ISSN: 0976-3031

Available Online at http://www.recentscientific.com

International Journal of Recent Scientific Research
Vol. 7, Issue, 12, pp. 14541-14543, December, 2016

International Journal of Recent Scientific Research

Research Article

IN-VIVO DERMAL IRRITATION STUDY OF NOVEL SEMI-PERMANENT HAIR COLOUR SHAMPOO

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ARTICLE INFO

Article History:

Received 06th September, 2015
Received in revised form 14th October, 2016
Accepted 23rd November, 2016
Published online 28th December, 2016

Key Word:

Semi-permanent Hair Colour Shampoo, Dermal Irritation, Non-oxidative hair dye, Direct dyes, and basic dyes.

ABSTRACT

Study performed to evaluate the dermal irritation potential of newly developed semi- permanent hair colour shampoo as per the Organization for Economic Cooperation and Development (OECD) Guidelines. It was observed that no clinical signs of toxicity and mortalities noticed during the study. In initial test and confirmatory tests, there was no evidence of dermal irritation. Semi-permanent hair colorant can be classified as "Non-Irritant".

INTRODUCTION

Hair coloring is currently a globally accepted fashion for changing on colour of hair[1]. From younger generation with playful attitude to older generation who shows interest either to change or restore their original hair colour. Taking into account the extent and frequency of human contact with hair colouring products, their ingredients must be safe. Risk assessment of hair dyes and their ingredients must take into an account a highly restrictive aspect[2]. The scope of the study was to evaluate the dermal irritation/corrosion potential of newly developed Semi-permanent Hair Colour Shampoo (patent pending) to the New Zealand White rabbits as per the OECD Guideline for the testing of chemicals. Semi-permanent hair pigments only coat the outer hair shaft and don't require either ammonia or bleaching ingredients. Hence it is much gentler than permanent hair color.

Ingredients Used In Semi-Permanent Hair Colour Shampoo

Aqua, Hydroxyethyl Cellulose, Decyl Glucoside, Sodium Sulphite, Isopropyl Alcohol, PEG-12 Dimethicone, Ethanolamine, patent pending composition of direct and basic dyes and perfume. The prototypes were generated as per the guidelines[3].

MATERIALS AND METHODS[4]

Product Details

The test item information as per Study Information Document is furnished below:

Physical Appearance	:	Black colour
Date of Manufacturing	:	02/2016
Date of Expiry	:	36 months from date of manufacture
Storage conditions	:	At Room Temperature

Dose Selection and Justification

An amount of 0.5 g of test item was applied per site as per OECD test guideline 404[4].

Test System and Husbandry

Animals

Species/ Strain	:	Rabbit/New Zealand White
Body weight range at receipt	:	1.90 to 2.01 kg
Reason for Selection of Species	:	New Zealand White Rabbit have been selected as per OECD Test Guideline recommendation.
No. of animals	:	03 Female Females selected were nulliparous and non-pregnant.

Animal Identification

Each animal were identified by ear marking with permanent marker. The cages were labeled with cage cards indicating study code, sex and experimentation dates etc.

Housing Conditions

Animal Cage	:	Animals were housed in stainless steel cages having facility for holding pelleted feed and drinking water in water bottle fitted with stainless steel sipper tube.
Cage Size	:	Size LXBXH – 450 (L)X600 (B)x450 (H) mm
Number of Animals Per Cage	:	1

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Environmental Conditions

Air Change	:	12-15 air changes per hour
Temperature	:	20.0 - 22.8 °C
Relative Humidity	:	40 - 63 %
Lighting	:	Artificial fluorescent light with 12 hours light and 12 hours dark cycle

Feed

Standard laboratory rabbit feed (VRK Nutritional Solutions, Batch No. 0000182, Exp. Date 30 May 2016) was provided *ad libitum* throughout the experimental period.

Reverse Osmosis (RO) purified water was provided *ad libitum* throughout the experimental period with help of water bottles.

Acclimatization

The animals used for initial test and confirmatory test were acclimatized for five and six days respectively. Only healthy animals were used in the study.

Study Design

The test was performed using three female rabbits as shown in Tale 1 below

Table 1 Study Design

Test		Initial Test				Confirmatory Test	
Animal No.		1				2 and 3	
Site No.		1	2	3	4	1	2
Treatment	Distilled water	Yes	No	No	No	Yes	No
	Test item	No	Yes	Yes	Yes	No	Yes

TEST METHODS

Preparation of Animals

Twenty four hours before the test, fur was removed by closely clipping the dorsal area of the trunk of the animals using electric hair clipper. Care was taken to avoid abrading the skin, and only animals with healthy, intact skin were used.

