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Research Article

OCULAR IRRITATION POTENTIAL ASSESSMENT; IN-VIVO STUDY ON NOVEL SEMI-PERMANENT HAIR COLOUR SHAMPOO

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ABSTRACT

The evaluation of eye irritation potential is essential to ensuring the safety of individuals in contact with wide range of substances designed for industrial, pharmaceutical or cosmetic use. Study executed to access the eye irritation/corrosion potential of newly developed semi-permanent hair colour shampoo as per Organization for Economic Cooperation and Development (OECD). Test material produced no clinical signs of toxicity and mortalities noticed during the study. In both initial test and confirmatory tests, there was no evidence of eye irritation / corrosion. Semi-permanent hair color shampoo can be classified as "Non-Irritant".

INTRODUCTION

The main goal of toxicological endeavor is to safeguard the human beings against the possible adverse effects of diverse types of chemicals, including pharmaceuticals, cosmetics, household products, industrial chemicals and agrochemicals[1]. The scope of the study was to access the irritation/corrosion potential of newly developed Semi-permanent hair color shampoo (patent pending) to the eye of New Zealand White rabbits as per the Economic Cooperation and Development (OECD) Guideline for the Testing of Chemicals.

Ingredients Used In Semi-Permanent 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[2,3]

MATERIALS AND METHODS[4]

Product Details

The Product details as per Study Information Document are furnished below:

Name of Test Item	:	Semi-permanent Hair Colour
Physical Appearance	:	Black Colour
Date of Manufacturing	:	02/2016
Date of Expiry	:	36 months from date of manufacturing
Storage conditions	:	At Room Temperature

Dose Selection and Justification

An amount of 100 mg of test item was instilled in to the eye as per OECD test guideline 405.

Test system and husbandry

Animals

Species/ Strain	:	Rabbit/New Zealand White
Body weight range at receipt	:	2.16 to 2.43 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.

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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

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.

Water

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 below

Table 1 Grading of Ocular Lesions

Test	Animal No.	Dose (mg)
Initial test	1	100
Confirmatory test	2	100
	3	100

Test Methods

Preparation of Animals

Both eyes of each experimental animal provisionally selected for testing and were examined one hour before test item instillation using ophthalmoscope. Animals with normal eyes were used for experiment.

Pre-Instillation Procedure

Sixty minutes prior to test item instillation, buprenorphine (0.01 mg/kg) was administered by subcutaneously (SC) to provide a therapeutic level of systemic analgesia. Five minutes prior to instillation, two drops of a topical ocular anesthetic (0.5% proparacaine hydrochloride) was instilled to each eye.

Instillation of Test Item

The test item was placed in the conjunctival sac of left eye of each animal after gently pulling the lower lid away from the eyeball. The lids were then gently held together for about one second in order to prevent loss of the material. The right eye, which remained untreated, served as control. The eye was washed with water after 24 hours of test item instillation.

Post-Instillation Procedure

As no irritant effect was observed, post instillation procedure was not carried out.

Initial Test

Initial test was performed using single animal. 100 mg of test item was instilled in to the conjunctival sac of left eye and observed for eye lesions.

Confirmatory Test

Since, no corrosive or irritant effect was found in initial test, the response was confirmed using two additional animals.

Observations

Clinical observations

Animals were evaluated for the entire duration of the study for clinical signs of pain and/or distress (e.g. repeated pawing or rubbing of the eye, excessive blinking, excessive tearing) twice daily, with a 6 hours gap between observations. All animals were observed twice daily for mortality and morbidity during experimental period.

Body Weight

Individual animal body weight was recorded on day 1 of the experiment and on the day of termination.

Grading of Eye Reactions

The grades of ocular reaction (conjunctivae, cornea and iris) were recorded at 1, 24, 48, and 72 hours following test item instillation as mentioned bellow. As no ocular lesions were observed, all animals were terminated after 72 hours observation. Mean score was calculated by summing the score of all time points (1, 24, 48, and 72 hrs) from all animals together and divided by 12 (4 time point X 3 animals)

Table 2 Grading of Ocular Lesions

Cornea (Opacity: degree of density - readings will be taken from most dense area)	**Grade**
No ulceration or opacity	0
Scattered or diffuse areas of opacity (other than slight dulling of normal lustre); details of iris clearly visible	1
Easily discernible translucent area; details of iris slightly obscured	2
Nacreous area; no details of iris visible; size of pupil barely discernible	3
Opaque cornea; iris not discernible through the opacity	4
Maximum possible: 4	
*The area of corneal opacity will be noted	

