REPORT NO. CH035/1415/0099e

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REGISTRATION NO. 40/1999/CPCSEA

MINISTRY OF ENVIRONMENT AND FORESTS, GOVERNMENT OF INDIA

REPORT

STUDY TITLE

ACUTE DERMAL IRRITATION / PRIMARY SKIN IRRITATION OF "TRENDS APS" IN RABBITS.

OECD GUIDELINES FOR TESTING OF CHEMICALS,

404, ADOPTED 17TH JULY 1992.

TESTING FACILITY:	SPONSOR:
NATIONAL TOXICOLOGY CENTRE,	M/S. ALTRET INDUSTRIES PVT. LTD.,
S.N.36/1/1, M.N.199,	SURVEY NO.387/1,
VADGAON KHURD, PUNE 411 041,	BHUJ – DUDHAI HIGHWAY ROAD,
MAHARASHTRA, INDIA.	AT. VILLAGE PADDHAR, TAL-BHUJ,
	DIST. KUTCH – 370105. GUJARAT, INDIA.

STUDY NUMBER: "CH035/1415/0099e" **REPORT NUMBER: "CH035/1415/0099e"**

DATE: 27/AUGUST/2014

TOTAL NO. OF 15 PAGES IN THIS REPORT

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STATEMENT OF COMPLIANCE

We, the Undersigned hereby declare that this Study No. "CH035/1415/0099e" entitled Acute Dermal Irritation/Primary Skin Irritation Test of "TRENDS APS" in rabbits was performed under our supervision in compliance with the OECD principles of Good Laboratory Practices (OECD, 1998). Characterization of the test material was performed by the sponsor and GLP compliance has not been claimed for the same. The objective laid down in the study protocol was achieved. No Unforeseen circumstances were observed which might have affected the quality or integrity of the study.

This report represents a true and accurate report of the results obtained. We accept the responsibility for validity of the data, as well as the interpretation, analysis, documentation and reporting of the results.

This report contains 15 pages including Contents, Certificate and Tables.

Dr. K. G. Apte, **Mrs. M. N. Garge,**

Study Director. **Q. A.**

Date: 27/August/2014.

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QUALITY ASSURANCE STATEMENT

This study report has been reviewed by the Quality Assurance Unit of National Toxicology Centre, for compliance with the OECD Principles of GLP, Study Data and applicable Operating Procedures.

This statement confirms that the study report accurately reflects Study data.

The summary of inspections performed during the course of the study is as follows:

S. No.	Type of Inspection	Date of Inspection	Phases of Study inspected
1	Study Based Inspection	26/June/2014	Draft Study Plan
2	Study Based Inspection	28/June/2014	Definitive Study Plan
3	Study Based Inspection	09/August/2014	Test Material Application
4	Study Based Inspection	16/August/2014	Raw Data
5	Study Based Inspection	20/ August /2014	Draft Report
6	Study Based Inspection	27/August/2014	Final Report

Name: Mrs. M. N. Garge **Date: 27/August/2014**

Head QA:

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1. STUDY INFORMATION

Study Number : "CH035/1415/0099e"

Report Number : "CH035/1415/0099e"

Study Title : Acute Dermal Irritation/Primary Skin Irritation Test of "TRENDS APS" in Rabbits.

Sponsor : M/S. ALTRET INDUSTRIES PVT. LTD.,
Survey No.387/1,
Bhuj – Dudhai Highway Road,
At. Village Paddhar, Tal-Bhuj,
Dist.- Kutch – 370105. Gujarat, India.

Testing Facility : NATIONAL TOXICOLOGY CENTRE,
S.N. 36/1/1, M.N. 199
Vadgaon Khurd, Pune 411 041,
Maharashtra, India.

Date of Submission of Final Report: 27/August/2014.

Study Director : Dr. K. G. Apte

Date : 27/August/2014.

Approved for issue

Sign :

2. SUMMARY

The objective of the study now reported was to determine the Primary Skin Irritation test of "TRENDS APS" in rabbits, following the OECD Guidelines Adopted 1992.

