

# Clinical trial report: Evaluation of the efficacy and safety of Sun Screen Lotion in sunburns

Dr. S. A. Kolhapure\*, M.D.,

Senior Medical Advisor, R&D Center, The Himalaya Drug Company, Bangalore, India

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[\*Corresponding author]

## ABSTRACT

*Sunburn is a popular term applied to the marked erythema and pain that commonly follows injudicious sun exposure. Sunburn is a delayed ultraviolet B-induced erythema caused by an increase in blood flow to the affected skin that begins about 4 hours and peaks between 8-24 hours following exposure. The underlying cause of this vascular reaction is direct and indirect damage to specific cellular targets from photochemical reactions and the generation of reactive oxygen species. Damage to DNA, and the activation of several inflammatory pathways, particularly involving prostaglandins are thought to trigger this reaction, ultimately leading to vasodilation and edema. Biologic response modifiers released by both keratinocytes and lymphocytes also play a role. The development of erythema therefore implies that enough UV damage has occurred and that inflammatory pathways have been activated. Erythema is probably best thought of as a total failure of sun protection, and is a marker for severe UV damage.*

## ABBREVIATIONS

DNA : Deoxyribonucleic acid  
MSH : Melanocyte-stimulating hormone  
UV : Ultraviolet

*This study was planned to evaluate the efficacy and safety of Sun Screen Lotion in providing protection against sunburns and in prevention of skin tanning effect.*

*Seven volunteers were selected from the list of volunteers and all the 7 volunteers were included in the study. All volunteers were subjected to 40 minutes sun exposure following application of study lotions. Each volunteer applied 100 ml of study lotion to their forearm with the use of the rubber sheet as regulator. For universal spread of lotion, 5 standardized circular hand movements were used. All the volunteers were examined at 10, 20, 30 and 40 minutes.*

*The study was conducted on two consecutive days by exposing the skin for 1 hour between 11.45 a.m. to 12.45 p.m. On both days, Sun Screen Screen was comparable to control lotion in terms of redness, tanning, sunburn and skin lightening effects after 10, 20, 30 and 40 minutes. Skin lightening effect persisted longer (3 hours) with study lotion and both the lotions were comparable in terms of prevention of tanning and skin lightening effect during the sun exposure time. No adverse effects (inflammatory and allergic reactions) were reported or observed during the study.*

*From the study results it can be concluded that, Sun Screen Lotion is effective in providing protection against sunburns and in prevention of skin tanning effect and is safe for long-term usage.*

## INTRODUCTION

Skin is made up of very specific cells and tissues and in the subcutaneous layer of skin the blood vessels branch infinitely into the dermis to supply the sweat glands, hair follicles,

sebaceous glands and erector muscles with blood. Dermis contains capillaries, which take care of the nutritional needs of the cells in the dermis, and they also help the skin perform an important cooling function. The epidermis has no direct blood supply, instead is supported and fed by the dermis. Dermis contains several different types of nerve endings: heat-sensitive, cold-sensitive, pressure-sensitive, itch-sensitive and pain-sensitive. Epidermis contains one inner layer is called the malpighian layer, which creates the dead cells and is in direct contact with the dermis, which feeds and supports it and is the malpighian layer which gets affected during sun tanning.

The malpighian layer has a basal layer, a spinous layer, a granular layer, and an outer stratum corneum. The cells in stratum corneum are filled with a protein called keratin. Keratin is a very interesting protein because it is tough - horns, hair, hoofs, fingernails and feathers all gain their strength from keratin.

In the basal cells in the malpighian layer is another type of cell called a melanocyte, which produces melanin, which is a pigment that is the source of tanning. The appearance of the skin is partly due to the reddish pigment in the blood of the superficial vessels and it is determined by melanin, a pigment manufactured by the dendritic cells called melanocytes, found among the basal cells of the epidermis. Their numbers in any one region of the body, which ranges from about 1,000 to more than 2,000 per square millimeter are roughly the same within and between races; the blondest whites have as many as the darkest blacks. Color differences are due solely to the amount of melanin produced and the nature of the pigment granules. When the skin becomes tanned on exposure to sunlight, the melanocytes do not increase in number, they only became more active. Not only do melanocytes produce a tan, they are also responsible for the form of cancer called melanoma. Melanoma is caused by UV radiation damage to melanocytes. Repeated exposure to UV can cause cancerous mutations.

Sunlight has three forms: infrared (heat/invisible), visible light and ultraviolet. Ultraviolet light is classified into three categories: UVA (315 to 400 nm), also known as black light, which causes tanning, UVB (280 to 315 nm), which causes damage in the form of sunburn and UVC (100 to 280 nm), which is filtered out by the atmosphere and never reaches us. Ninety nine percent of the sun's UV radiation at sea level is UVA. It is the UVB that causes most of the problems related to sun exposure: like aging, wrinkles and cancer.

Ultraviolet radiation is reflected by different surfaces and these reflections can amplify the effects of UV exposure. For example, snow reflects 90% of UV light and sand can reflect up to 20% of UVB. On the other hand, certain things absorb almost all UV radiation partially or completely, e.g. glass. Most sunscreens use chemicals that have the same UV-absorbing properties. Ultraviolet light stimulates melanin production and melanin has the effect of absorbing the UV radiation in sunlight, so it protects the cells from UV damage and melanin production takes about over 5 to 7 days. Melanocytes produce 2 different pigments: eumelanin (brown) and pheomelanin (yellow and red). In albinos, the chemical pathway that produces melanin cannot proceed because an enzyme called tyrosinase is missing and therefore albinos have no melanin in their skin, hair or irises. Melanocyte-stimulating hormone is produced by the pituitary gland. In humans, light affects the pituitary gland as well and one result is the production of MSH. A funny side effect of all this is that wearing sunglasses may make you more susceptible to sunburn!

