site(s)
- ✓ medication which may affect skin response and/or past medical history
- ✓ presenting skin pathology which may interfere with the aim(s) of the study
- ✓ presenting contact allergy to one of the ingredients of the tested product
- ✓ participation in another simultaneous study
- ✓ participation in a previous study without an appropriate rest period between studies
- ✓ minors or majors protected by the law and people admitted in a sanitary or social institution.
- ✓ persons deprived of liberty by legal or administrative decision, patients in emergency situation
- ✓ volunteers who refused to give their free and informed consent.

Study constraints
During the length of the study, the volunteers are asked:
- ✓ Not to put any product, also water on the patches area.
- ✓ Not to have a bath, neither to expose themselves to UV.
- ✓ To avoid all intense sportive activities that could remove the patch.
- ✓ Not to take aspirin, anti-histaminics, corticoids, anti-inflammatories and any other treatment decreasing or avoiding inflammations or allergies or interfering with the skin metabolism.

Volunteers withdrawals
Participants will be withdrawn for the following reasons:
- ✓ they do not follow the conditions of the Study Information Sheet;
- ✓ they undergo any condition which could affect the outcome of the study;
- ✓ they no longer wish to participate in the study.

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METHOD PRINCIPLE

Human Repeated Insult Patch Test (HRIPT)

The methodology used by the laboratory is an adaptation from that described by Marzulli and Maibach Human 'Repeated Insult Patch Test for delayed contact hypersensitivity: Marzulli F.N., Maibach H.I., Contact allergy : predictive testing in man, Contact Dermatitis, '1976, 2, pp. 1-17.

Table 1. Methodology used

Test	No. Subjects	Induction site	No. of exposures	Duration of exposure (h)	FrequencyOf exposure	Rest (days)	Challenge
Adaptation of the Modified Draize human sensitisation test	Min 50	Lower or upper back	9	48	Continuous	14	48 h patch test (followed by evaluations at 0, 24, 48, 72 and 96 hours)

According to the protocol the products to be tested are applied on 50 volunteer test subjects. The application is effected under occlusive conditions by the application of patches for a defined period of time. The applications are repeated 9 times on the same site (induction site) over a period of 3 consecutive weeks, period necessary to induce a possible allergy (induction phase).

After a minimal 2-week (rest period) with no product application, a single application of the product is effected, again under patch, to the induction site and to a virgin site and for a defined time, enabling to reveal a possible induced allergy (challenge).

A skin examination of the application site is performed by the dermatologist before the 1st product application of the induction phase, after each patch removal, the application of the challenge and its removal.

Table 2. HRIPT time table

<table>
<tr><th>W1</th><th>W2</th><th>W3</th><th>W4</th><th>W5</th><th>W6</th></tr>
<tr><td colspan="3">Induction phase</td><td colspan="2" rowspan="2">Rest period</td><td rowspan="2">Challenge</td></tr>
<tr><td colspan="3" rowspan="2">The applications are repeated 9 times on the same site (induction site) over a period of 3 consecutive weeks, period necessary to induce a possible allergy.</td></tr>
<tr><td colspan="2" rowspan="2">No product application.</td><td>Single application</td></tr>
</table>

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EQUIPMENT

The equipment used for the occluded patch is composed of a small plastic cavity of 0.64 cm^2 with a filter tissue at the bottom which is made to receive the product to test. All this is fixed to a hypoallergenic non woven adhesive tape.

DOSE LEVEL

The amount of test material applied to each patch 0.02ml is sufficient to fill the chamber and saturate the pad without overflowing from it when applied to the skin.

TEST MATERIAL APPLICATION

The area on which the patch is applied is previously cleaned up with demineralised water and dried with cellulose cotton wool tissue.

The patches are put on the back of the volunteer.

The products are tested pure or diluted depending on their type and their use.

