广州海关技术中心
GUANGZHOU CUSTOMS DISTRICT TECHNOLOGY CENTER

地址：中国广州市天河区珠江新城花城大道66号B座
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CNAS 中国认可 国际互认 检测 TESTING CNAS L2322

No.: 01042000005457
Date: August 20, 2020

TEST REPORT

Applicant: Foshan Nanhai Keri Electronic Co.,Ltd
Applicant address: 13 Keyun North Road,B Zone,Shishan Science Park,Nanhai Foshan City,Guangdong Province,China
Description: KD001 Air Sterilization Humidifier（Liquid in the atomizer cavity in the humidifier）
Sample quantity: Tow humidifiers from applicant should be sent to our lab for uniform inspection.
Sample details: Colorless transparent liquid
Mark: Manufacturer：Foshan Nanhai Keri Electronic Co.,Ltd
Date of Receipt: June. 22, 2020
Testing Period: June. 22, 2020~August 20, 2020
Testing Item: Acute oral toxicity test, The micronucleus test of mouse bone marrow polychromatic erythrocytes, Acute inhalation toxicity test, Acute Eye Irritation Test
Test Method: Technical Standard For disinfection, Ministry of Health, PRC, 2002 edition

1. Acute oral toxicity test

(1) Materials and methods

1.1 Test environment: Laboratory Animal's SPF Housing Facilities, Use of License No. NO. SYXK(粤) 2018-0086, Guangdong. Room temperature 22±1℃, Relative humidity 60±5%.

1.2 Laboratory animals and feed: 20 Healthy SPF Kunming mice (10 females and 10 males) were selected, weighing 18.2 ~ 19.8 g. Animals and feed were supplied by Guangdong Medical Laboratory Animal Center. The Animal Production License No. SCXK(粤) 2018-0002, Guangdong. The Animal certificate No. 44007200077177.

1.3 Preparation of Sample: According to the client's request, the liquid in the atomization chamber was taken as test substances after the humidifier was operated for 30 min. Took 25.0g liquid in the atomization chamber , added distilled water and mixed up to 100ml as test solution.

1.4 Test procedure：

1.4.1 Dose: A limit test. The test substance dose was 5000 mg/kg·bw.

1.4.2 Administration of Doses: The test solution was administered in a single dose by gavage using a stomach tube, 0.2 ml/10g·bw. Fasted for 4 h prior to dosing, water was available any time. After the test solution had been administered, fasted for 1 h, and ordinary diet.

1.4.3 Observation: The test observation lasted for 14 days. Recorded signs of toxicity and death of animals, and calculated LD50.

(2) TEST RESULT:

After dosing, no obvious toxic signs and death were observed. The LD_{50} of the test substance in mouse was more than 5000 mg/kg·bw.

The result of acute oral toxicity test for mice by the test substance

Gender	Dose(mg/kg·bw)	Test animals	Weight（$\bar{X}$±SD）(g)	Death animals	Mortality (%)
Females Males	5000	20	19.2±0.4 19.1±0.5	0	0

(3) CONCLUSION:

The acute oral toxicity LD_{50} of the test substance in mouse was more than 5000 mg/kg·bw. According to the acute toxic classification standard of *Acute Toxicity Test* of Technical Standard For disinfection, Ministry of Health, PRC, 2002 edition, the sample "KD001 Air Sterilization Humidifier（Liquid in the atomizer cavity in the humidifier）" is classified as practice non-toxic grade.

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TEST REPORT

2. The micronucleus test of mouse bone marrow polychromatic erythrocytes

Test environment: SPF Laboratory Animal Room.The number of the using of laboratory is NO. SYXK(粤) 2018-0086. Room temperature 22±1℃, Relative humidity 60±5%.

Laboratory animals and feed: 50 Healthy SPF Kunming mice (25 females and 25 males) were selected, weighing 25.1 ~ 29.8 g. Animals and feed were supplied by Guangdong Medical Laboratory Animal Center . The number of the production of laboratory animals is NO. SCXK(粤) 2018-0002, Guangdong. The animal certificate number is No. 44007200077680.

Sample Preparation:

（1）Dose: The acute oral toxicity LD50 of the sample was more than 5000mg/kg·bw. Three dose groups were determined for the test, including 5000mg/kg·bw, 2500mg/kg·bw and 1250mg/kg·bw .

（2）Preparation of Sample: According to the client's request, the liquid in the atomization chamber was taken as test substances after the humidifier was operated for 30 min. Took 25.0g liquid in the atomization chamber , added distilled water and mixed up to 100ml as 5000mg/kg·bw test solution, and the rest groups are diluted to set concentrations respectively.

（3）Control group: Cyclophosphamide was used as the positive control group, the test dose was 40mg/kg·bw . Took 40mg cyclophosphamide and added distilled water to 20mL for the positive control; the negative control group was distilled water.

Test Procedures

（1）Test group, the mice were administrated twice by gavage of 0.2ml/10g·bw, with an interval of 24h; the animals were killed 6h after the last exposure, took the femurs , removed the muscles,wiped the blood, and cut off the two ends of the femurs , rinsed the marrow cavity with 0.1mL fetal bovine serum, smeared with rinse solution. After drying, the slides were fixed in methanol for 7 minutes, dyed with Giemsa dye for 8-10 minutes, and then rinsed with PBS buffer (PH6.8) and dried it.

（2）Observed 1000 polychromatic erythrocytes (PCE) for every mouse, recorded the number of cells with micronucleus, calculated the micronucleus rate , statistical treatment with U-test of Poisson distribution , meanwhile , counted the number of NCE in 200 PCE, calculated the PCE / NCE ratio.