Application of Test Item

The test item was applied to a small area (approximately 6 cm^2) of skin and covered with a gauze patch, which was held in place with non-irritating tape. The patch was loosely held in contact with the skin by means of a suitable semi-occlusive dressing for the duration of the exposure period. The patch was attached to the skin in such a manner that there was good contact and uniform distribution of the substance on the skin. Access by the animal to the patch and ingestion or inhalation of the test item was prevented by wrapping with crepe bandage. After completion of exposure period patch was removed and test site was cleaned with cotton dipped in water.

Initial Test

The initial test was performed by applying three test patches sequentially to the one animal. The first patch was applied at site 2 and removed after three minutes. As no skin reaction was observed, second patch was applied at site 3 and removed after one hour. As no skin reaction was observed, third patch was applied and removed after four hours, and the response was graded. At control site (site 1) distilled water was applied and removed during third patch removal.

Confirmatory Test

Since, no erythema and oedema found in initial test, the response was confirmed using two additional animals. For both the animals test item was applied at site 2 for an exposure period of four hours. Control site (Site 1) was applied with distilled water.

OBSERVATIONS

Clinical Signs and Mortality

All animals were observed once daily for clinical sings and twice daily for mortality and morbidity during treatment period. Individual animal body weight was recorded on day 1 of the experiment and on the day of termination.

Evaluation of Skin Reactions

All animals were examined for signs of erythema and oedema, and the responses were scored. For the initial test, test sites were examined immediately after the patch removal. Site 1 and 4 was scored at 60 minutes, 24, 48 and 72 hours after patch removal. In confirmation test site was scored at 60 minutes, and then at 24, 48 and 72 hours after patch removal.

Dermal reactions were evaluated and recorded according to the evaluation criteria listed below:

Table 2 Evaluation of Skin Reactions

Erythema and Eschar Formation	Score
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beef redness) to eschar formation preventing grading of erythema	4
Maximum possible: 4	

Oedema Formation	Score
No oedema	0
Very slight oedema (barely perceptible)	1
Slight oedema (edges of area well defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4
Maximum possible: 4	

Necropsy and Gross Pathology

At the end of experiment all animals were sacrificed by intravenous injection of sodium thiopentone. Animal were not subjected to necropsy and gross pathology as animals did not shown any signs of equivocal response.

RESULTS AND DISCUSSION

Clinical Observations

There were no signs of toxicity and mortalities noticed in the study. Data presented in Table 3.

Table 3 Individual Animal Clinical Observations

Study Type	Animal No.	Sex	Days			
			1	2	3	4
Initial Test	01	F	0	0	0	0
Confirmatory	02	F	0	0	0	0
Test	03	F	0	0	0	0

Body Weight

There was no effect on the body weight and body weight gain. Data presented in Table 4

Table 4 Individual Animal Body Weight (Kg) and Body Weight Gain (%)

Study Type	Animal No.	Sex	Body weight on days		% Body weight gain
			1	4	1-4
Initial Test	01	F	1.99	2.10	5.5
Confirmatory	02	F	1.92	2.11	9.9
Test	03	F	2.15	2.26	5.1

Skin Reactions

In the both initial test and confirmatory tests, there was no evidence of skin irritation / corrosion. Data presented in Table 5 and fig 1

Table 5 Individual Animal Skin Grading

Study Type	Animal No.	Sex	Time points (hrs.)							
			1		24		48		72	
			ER	ED	ER	ED	ER	ED	ER	ED
Initial Test	01	F	0	0	0	0	0	0	0	0
Confirmatory	02	F	0	0	0	0	0	0	0	0
Test	03	F	0	0	0	0	0	0	0	0
Mean Score for ER						0				
Mean Score for ED						0				

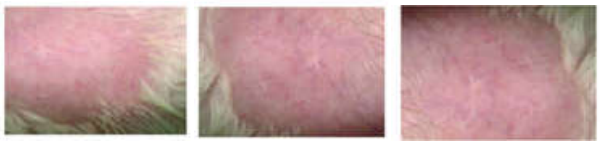

Fig1 Non-irritant on skin

CONCLUSION

Based on the results of the study, semi-permanent hair colour shampoo can be classified as "Non-irritant" as per Organization for Economic Cooperation and Development (OECD) guideline for testing of chemicals. Our findings suggest that semi-permanent hair colour shampoo is safe since it did not induce dermal irritation and corrosion.

Acknowledgment

Authors would like to thank "Edara Research Foundation" located at Sanath Nagar, Hyderabad, Telangana 500018 for executed the study".

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How to cite this article:

Samuelraj Isaiah and Shanmugam Karthikeyan.2016, *In-Vivo* Dermal Irritation Study of Novel Semi-Permanent Hair Colour Shampoo. *Int J Recent Sci Res.* 7(12), pp. 14541-14543.