- ✓ Mostly, the products are tested pure.
- ✓ Rinse-off products are tested diluted at 5%.
- ✓ Detergents are tested diluted at 10%.
- ✓ Hydrophilic products are diluted in demineralised water
- ✓ Lipophilic products are diluted in mineral oil.
- ✓ Powders are put pure in the patch small cavity and then moistened sufficiently with a drop of mineral oil in order to ensure good contact with the skin and avoid the product dispersion while applying the patch.

The patches thus prepared are left in contact 48 hours.

NEGATIVE CONTROLS

Whilst this activity is always be on a case-by-case basis and will depend on the nature and type of study, the most common approach is to compare the results obtained for the test materials with those of suitable positive and/or negative controls, or with similar materials.

A "negative" control is a patch without any product, applied in the same conditions as the product to be tested:

- ✓ if the product is tested pure: empty patch.
- ✓ if the product is tested diluted: patch with 0.02ml of the solvent used (demineralised water or mineral oil).

VISUAL ASSESSMENT

Treatment sites are assessed before the first application of test material (baseline) and after treatment at 30 minutes after patch removal during the induction period.

After a rest period of 2 weeks a patch was applied on a previously unpatched and patched skin site. This site was evaluated on 30 minutes, 24, 48, 72 and 96 hours after removal.

Skin reactions are scored throughout the test by the same experienced assessor who made the baseline assessment and under the same lighting source, following a pre-defined irritation and sensitization scoring scales.

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RECORDINGS

EXAMPLE OF IRRITATION SCORING SCALE

ERYTHEMA

0 = no evidence of erythema

0.5 = minimal or doubtful erythema

1 = slight redness, spotty and diffuse

2 = moderate, uniform redness

3 = strong uniform redness

4 = fiery redness

DRYNESS (SCALING)

0 = no evidence of scaling

0.5 = dry without scaling; appears smooth and taut

1 = fine/mild scaling

2 = moderate scaling

3 = severe scaling with large flakes

OEDEMA

_ = absence of oedema

+ = presence of oedema

EXAMPLE OF SENSITISATION SCORING SCALE

According to the I.C.D.R.G. (International Contact Dermatitis Research Group).

-	Negative
+?	Doubtful reaction
+	Weak reaction
++	Strong reaction
+++	Extreme
NT	Not tested
IR	Irritant reaction of different types

In case of negative evidence of any effect, the indication "-" is recorded.

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TEST MATERIAL

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PRODUCT MANUFACTURED BY	:	HAYAT KIMYA SAN. A.S
RECEIPT DATE	:	31/07/2017
STUDY PERIOD	:	02/10/2017 – 10/11/2017
LAB ID	:	5261 - 17 24 01720
PRODUCT NAME	:	FOCUS TOWEL
BRAND	:	FOCUS
PRODUCT TYPE	:	LEAVE ON, PAPER
LOT	:	NOT LISTED
STUDY SPONSOR	:	QACS Ltd
TEST METHOD	:	Human Repeated Insult Patch Test
PANEL	:	50 healthy adult volunteers.
APPLICATION AREA	:	On the back
QUANTITY OF PRODUCT	:	0.02 ml

Panel description
This study included 50 healthy adult volunteers.
A number of 50 subjects satisfactorily completed the test procedure.
Subject skin characteristics are described on the results table.
None of the volunteers selected took a treatment contraindicated with the study.

Study withdrawals
No withdrawal occurred.
No irritation or sensitization reactions occurred on the subjects that decided to withdraw.

Skin reactions
No skin reaction was noticed by the dermatologist on the reference area for all subjects.

Results analysis
Results obtained for each volunteer.

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RESULTS

In case of negative evidence of any effect, the indication "-" is recorded.