Sunburn is a popular term applied to the marked erythema and pain that commonly follows injudicious sun exposure. Sunburn is a delayed ultraviolet B-induced erythema caused by an

increase in blood flow to the affected skin that begins about 4 hours and peaks between 8-24 hours following exposure. The underlying cause of this vascular reaction is direct and indirect damage to specific cellular targets from photochemical reactions and the generation of reactive oxygen species. Damage to DNA, and the activation of several inflammatory pathways, particularly involving prostaglandins are thought to trigger this reaction, ultimately leading to vasodilation and edema. Biologic response modifiers released by both keratinocytes and lymphocytes also play a role. The development of erythema therefore implies that enough UV damage has occurred and that inflammatory pathways have been activated. Erythema is probably best thought of as a total failure of sun protection, and is a marker for severe UV damage.

Several lines of evidence suggest a relationship between erythema and DNA damage and there is enough correlation between pyrimidine dimer yield and susceptibility to erythema with sun exposure. Wavelengths that are the most efficient at producing erythema are also the most efficient at producing pyrimidine dimers. From a scientific point of view, sunburn can be viewed as a marker for a substantial ultraviolet over-exposure that has clinical implications for skin cancer risk. It is now appreciated that there is a linkage between a history of repeated, severe sunburn and increased risk for melanoma and non-melanoma skin cancer. Ultraviolet light converts 7-dehydrocholesterol flowing in bloodstream into Vitamin D and sunscreens block or absorb UV light.

<b>Sun protection factor (SPF) rating, by the way, applies only to UVB radiation</b>		
<b>Skin type</b>	<b>Details</b>	<b>Ideal sun screen lotion with SPF</b>
I	Always burns easily, never tans (Sensitive)	8 or more
II	Always burns easily, tans minimally (Sensitive)	6-7
III	Burns moderately, tans gradually (Light brown, Normal)	4-5
IV	Burns minimally, always tans well (Moderate brown, Normal)	2-3
V	Barely burns, tans profusely (Dark brown, Insensitive)	2
VI	Never burns, deeply pigmented (Insensitive)	Not indicated

### **Aim of study**

This study was planned to evaluate the efficacy and safety of Sun Screen Lotion in providing protection against sunburns and in prevention of skin tanning effect.

### **Design of study**

This was a double blind, comparative clinical trial conducted at the R&D Center of The Himalaya Drug Company, Bangalore, India on 24<sup>th</sup> and 25<sup>th</sup> March, 2003.

### **Study drugs**

The drug group used the Sun Screen Lotion, manufactured by The Himalaya Drug Company, Bangalore (SSL-01: SPF value of 15) and the control group used commercially available Sun Screen Lotion.

### **Study procedure**

Seven volunteers were selected from the list of volunteers and all the 7 volunteers were included in the study. All volunteers were subjected to 40 minutes sun exposure following

application of study lotions. A rubber sheet of the forearm length, with three circles of 3 cms diameter each was used to cover the forearm. Each volunteer applied 100 ml of study lotion to their forearm with the use of the rubber sheet as regulator. For universal spread of lotion, 5 standardized circular hand movements were used. All the volunteers were examined at 10, 20, 30 and 40 minutes.

### Primary and secondary outcome measures

The predefined primary outcome measures were development of erythema (redness), skin tanning, skin burns, skin lightening effect; while, secondary outcome measures were adverse dermal reactions like burning sensation, inflammatory or allergic skin reactions.

### RESULTS

The study was conducted on two consecutive days by exposing the skin for 1 hour between 11.45 a.m. to 12.45 p.m. On both days, Sun Screen Lotion was comparable to control lotion in terms of redness, tanning, sunburn and skin lightening effects after 10, 20, 30 and 40 minutes. Skin lightening effect persisted longer (3 hours) with study lotion and both the lotions were comparable in terms of prevention of tanning and skin lightening effect during the sun exposure time. No adverse effects (inflammatory and allergic reactions) were reported or observed during the study.

### CONCLUSION

From the study results it can be concluded that, Sun Screen Lotion is effective in providing protection against sunburns and in prevention of skin tanning effect and is safe for long-term usage.

<b>Table : Average score of sun protection on treatment with Sun Screen Lotion</b>									
Day	Minutes	Redness		Tanning		Sun burn		Skin lightening effect	
		SSL-01	Control	SSL-01	Control	SSL-01	Control	SSL-01	Control
Day 1	10	0.00	0.00	0.00	0.00	0.00	0.00	1.29	1.29
	20	0.00	0.00	0.14	0.00	0.29	0.00	1.57	1.14
	30	0.00	0.00	0.07	0.00	0.14	0.00	1.43	1.21
	40	0.00	0.00	0.29	0.43	0.14	0.14	0.57	1.57
Day 2	10	0.29	0.29	0.00	0.57	0.00	0.00	1.00	1.00
	20	0.00	0.00	0.00	1.29	0.00	0.00	1.00	1.00
	30	0.00	0.00	0.00	1.00	0.00	0.00	1.57	1.00
	40	0.00	0.14	0.00	1.29	0.00	0.00	1.29	1.14

Score: Nil: 0; Mild: 1; Moderate: 2; Severe: 3