The test material, in the amount of 0.50 ml was applied to the shaven areas to three rabbits, at intact skin sites. Each animal was carefully observed and the reaction evaluated at 24, 48 and 72 hours post application. All the animals were observed for a period of 7 days till the end of the study.

The test material caused NO IRRITATION to the skin in rabbits.

The primary skin Irritation score of "TRENDS APS" in rabbits was found to be 0.00.

3. INTRODUCTION

3.1 OBJECTIVE

The study was conducted to establish the skin irritation potential of "TRENDS APS" when applied by the dermal route in the albino rabbits following the OECD Guidelines Adopted 17th July1992.

3.2 TEST GUIDELINES:

OECD Guidelines for the testing of the chemicals No. 404 Adopted 17th July 1992.

3.3 STUDY PERSONNEL

Study Director	**: Dr. K. G. Apte, M.Sc., Ph.D.**
Study Veterinarian	**: Dr. Prachi Doiphode, M. V. Sc.**
Research Associate	**: Mr. Y. P. Talekar, M. Pharm.**
Q. A.	**: Mrs. M. N. Garge, M. Sc.**

4. MATERIALS AND METHODS

4.1 TEST ARTICLE

SAMPLE NOT DRAWN BY NTC

Characterization of the test article was done by the Sponsor. Certificate of analysis has been appended to this report.

Test Article	**:**	**"TRENDS APS"**
Physical State	**:**	**Liquid**
Batch No.	**:**	**LAB-14-003**
Manufacturing Date	**:**	**19/June/2014**
Expiry Date	**:**	**18/June/2015**
Sponsor	**:**	**M/S. ALTRET INDUSTRIES PVT. LTD.,** **Survey No.387/1,** **Bhuj – Dudhai Highway Road,** **At. Village Paddhar, Tal-Bhuj,** **Dist. Kutch – 370105. Gujarat, India.**
Date of Sample Receipt	**:**	**24/June/2014.**
Date of Acclimatization	**:**	**04/August/2014.**
Date of Initiation of Study	**:**	**09/August/2014.**
Date of Completion of Study	**:**	**16/August/2014.**

4.2 FORMULATION OF THE TEST ARTICLE

Formulation of the test article was prepared shortly before dosing on each day of dosing.

4.3 TEST SYSTEM AND MANAGEMENT

1. Species	**:**	**Rabbits**
2. Strain	**:**	**New Zealand White**
3. Source	**:**	**NATIONAL TOXICOLOGY CENTRE**
4. Age and Sex	**:**	**Females 6 to 8 months old at the Time of treatment, were used**
5. Body weight range	**:**	**2.0 to 2.5 Kg**
6. Identification	**:**	**By unique identification number marked by writing on cage tag and by corresponding colour body markings.**
7. No. of animals	**:**	**03 males were tested**
8. Acclimatization	**:**	**The rabbits were housed in their cages for six days prior to start of dosing in the experimental room after veterinary examination.**
Husbandry		
9. Environmental conditions	**:**	**Room temperature between $22^0 \pm 3^0$ C, relative humidity 55 ± 5 % and illumination cycle set to 12 hours light and 12 hours dark.**
10. Accommodation	**:**	**Single housed in cages, facilities for food and water, and bedding of clean paddy husk.**
11. Diet	**:**	**Pelleted feed supplied by Nav Maharashtra Chakan Oil Mills Ltd., Pune, was provided ad**

libitum during acclimatization and during the study.

12. Water : Potable water passed through 'Aquaguard' water filter was provided ad libitum.

4.4 STUDY DESIGN

Three rabbits were used for this study. Approximately 24 hours before the test, the hair of the trunk was removed with the help of electric clippers, to expose approximately 6cm^2 patches.

The test material was applied in the amount of 0.50 ml to the intact skin sites of each test animal.