VOL ID	VOLUNTEER CODE	SEX	AGE	SKIN	Events occurred during the applications of induction period									Challenge
					1	2	3	4	5	6	7	8	9	Allergic reaction ICDRG scale
1	1006	M	50	Normal skin	-	-	-	-	-	-	-	-	-	-
2	1026	F	65	Normal skin	-	-	-	-	-	-	-	-	-	-
3	1141	F	47	Sensitive skin	-	-	-	-	-	-	-	-	-	-
4	1153	F	32	Normal skin	-	-	-	-	-	-	-	-	-	-
5	1208	F	27	Sensitive skin	-	-	-	-	-	-	-	-	-	-
6	1224	M	34	Normal skin	-	-	-	-	-	-	-	-	-	-
7	1263	F	64	Normal skin	-	-	-	-	-	-	-	-	-	-
8	1275	M	34	Normal skin	-	-	-	-	-	-	-	-	-	-
9	1283	M	41	Normal skin	-	-	-	-	-	-	-	-	-	-
10	1287	F	26	Sensitive skin	-	-	-	-	-	-	-	-	-	-
11	1288	F	32	Normal skin	-	-	-	-	-	-	-	-	-	-
12	1292	M	36	Sensitive skin	-	-	-	-	-	-	-	-	-	-
13	1298	M	34	Sensitive skin	-	-	-	-	-	-	-	-	-	-
14	1331	M	38	Normal skin	-	-	-	-	-	-	-	-	-	-
15	1334	F	49	Normal skin	-	-	-	-	-	-	-	-	-	-
16	1336	F	49	Normal skin	-	-	-	-	-	-	-	-	-	-
17	1345	F	27	Normal skin	-	-	-	-	-	-	-	-	-	-
18	1347	F	37	Normal skin	-	-	-	-	-	-	-	-	-	-
19	1348	F	25	Normal skin	-	-	-	-	-	-	-	-	-	-
20	1356	F	26	Sensitive skin	-	-	-	-	-	-	-	-	-	-
21	1357	F	52	Sensitive skin	-	-	-	-	-	-	-	-	-	-
22	1364	F	50	Normal skin	-	-	-	-	-	-	-	-	-	-
23	1372	F	56	Normal skin	-	-	-	-	-	-	-	-	-	-
24	1373	F	52	Normal skin	-	-	-	-	-	-	-	-	-	-
25	1390	F	30	Sensitive skin	-	-	-	-	-	-	-	-	-	-

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VOL ID	VOLUNTEER CODE	SEX	AGE	SKIN	Events occurred during the applications of induction period									Challenge
					1	2	3	4	5	6	7	8	9	Allergic reaction ICDRG scale
26	1392	M	37	Normal skin	-	-	-	-	-	-	-	-	-	-
27	1404	F	27	Sensitive skin	-	-	-	-	-	-	-	-	-	-
28	1435	F	54	Normal skin	-	-	-	-	-	-	-	-	-	-
29	1438	F	23	Sensitive skin	-	-	-	-	-	-	-	-	-	-
30	1442	F	24	Sensitive skin	-	-	-	-	-	-	-	-	-	-
31	1445	M	37	Sensitive skin	-	-	-	-	-	-	-	-	-	-
32	1458	F	22	Normal skin	-	-	-	-	-	-	-	-	-	-
33	1505	F	36	Sensitive skin	-	-	-	-	-	-	-	-	-	-
34	1531	M	24	Normal skin	-	-	-	-	-	-	-	-	-	-
35	1533	F	24	Sensitive skin	-	-	-	-	-	-	-	-	-	-
36	1535	M	43	Normal skin	-	-	-	-	-	-	-	-	-	-
37	1574	F	20	Normal skin	-	-	-	-	-	-	-	-	-	-
38	1589	M	34	Normal skin	-	-	-	-	-	-	-	-	-	-
39	1609	F	23	Sensitive skin	-	-	-	-	-	-	-	-	-	-
40	1612	F	24	Normal skin	-	-	-	-	-	-	-	-	-	-
41	1633	M	24	Normal skin	-	-	-	-	-	-	-	-	-	-
42	1635	M	24	Normal skin	-	-	-	-	-	-	-	-	-	-
43	1655	M	19	Normal skin	-	-	-	-	-	-	-	-	-	-
44	1656	M	55	Normal skin	-	-	-	-	-	-	-	-	-	-
45	1701	M	41	Normal skin	-	-	-	-	-	-	-	-	-	-
46	1721	F	52	Normal skin	-	-	-	-	-	-	-	-	-	-
47	1742	F	37	Normal skin	-	-	-	-	-	-	-	-	-	-
48	1752	M	26	Normal skin	-	-	-	-	-	-	-	-	-	-
49	1771	F	26	Normal skin	-	-	-	-	-	-	-	-	-	-
50	1781	M	51	Normal skin	-	-	-	-	-	-	-	-	-	-

