# SGS report: Non Toxic Oral Test



# **Test Report**

Report No: ASH18-033119-02

Issue Date: Aug 27 2018

Sample name: Sample Batch No.: Product Date: Manufacturer: AIR DEFENDER NANO TIO2 SOL / /

Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

 SGS Sample No.:
 ASH18-033119.001

 Date of sample received:
 Jul 11 2018

 Testing period:
 Jul 11 2018 ~ Aug 21 2018

TEST(S) REQUESTED: Selected test(s) as requested by applicant

TEST METHOD(S): Please refer to the next page(s)

TEST RESULT(S): Please refer to the next page(s)

CONCLUSION: Oral LD<sub>50</sub> of the sample on Rat is more than 5000mg/kg, which was non-toxic substance.

SAMPLE DESCRIPTION: Sample in bottle

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Report No: ASH18-033119-02

Issue Date: Aug 27 2018

## TEST METHOD(S):

Acute oral toxicity test: 16 CFR 1500.3

Test environment: Barrier system animal room. Certificate No. SYXK (Zhe) 2018-0003, room temperature 21.5°C~23.1°C, relative humidity 44.6%~57.8%.

Test animal: SD rat, obtained from Centre for Laboratory Animal of Zhejiang Province. Certificate No. SCXK (Zhe) 2014-0001.

No. of animals/sex: 5 males, 5 females

Sample preparation: 25.0012g samples were dissolved and poured into a 50mL volumetric flask respectively. The pure water was added to the calibration line, all these samples were fully shake into the reagent bottle, labeled standby.

Test method: The sample was administered as supplied at a limit dosage as 5000.24mg/kg. The animals were fasted for overnight before dosing. And the animals were fasted for 3 hours after dosing. The animals were checked for mortality or signs of morbidity at least twice a day during the observation period. The body weight of each animal was recorded once a week. Gross autopsies were performed on all animals that died during the observation period and on all survivors after 14 days observation.

#### TEST RESULT(S):

All animals No abnormal clinical symptoms and poisoning deaths were occurred in all experimental animals during 14 days observation. Body weights of animals were no significantly changes during the study. Gross anatomy no remarkable pathological findings on all survivor animals after 14 days observation. LD<sub>50</sub>>5000.24mg/kg.

Sex	Number of			Rate of			
	animals	Oday	7day	14day	weight gain	Mortality	Death
Male	5	214.1±4.63	256.7±7.38	301.1±4.16	87.0±7.14	0	0
Female	5	204.5±5.14	239.1±4.26	275.3±13.85	70.8±11.95	0	0

Attach Table 2 Results of acute oral toxicity tes	t
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REMARK: This report is the replace of the report 231800027255 issued in 2018.08.17, the original report was voided.

Remark: \* Test was carried out by NB CIQ laboratory assessed as competent.

\*\*\* End \*\*\*



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# SGS report: Skin Irritation Test



**Test Report** 

Report No: ASH18-033119-01

Issue Date: Aug 27 2018

Sample name: Sample Batch No.: Product Date: Manufacturer: AIR DEFENDER NANO TIO2 SOL

Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

SGS Sample No.: ASH18-033119.001 Date of sample received: Jul 11 2018 Testing period: Jul 11 2018 ~ Aug 21 2018

TEST(S) REQUESTED: Selected test(s) as requested by applicant

TEST METHOD(S): Please refer to the next page(s)

TEST RESULT(S): Please refer to the next page(s)

CONCLUSION: The primary irritation score is 0.

SAMPLE DESCRIPTION: Sample in bottle

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Report No: ASH18-033119-01

Issue Date: Aug 27 2018

#### TEST METHOD(S):

\* Method of testing primary irritant substances: 16 CFR 1500.41

Test environment: Rabbit room of conventional condition. Certificate No. SYXK (Zhe) 2018-0003,

Room temperature 20.9°C~23.8°C, Relative humidity 52.9%~69.3%.