The test material was held in contact with the skin with porous gauze and a nonirritant adhesive tape throughout the 24 hour exposure period. The animals were housed singly and were restrained with a plastic collar around their neck for 24 hours, in order to avoid the ingestion of the test material and to ensure that the test material does not get removed for at least 24 hours. At the end of the exposure period, the patch and the residual test material was removed. The animals were observed at 24, 48 and 72 hours and the observations extended to determine the reversibility or irreversibility till the end of the observation period of 14 days.

TABLE 1: Evaluation of Results: As Per IS 13424:1992

Irritancy Index	Classification
> 0.0 - 0.0	Non-Irritant
> 0.0 – 2.0	Mildly-Irritant
> 2.0 – 5.0	Moderately-Irritant
> 5.0 – 8.0	Severely-Irritant

4.5 APPLICATION OF TEST MATERIAL

The test material was applied in the amount of 0.50 ml to the intact skin sites of each test animal. The test material was held in contact with the skin with porous gauze and a nonirritant adhesive tape throughout the 24 hour exposure period. The animals were housed singly and were restrained with a plastic collar around their neck for 24 hours, in order to avoid the ingestion of the test material and to ensure that the test material does not get removed for at least 24 hours. At the end of the exposure period, the patch and the residual test material was removed. The animals were observed at 24, 48 and 72 hours and the observations extended to determine the reversibility or irreversibility till the end of the observation period of 7 days.

4.6 OBSERVATIONS

Other clinical signs were observed till the end of the study.

5. INTERPRETATION OF RESULTS:

The reaction evaluated according to Draize's method (Table I) at 24, 48 and 72 hours.

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6. RESULTS

A summary of the individual score following application of "TRENDS APS" to the rabbits.

		{--------HOURS POST APPLICATION-------}					
Rabbit No.	**Sex**	**24**		**48**		**72**	
		E	**Oe**	**E**	**Oe**	**E**	**Oe**
1	**F**	**0**	**0**	**0**	**0**	**0**	**0**
2	**F**	**0**	**0**	**0**	**0**	**0**	**0**
3	**F**	**0**	**0**	**0**	**0**	**0**	**0**

Hours **24** **48** **72**

Score **00** **00** **00**

Grand Total 0.00 **Irritation Index = 0.00**

Rabbit No.	**Sex**	**4**		**5**		**6**		**7**	
		E	**Oe**	**E**	**Oe**	**E**	**Oe**	**E**	**Oe**
1	**F**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
2	**F**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
3	**F**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

E = Erythema **Oe = Oedema** **0 = No reaction**

7. CONCLUSION:

“TRENDS APS” did not cause irritation in rabbits at the dose level of 0.50 ml.

“TRENDS APS” was found to be a NON – IRRITANT to the skin in rabbits and hence it can be concluded that the “TRENDS APS” is NON – TOXIC and SAFE for use.

The Skin Irritation Index was found to be 0.00.

Dr. K. G. Apte,

Study Director.

8. ARCHIVES

All raw data and other documents, a copy of the final report, will be stored in the archives of National Toxicology Centre, for a period of one year from the date of submission of the final report.

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Date: 27/August/2014

C E R T I F I C A T E

This is to certify that the Acute Dermal Irritation/Primary skin reaction of the test material "TRENDS APS" supplied by M/S. ALTRET INDUSTRIES PVT. LTD., Survey No.387/1, Bhuj – Dudhai Highway Road, At. Village Paddhar, Tal-Bhuj, Dist. Kutch – 370105. Gujarat., India, according to the OECD Guidelines Adopted 17th July 1992, in rabbits was found to be SAFE at the dose level of 0.5 ml.

The Skin Irritation Index was found to be 0.00.

The test material was found to be a NON – IRRITANT to the skin in rabbits and hence it can be concluded that the "TRENDS APS" is NON – TOXIC and SAFE for use.

The report of the toxicity test conducted has been submitted through Study Code No. "CH035/1415/0099e".

NTC is approved by the Food & Drug Administration, Maharashtra State, Pune, through License No. P.D-T-L-7.

(Dr. K. G. Apte),
Study Director.