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STUDY SUMMARY / ABSTRACT

ASSESSMENT OF DERMAL SENSITIZATION POTENTIAL OF A PREPARATION HUMAN REPEATED INSULT PATCH TEST ON 50 VOLUNTEERS

DISTRIBUTOR	:	HAYAT KIMYA SAN. A.S
PRODUCT MANUFACTURED BY	:	HAYAT KIMYA SAN. A.S
RECEIPT DATE	:	31/07/2017
STUDY PERIOD	:	02/10/2017 – 10/11/2017
LAB ID	:	5261 - 17 24 01720
PRODUCT NAME	:	FOCUS TOWEL
BRAND	:	FOCUS
PRODUCT TYPE	:	LEAVE ON, PAPER
LOT	:	NOT LISTED
STUDY SPONSOR	:	QACS Ltd
TEST METHOD	:	Human Repeated Insult Patch Test
PANEL	:	50 healthy adult volunteers.
APPLICATION AREA	:	On the back
QUANTITY OF PRODUCT	:	0.02 ml
METHODOLOGY ABSTRACT	:	Treatment sites are assessed before the first application of test material (baseline). Negative controls are used to facilitate evaluation. In an induction phase, a three times weekly exposure over three weeks is performed by subjecting the volunteers to a continuous patch exchange. The patches are reapplied to the same site, and only if moderate inflammation has developed, the next patch is moved to an adjacent skin site. After a resting phase of two weeks, challenge is performed on naive skin. In the challenge phase, single exposure is performed and potential skin reactions observed. Ref: Adaptation of the Modified Draize human sensitisation test, Marzulli and Maibach, 1973 and 1974.
RESULT	:	Throughout the study, the product induced no reaction or irritation. **The number of volunteers that presented an allergic reaction was zero (0%)**
CONCLUSION	:	According to the experimental conditions of the study, the test product, can be considered as **"Non Sensitizing"**, or **"Hypoallergenic"** or **"Formulated to minimize the risks of allergy under normal way of use".**

Results refer to the sample as received and analyzed on the period specified above.
The test report shall not be reproduced except in full, without written approval of the laboratory.
The samples will be stored by the laboratory during 1 month from the end test date.
The study report and raw data will be stored by the laboratory during 2 years.

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RESULTS (continued)

DISCUSSION AND CONCLUSION

In the experimental conditions, after assessment of the skin reactions before the first application, during the induction period and after the challenge phase, on 50 healthy adult volunteers and according to the scale used for the interpretation of the results, the FOCUS TOWEL can be considered as "Non Sensitizing", or "Hypoallergenic" or "Formulated to minimize the risks of allergy under normal way of use".

Investigator doctor:

Printed name : Christos Prevezas

Date

10/11/2017

RESULTS AUTHENTICITY

The study concerned by this report was carried out under my responsibility, according to the experimental protocol and the quality plan of the QACS Ltd laboratory, and follows the good clinical practices.
All the observations and data recorded during this trial are reported in this study report.

I certify the rereading of this report and do agree with its content,

Study Manager:

Printed name : Dimitrios Tzouvalis

Date

10/11/2017

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