Test animal: New Zealand White Albino Rabbit, supplied by Yinhai rabbit specialty cooperative organization of Tongxiang Zhejiang Province, Certificate No. SCXK (Zhe) 2013-0056. No. of animals/sex: 6/not specified

Test method: 0.5mL sample was applied to clipped test site (abraded and intact skin) and wrapped with rubberized cloth for 24 hours.

Observation period: After 24 hours of exposure, the patches were removed and the resulting reactions were evaluated. Readings were again made 48 hours after the first reading.

## TEST RESULT(S):

The value of skin reaction (abraded and intact skin) at any observation point was 0.

Ani Ani mal mal No. sex				Erythema and eschar formation					na form	A CONTRACTOR OF			Prim	
	B.W	200	, Intac	Intact skin Abraded skin		Subto	Intact skin		Abraded skin		Subt	Total	ary irrita ion	
	(kg)	24h	72h	24h	72h	tal	24h	72h	24h	72h	otal		scor e	
1	ð	2.5	0	0	0	0		0	0	0	0			
2	8	2.3	0	0	0	0		0	0	0	0			
3	Ŷ	2.5	0	0	0	0		0	0	0	0			
4	8	2.5	0	0	0	0	0	0	0	0	0	0	0	0
5	Ŷ	2.6	0	0	0	0		0	0	0	0			
6	Ŷ	2.3	0	0	0	0		0	0	0	0			
	Value		0	0	0	0		0	0	0	0			

#### Attach Table 1 Result of thetesting primary irritant substances

REMARK: This report is the replace of the report 231800027255 issued in 2018.08.17, the original report was voided.

Remark: \* Test was carried out by NB CIQ laboratory assessed as competent.

\*\*\* End \*\*\*



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# SGS report: Eye Irritation



**Test Report** 

Report No:	ASH21-001085-02
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Date: Feb 23 2021

Sample name:	AirDefender <sup>®</sup> Antibacterial Solution
Sample Batch No.:	AD4220
Product Date:	/
Manufacturer:	1

Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

Date of sample received:	2021-01-07
Testing period:	2021-01-07-2021-02-23
Test Requested:	Selected test(s) as requested by applicant
Test Method:	Please refer to the next page(s)
Test Result(s):	Please refer to the next page(s)

This Test Report supersedes the Test Report No. ASH21-001085-01 issued by SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Original test report will be invalid from today. " Sample name " information was modified by the request of the client after the Test Report was issued.

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Test	Re	port
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Report No: ASH21-001085-02

Date: Feb 23 2021

Sample Description:

Specimen No.	SGS Sample ID	Description
1	ASH21-001085.001	sample in bag

TEST RESULT(S):

Test standard	16 CFR Part 1500.42
Test type	*Acute Ocular Irritation Test
Test environment	Rabbit room of conventional condition. Certificate No. SYXK (Zhe) 2018-0003, Room temperature 20.5°C ~22.7°C; Relative humidity 56.2% ~67.4%.
Test animal	Healthy adult New Zealand Albino Rabbit, 2.27kg~2.88kg, supplied by Yinhai rabbit specialty cooperative organization of Tongxiang Zhejiang Province, Certificate No. SCXK (Zhe) 2018-0002. Animal Quality Certificate No.: 20210117Cezz0610038319.
Number of animals/sex	6, female animals are nulliparous and non-pregnant
Test method	In 24h before the test, 1drop of 2% fluorescein sodium solution was dropped directly on the comea of the eyes of the animals. After 15s, the eyes were gently flushed with warm saline and examined under the hand slit-lamp, and only those animals without eye defects or irritation shall be used. The 0.1mL of the original sample was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test sample was dropped. The lids were then gently held together for one second and the animal was released. The other eye, remaining untreated, was served as a control. The eyes were not washed after instillation of test sample.
Observation period	24h, 48h and 72h after dosage.
Results	No ocular reaction was observed at 24h, 48h and 72h after instillation of test sample.
Conclusions	The test was regarded as negative, and the test sample was considered as non-irritant under the non-flush test condition.