Iris	**Grade**
Normal	0
Markedly deepened rugae, congestion, swelling, moderate circumcorneal hyperaemia; or injection; iris reactive to light (a sluggish reaction is considered to be an effect	1
Hemorrhage, gross destruction, or(no)reaction to light	2
Maximum possible: 2	

Conjunctivae (Redness - refers to palpebral and bulbar conjunctivae; excluding cornea and iris)	**Grade**
Normal	0
Some blood vessels hyperaemic (injected)	1
Diffuse,crimson colour; individual vessels not easily discernible	2
Diffuse beefy red	3
Maximum possible: 3	

Chemosis (Swelling - refers to lids and/or nictating membranes)	Grade
Normal	0
Some swelling above normal	1
Obvious swelling, with partial eversion of lids	2
Swelling, with lids about half closed	3
Swelling, with lids more than half closed	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 eye lesions.

RESULTS AND DISCUSSION

Clinical Observations

Test product does not show any sign of toxicity and mortalities noticed the study. Data presented in Table 3.

Table 3 Individual Animal Clinical Observations

Study Type	Animal No.	Sex	Days							
			1	1	2	2	3	3	4	4
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

Body Weight

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

Table 4 Individual Animal Clinical Observations

Study Type	Animal No.	Sex	Body weight on days		% Body weight gain
			1	4	1-4
Initial Test	01	F	2.38	2.43	2.1
Confirmatory	02	F	2.51	2.57	2.4
Test	03	F	2.23	2.28	2.2

Eye Reactions

In the both initial test and confirmatory tests, there was no evidence of eye irritation / corrosion. Data presented in Table 5 and Fig1:

Table 5 Individual Animal Skin Grading

Study Type	Animal No.	Sex	Observation	Time points (hrs)							
				1		24		48		72	
				RE	LE	RE	LE	RE	LE	RE	LE
Initial Test	01	F	Cornea	0	0	0	0	0	0	0	0
			Iris	0	0	0	0	0	0	0	0
			Redness	0	0	0	0	0	0	0	0
			Chemosis	0	0	0	0	0	0	0	0
Confirmatory Test	02	F	Cornea	0	0	0	0	0	0	0	0
			Iris	0	0	0	0	0	0	0	0
			Redness	0	0	0	0	0	0	0	0
			Chemosis	0	0	0	0	0	0	0	0
	03	F	Cornea	0	0	0	0	0	0	0	0
			Iris	0	0	0	0	0	0	0	0
			Redness	0	0	0	0	0	0	0	0
			Chemosis	0	0	0	0	0	0	0	0
Mean Score for Cornea				**RE - 0**				**LE - 0**			
Mean Score for Iris				**RE - 0**				**LE - 0**			
Mean Score for Redness				**RE - 0**				**LE - 0**			
Mean Score for Chemosis				**RE - 0**				**LE - 0**			

Key: LE=Left Eye; RE=Right Eye

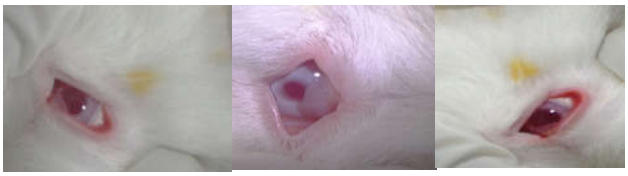

Fig1 Non-Irritant on Eye

CONCLUSION

It is an essential step in the progression to regulatory acceptance of the product. Based on the results of the study, semi-permanent hair colour shampoo classified as non-irritant as per Organization for Economic Cooperation and Development (OECD) guidelines for testing of chemicals.

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References

1. M.P. Vinardell, M. Mitjans. Alternative Methods for Eye and Skin Irritation Tests: An Overview. *Journal of pharmaceutical sciences*, Vol 97, 46-59 (2008)
2. Samuelraj Isaiah, Shanmugam Karthikeyan. Challenges for Formulating Natural Cosmetics: Comparative Physicochemical Studies on Natural and Synthetic made Shampoo. *Int J Pharm Bio Sci*, 6(1): (B) 1269 - 1274 (2015)
3. Samuelraj Isaiah and Shanmugam Karthikeyan. 2016, *In-Vivo* Dermal Irritation of Novel Semi-Permanent Hair Colour Shampoo. *Int J Recent Res*. 7(12), pp.14541-14543
4. OECD (2012), *Test No. 405: Acute Eye Irritation/Corrosion*, OECD Publishing, Paris.

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