

Wednesday, January 20, 2021

Acute Dermal Irritation/Corrosion Test



To the Company: "Aria Rahavard Behnoud"

Hereby I report the results of acute dermal irritation/corrosion test for the "Non-Alcoholic Hand Sanitizer Solution" provided by your company. Full descriptive data are provided within tables and figures. To carry out this test, the Organization for Economic Cooperation and Development (OECD) Acute Dermal Irritation/Corrosion Guideline 404 was used.

Description of the method:

Six male white albino rabbits, in the range of 2–3 kg body weight were used in the experiments. Animals used were nulliparous and non-pregnant. Animals were housed individually in standard stainless steel cages and sterilized paddy husk as bedding. Bedding material was changed daily, whereas water bottles were changed on alternate days. Animals were acclimated for minimum period of five days in the controlled environment (temperature: $20 \pm 3^{\circ}\text{C}$; relative humidity: $50 \pm 20\%$ and light: 12 h light/dark cycle) and ad libitum water and standard rabbit pellet food. Animals were distributed randomly into two groups; Normal control (0.5 ml of vehicle) and test-dose group (0.5 ml of test chemical). Approximately, 24 h before the test, fur was removed by closely clipping to an area of about 6 cm^2 on both sides of the dorsal surface of the trunk of the animals. Care was taken to avoid abrading the skin, and only animals with healthy, intact skin were used. Substances were applied to the clipped skin area on the left side of animals and the areas were covered with a gauze patch, which was held in place with non-irritating tape. The right untreated side was kept as control area. 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. Restrainer (neck collar) was used to prevent the ingestion of the test substance from the application site. At the end of the 4 h exposure period, the residual test substance was removed, using water without altering the existing response or the integrity of the epidermis.

Skin reaction at the site of application was subjectively assessed and scored once daily at 1, 24, 48, 72 hours, 7 and 14 days after patch removal (post-test observation period) accordingly. The reaction at the site of application was assessed and scored according to Draize Dermal Irritation Scoring System. The results with detailed data can be found in the attached tables 1-3 and figure 1.

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Expert opinion: According to the results of Draize's scoring system and histological examinations, the given sample of "Non-Alcoholic Hand Sanitizer Solution" was found to be "**Negligible-Irritant**" to the skin of rabbits when compared with the normal control sample. Furthermore, there were no signs of gross toxicity, adverse pharmacologic effect, or abnormal behavior.

Reference: OECD (2002) OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Acute Dermal Irritation/Corrosion

Acknowledgment: This letter is attached with further 4 pages containing 3 tables and 1 figure. This study was accomplished upon request of Aria Rahavard Behmoud Company who financially supported the study.

Approved by Amir Baghaei

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Table 1. Draize Dermal Irritation Scoring System (DRISS)

Erythema and Eschar Formation	Value	Edema Formation	Value
No erythema	0	No edema	0
Very slight erythema (barely perceptible)	1	Very slight edema (barely perceptible)	1
Well-defined erythema	2	Slight edema (edges of area well defined by definite raising)	2
Moderate to severe erythema	3	Moderate edema (raised approximately 1 mm)	3
Severe erythema (beet-redness) to slight, eschar formation (injuries in depth)	4	Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4

Source: From Draize, J.H. (1959).¹

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Table 2. Evaluation of primary skin irritation index

EVALUATIONS	SCORE
Non Irritant	0.0
Negligible Irritant	0.1-0.4
Slight Irritant	0.41-1.9
Moderate Irritant	2.0-4.9
Severe Irritant	5.0-8.0

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دانشگاه علوم پزشکی و خدمات
بهداشتی درمانی البرز
دانشکده داروسازی

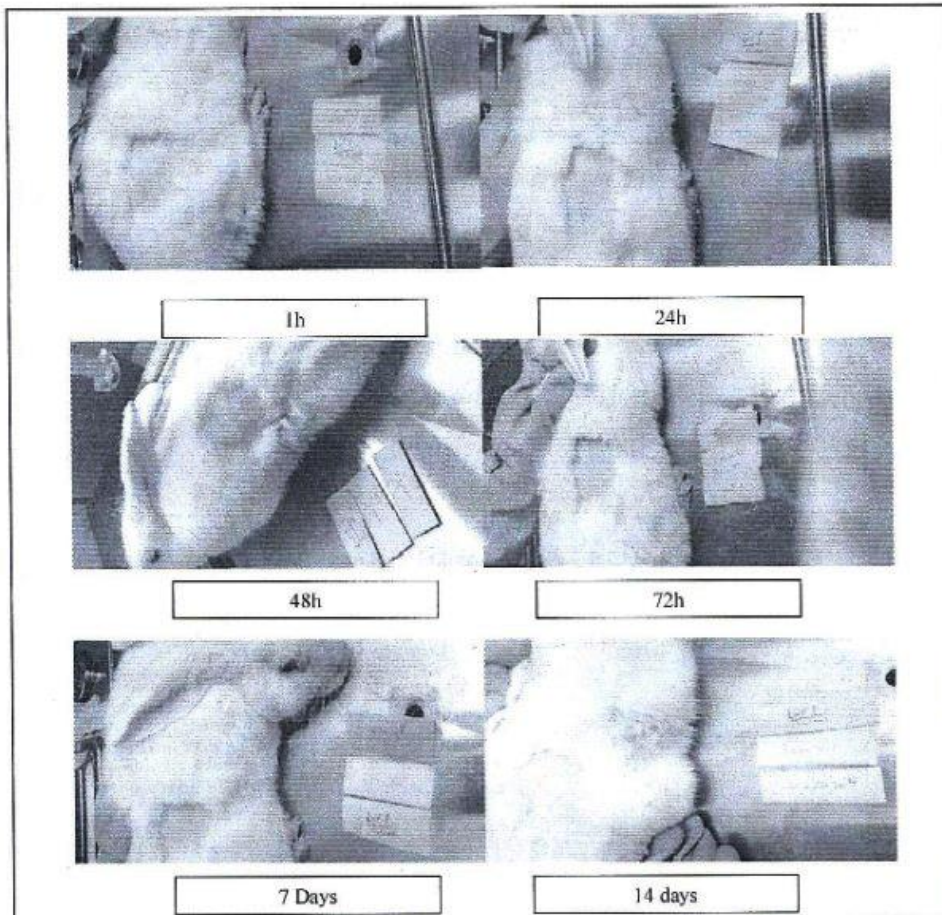
Table 3. Evaluation of test group reactions (Draize's Method)

	Rabbit Number			Average	Combined Index
	1	2	3		
1 Hrs					
Erythema Score	0	0	0	0.00	0.00
Edema Score	0	0	0	0.00	
24 Hrs					
Erythema Score	0	1	1	0.66	0.33
Edema Score	0	0	0	0.00	
48 Hrs					
Erythema Score	0	1	1	0.66	0.33
Edema Score	0	0	0	0.00	
72 Hrs					
Erythema Score	0	1	1	0.66	0.33
Edema Score	0	0	0	0.00	
7 days					
Erythema Score	0	1	1	0.66	0.33
Edema Score	0	0	0	0.00	
14 days					
Erythema Score	0	0	0	0.00	0.00
Edema Score	0	0	0	0.00	
Average					0.22

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Figure 1. Macroscopic skin observation in different times showing normal skin condition.



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