

Wednesday, January 20, 2021

Acute Inhalational Toxicity Test



دانشگاه علوم پزشکی و خدمات
بهداشتی درمانی گیلان
دانشکده داروسازی

To the Company: "*Aria Rahavard Behnoud*"

Hereby I report the results of acute inhalational toxicity tests for the "*Non-Alcoholic Surface Disinfectant Solution*" provided by your company. Full descriptive data are provided within appendix tables. To carry out this test, the Organization for Economic Cooperation and Development (OECD) revised acute inhalation test Guideline 403 (IG 403) was used.

Description of the method:

Nine-week-old male and female Sprague-Dawley rats were purchased and acclimated for 1 week before starting the experiments. During the acclimation and experimental periods, the rats were housed in five mesh cages (five rats per cage each was placed in an isolated chamber) in a room with controlled temperature ($23^{\circ}\text{C} \pm 2^{\circ}\text{C}$) and humidity ($55\% \pm 7\%$) with a 12-hour light/dark cycle. The rats were fed a rodent diet and filtered water ad libitum. The 10-week-old rats, weighing approximately 320 g for the males and 225 g for the females, were then divided into two groups (five rats in each group/scx): fresh-air control, test-dose group (target dose, 2000 ppm). The animals were exposed to for 4 hours and then observed for 2 weeks following OECD test guideline 403, based on acute inhalation toxicity applying good laboratory practice (G.L.P). During the exposure period, the animals were housed in individual wire cages. Thereafter, the animals were examined daily on weekdays for any evidence of exposure-related effects, including respiratory, dermal, behavioral, nasal, or genitourinary changes suggestive of irritation. The animals were not provided food during the 4-hour exposure period. The body weights were evaluated at the time of purchase, at the time of grouping, plus 7 and 14 days after the 4-hour inhalation exposure and before necropsy. The results with detailed data can be found in the attached tables 1-3 and figure 1.

Expert opinion: All animals survived inhalation exposure to test compound and gained weight through the observation period. All animals appeared active and healthy over the entire 14-day observation phase following exposure to the maximum dose (2000 ppm). There were no signs of gross toxicity, adverse pharmacologic effect, or abnormal behavior. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of 14-day period, therefore no further tests were examined. Furthermore, macroscopic and histological observations of tissue samples revealed no pathological changes as compared to control group. According to

Amir Baghlaei

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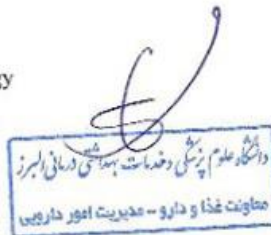
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OECD guidelines, this compound is categorized in the **non-toxic** group. Further tests by longer duration of exposure can be done if there would be case reports in future.

Reference: OECD (2008) Revised Test Guideline 403. OECD Guideline for Testing of Chemicals. Acute Inhalation Toxicity Testing.

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

Approved by Amir Baghaci
Assistant Professor and Dean
Department of Toxicology and Pharmacology
Faculty of Pharmacy
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Table 1. Individual body weights of fresh air control group

Animal No.	Sex	Body weight		
		Initial	Day 7	Day 14
1	M	201	209	219
2	M	193	201	211
3	M	170	177	186
4	M	166	173	181
5	M	195	203	213
6	F	162	169	177
7	F	158	165	173
8	F	206	215	225
9	F	204	213	223
10	F	177	184	193

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Table 2. Individual body weights of test group

Animal No.	Sex	Body weight		
		Initial	Day 7	Day 14
11	M	205	212	222
12	M	207	214	224
13	M	169	175	183
14	M	177	183	191
15	M	188	194	203
16	F	213	221	231
17	F	181	187	196
18	F	219	227	237
19	F	173	179	187
20	F	217	225	235

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Table 3- Individual cage-side observations

Animal No.	Findings	Day of occurrence
Males 1-5	Active and healthy	CR-14 ⁱ
Females 5-10	Active and healthy	CR-14 ⁱ
males 11-15	Active and healthy	CR-14 ⁱ
Females 16-20	Active and healthy	CR-14 ⁱ

ⁱCR- removal from the exposure tube

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Figure 1. Macroscopic (A) image of test group lung samples showing normal lung tissue.

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