#### Attached Table Result of the acute ocular Irritation Test

			Test condition: Non-flus
Sex	Body weight (kg)	Parts of eye	Observation Time Point
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		the second s	Sex Body weight (kg) Parts of eye SGS-CSTC Standards Technical Services (

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Report No: ASH21-001085-02

Date: Feb 23 2021

				24h	48h	72h
			Cornea	0	0	0
1 8 2.27	Iris	0	0	0		
			Conjunctivae	0	0	0
			Cornea	0	0	0
2	Ŷ	2.46	Iris	0	0	0
	10.010		Conjunctivae	0	0	0
			Cornea	0	0	0
3	ę	2.88	Iris	0	0	0
		Conjunctivae	0	0	0	
			Cornea	0	0	0
4	2.59	Iris	0	0	0	
		Conjunctivae	0	0	0	
			Cornea	0	0	0
5	8	2.62	Iris	0	0	0
			Conjunctivae	0	0	0
			Cornea	0	0	0
6 Q 2.35	Iris	0	0	0		
	1000		Conjunctivae	0	0	0

#### Remark:

\*Test items were carried out by Ningbo Customs District Technology Center assessed as competent.

\*\*\* End \*\*\*

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SGS report: Test for In Vitro Cytotoxicity

**Test Report** 



•	•		

Report No: ASH21-010934-01

Sample name:	AirDefender <sup>®</sup> Anti-bacterial Solution
Sample Batch No.:	/
Product Date:	/
Manufacturer:	/

# Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

Date of sample received:	Mar 01 2021
Testing period:	Mar 01 2021 ~ Mar 26 2021
Test Requested:	Selected test(s) as requested by applicant
Test Method:	Please refer to the next page(s)
Test Result(s):	Please refer to the next page(s)

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Date: Mar 26 2021

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Report No: ASH21-010934-01

Date: Mar 26 2021

Sample Description:

Specimen No.	SGS Sample ID	Description
1	ASH21-010934.001	sample in bottle

# TEST METHOD(S):

ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

Test Article: The sample preparation was in accordance with ISO 10993-12:2012. Extration condition is 24h at 37  $^{\circ}$ C in culture medium. The volume of extract is determined by the standard surface area.

Cell lines: L-929 cells (mouse fibroblast)

Medium: MEM medium (Gibco) with 10% FBS

Negative control: Medical PE gloves

Positive control: Medical latex gloves

General Procedure: Test on extracts(microscopic observation)

The prepared cell suspension was seeded in 96-well culture plate, set blank control, negative control, the positive control and the test sample group, inoculated with 100µL of cell suspension per well. Set  $CO_2$  incubator (5%  $CO_2$ , the same below) 37 °C cultured for 24 h, discard the original culture medium. Adding fresh cell culture medium in blank control group, added extracts of the negative control in negative control group, added positive control solution or positive control extracts in the positive control group, added the extracts of the experimental material in the test sample. The test volume is 100µL per well, set  $CO_2$  incubator cultured for 24h. Observed cell morphology under the microscope.

# TEST RESULT(S):

Tests for in vitro cytotoxicity (test on extracts)

The cytotoxicity of the sample was grade 1, cell growth state in blank control, negative control and positive control is normal

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmatic granules, no cell
0	None	lysis, no reduction of cell growth
		Not more than 20 % of the cells are
	Slight	round, loosely attached and without
1		intracytoplasmatic granules, or show changes
		in morphology; occasional lysed cells are
		present; only slight growth inhibition

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Test Report		rt Report No: AS	H21-010934-01 Date: Mar 26 2021
			observable.
	2	Mild	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50 % growth inhibition observable.
	3	Moderate	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completly destroyed, but more than 50 % growth inhibition observable.
	4	Severe	Nearly complete or complete destruction of the cell

## **CONCLUSION:**

The cytotoxicity of the sample was grade 1, which is slight cytotoxic. The negative positive controls have the expected response in the test system.