Results:

The micronucleus rate and PCE / NCE ratio are shown in the table below. The results of U-test Poisson distribution showed that there was no significant difference between each dose group and the negative control group ($P > 0.05$), and there was significant difference between the positive control group and the negative control group ($P < 0.05$).

Tab.1 The result of mice bone marrow micronucleus

Group	Dose(mg/kg·bw)	Test animals(n)	Number of PCE	Number of PCE with micronucleus	Micronucleus Rate (‰)	PCE/NCE
Test	5000	10	10000	27	2.7±0.7	1.05±0.12
	2500	10	10000	28	2.8±0.9	1.08±0.12
	1250	10	10000	26	2.6±0.8	1.13±0.11
Negative control	---	10	10000	24	2.4±0.8	1.13±0.11
Positive control	40	10	10000	252	25.2±2.8	1.09±0.15

Conclusion:

According to the test results ,the test substance had no chromosome damage effect on SPF Kunming mice.

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3. Acute inhalation toxicity test

(1) Materials and methods

1.1 Test environment: Laboratory Animal's SPF Housing Facilities, Use of License No. NO. SYXK(粤) 2018-0086, Guangdong. Room temperature 22±1℃, Relative humidity 60±5%.

1.2 Laboratory animals and feed: 20 Healthy SPF Kunming mice were randomly selected，in half respectively male and female, weighing 18.0 ~ 20.0 g. Animals and feed were supplied by Guangdong Medical Laboratory Animal Center. The Animal Production License No. SCXK（粤） 2018-0002, Guangdong. The Animal certificate No. 44007200077399.

1.3 Preparation of Sample: According to the client's request, the liquid in the atomization chamber was taken as test substances after the humidifier was operated for 30 min.

1.4 Exposure concentrations of Sample: The main study exposure concentrations was 10000 mg/m^3 for 2 h.

1.5 Test procedure:

1.5.1 Exposure equipment: A dynamic inhalation equipment was used, type HOPE-MED 8050. The duration of exposure was 2 h after equilibration of the inhalation chamber.

1.5.2 Exposure condition: Inhalation chamber vol: 0.3 m^3, airflow rates: 3.6 m^3/h, totalled 7.5 m^3. The temperature: 22±1℃, the relative humidity: 55~85%, oxygen concentrations: 20±0.5%. The test substance relative density: 1.000. Fasted during exposure, water also was withheld. After exposure, ordinary diet.

1.5.3 Observation: The test observation were lasted for 14 days. Recorded signs of toxicity and death of animals, individual weights of animals in weekly intervals. At the end of the test surviving animals were weighed and then humanely killed, record necropsy findings. Calculated LC_{50}.

(2) TEST RESULT:

After exposure 14 days, no obvious toxic signs and death were observed. No obvious change were observed in gross necropsy. The 2 h LC_{50} was more than 10000 mg/m^3. The result of acute inhalation toxicity test see table 1.

Table 1 The result of acute inhalation toxicity test for mice by the test substance

Gender	Concentration (mg/m^3)	Test animals(n)	Body Weight ($\bar{X}$±SD) (g)			Death animals(n)	Mortality (%)
			0 d	7 d	14 d		
female	10000	10	19.0±0.6	27.9±1.0	33.2±1.8	0	0
male	10000	10	19.4±0.5	29.8±1.3	38.2±1.7	0	0

(3) CONCLUSION:

The acute inhalation toxicity 2 h LC_{50} of the test substance in mouse was more than 10000 mg/m^3. According to *the acute inhalation toxicity test* evaluation criteria of Technical Standard For disinfection, Ministry of Health, PRC, 2002 edition, the sample "KD001 Air Sterilization Humidifier（Liquid in the atomizer cavity in the humidifier）" is classified as practice non-toxic grade.

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TEST REPORT

4. Acute Eye Irritation Test

(1) Materials and methods

1.1 Test environment: Rabbit room with conventional condition. The license number of using laboratory animals is No. SYXK(粤) 2018-0086. The room temperature was 21℃ ~ 24℃ and the relative humidity was 50% ~ 60%.

1.2 Laboratory animals: New Zealand white albino rabbits, weighing between 2.2kg and 2.4kg at the start of the test, were used. They were supplied by Guangdong Medical Laboratory Animal Center (Sanshui Base). The production license number of laboratory animals is No. SCXK(粤)2019-0035. The animal certificate number is No. 44411600006790.

1.3 Quantity of animals/sex:3/ Female

1.4 Preparation of Sample: According to the customer's requirement, removed the water tank and added tap water inside, installed the water tank back into the machine, started the function of sterilizing module, ran the machine for 30 minutes, removed the water tank, and took the liquid in the atomization cavity as test sample.

1.5 Observation period: 1h, 24h, 48h, 72h after dosage.

1.6 Test procedure: 0.1 mL of the test substance was placed in the conjunctival sac of the left eye of each animal, the eyelids were gently held together for 4 seconds, 30 seconds after test substance application, the test eyes was rinsed with enough physiological saline. 0.1 mL of physiological saline was placed in the other eye as a control. Examined both eyes of each animal approximately 1h, 24h, 48h, 72h after test substance application, graded and recorded the ocular reactions on the basis of the test method. Evaluated the ocular reactions (conjunctival congestions, conjunctival chemosis, iris lesions and cornea lesions) accordance with the mean scores of 24h, 48h, 72h and the recover time on the basis of the test method.

(2) Test result

The ocular reactions were not found at each observation period. The mean scores of the three animals: conjunctival congestions were less than 2, conjunctival chemosis were less than 2, iris lesions were less than 1, cornea lesions were less than 1.

(3) Test Conclusion

According to the test method, the irritation of the test substance was considered as no irritant to rabbit's eyes.

***** THE END *****

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Report approver: Chen Wenrui

Chen Wenrui（Director of the food laboratory）

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