\*\*\* End \*\*\*

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•	
Sample name:	AirDefender <sup>®</sup> Anti-bacterial Solution
Sample Batch No.:	/
Product Date:	/
Manufacturer:	/

Report No: ASH21-010951-01

Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

Date of sample received:	2021-03-01
Testing period:	2021-03-01 ~2021-04-20
Test Requested:	Selected test(s) as requested by applicant
Test Method:	Please refer to the next page(s)
Test Result(s):	Please refer to the next page(s)

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Date: Apr 20 2021

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Report No: ASH21-010951-01

Date: Apr 20 2021

Sample Description:

Specimen No.	SGS Sample ID	Description		
1	ASH21-010951.001	sample in bag		

## TEST RESULT(S):

Test Item: Acute inhalation toxicity test

Test Standard: OECD TG 403

Conclusions: Under the conditions of this test, Inhalation  $LC_{50}$  of the sample on ICR mice is more than 21.9mg/L.

# Acute inhalation toxicity test

## 1. Materials and methods

# 1.1. Sample preparation

Original sample

- 1.2. Experimental animals and feeding environment
- 1.2.1. Experimental animals

Species: mice;

Strain: ICR;

Microbial status: SPF;

Quantity: 6;

Sex: 3 males, 3 females, females were nulliparous and non-pregnant;

Weeks of age: 4 ~ 5 weeks

Body weight:  $18g \sim 22g$ , Body weight was in an interval within  $\pm 20$  % of the mean weight of animals day

## 0;

Animal source: Laboratory Animal Center for Hangzhou Medical College;

Experimental Animal Production License Number: SCXK (Zhe) 2019-0002;

Animal Quality Certificate No.: 20210323Abba0100018337.

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#### Report No: ASH21-010951-01

Date: Apr 20 2021

1.2.2. Feeding environment

Facilities: Barrier system;

Temperature: 23.2°C ~ 24.8°C;

Relative humidity: 47.9% ~ 61.2%;

Experimental Animal Use License Number: SYXK (Zhe) 2018-0003.

1.2.3. Feed

Name: Co 60-irradiated standard commercial pelleted rat feed;

Manufacturers: Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Production License Number: Susi license (2019) 01008;

Production Date: 2021.01.05;

Quality guarantee period: 6 months;

Qualification certificate number: No.120210105024.

1.2.4. Drinking water

Grade I RO ultrafiltration water (The free chlorine in water was kept at 2-3ppm for sterilization by adding

sodium hypochlorite) was provided for animals to drink ad libitum by the spout.

## 1.3. Test method

Before the experiment, the animals were acclimatized in the laboratory animal room environment for 7 days. The sample was administered as supplied at a limit dose. Using a single-concentration oral and nasal exposure system, the parameters were set before the exposure (concentration 20mg/L, average aerosol flow 9.072L/min, average dilution flow 0.305L/min, average pumping flow 1.986L/min). The results of the operation (concentration 21.9mg/L) were obtained directly after the end of the exposure, and the cumulative injection was 47.6g. Inhalation was conducted for 4 hours at a time. The animals were observed for signs of toxicity or behavioral changes frequently per day thereafter. Individual weights were recorded weekly. Gross autopsies were performed on all animals that died during the observation period and on all survival animals after 14 days.

2. Results

Neither abnormal clinical symptoms nor poisoning deaths occurred in all experimental animals during 14 days observation. Body weights of animals were no significantly changes during the study. Gross anatomy no

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remarkable pathological findings on all survivor animals after 14 days observation.  $LC_{50}>21.9$ mg/L. (See Table 1).

## 3. Conclusions

Under the conditions of this test, Inhalation  $LC_{50}$  of the sample on ICR mice is more than 21.9mg/L.

Sex	Number	weight $(\overline{X} \pm SD)$ (g)							Rate
	of animals	0 day	1day	3 days	7 days	14 days	14 days weight gain	Mortality	of death
Male	3	21.1±0.42	21.9±0.47	23.3±0.50	25.3±0.42	30.6±0.25	9.4±0.40	0	0
Female	3	18.8±0.47	19.3±0.49	20.3±0.42	22.3±0.25	25.2±0.70	6.3±0.32	0	0

Table 1 Results of acute inhalation toxicity test

## **Remark:**

Test items were carried out by Ningbo Customs District Technology Center assessed as competent.

\*\*\* End \*\*\*

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