



ATTESTATION REPORT

Date: 2019-09-11
No.: T01607-12

Page 1 of 6

Applicant : Chiaphua Industries Ltd.
Unit A, 2/F, Chiaphua Industries Building, Nos 8-10 Siu Lek
Yuen Road, Sha Tin, New Territories, Hong Kong

Description of Sample(s) : Product name in English: THYME DISINFECTION SPRAY
Product name in Chinese: 百里香消毒噴劑
Model no.: GMTHYME; 1/128THYME
Brand name: GERMAGIC; 菌魔力, 霉菌滅
Quantity submitted: 4 bottles

Date Sample(s) Received : 2019-03-18

Date Testing : 2019-03-18 to 2019-06-28

Investigation Requested : 急性眼刺激試驗.

Conclusions : Referring to Test Summary.

Remark(s) : Report content referring to SCTR No.:2019SP1434R01a.



Lee Mei Yu, Amy
Certification Officer
For and on behalf of
The Hong Kong Certification Centre Ltd



ATTESTATION REPORT

Date: 2019-09-11

Page 2 of 6

No.: T01607-12

Test Summary

1. 急性眼刺激試驗

一. 材料

1. 受試樣品 : 送檢樣品原液.
2. 動物 : 健康成年雌性普通級新西蘭兔 3 隻, 體重範圍為 2~3kg, 單籠飼養, 試驗前動物在動物檢疫室中適應 3d 時間. 來源於廣州市花都區花東信華實驗動物養殖場. 動物生產許可證號: SCXK(粵)2014-0023, 動物合格證號為 44007600006301. 本中心實驗動物使用許可證號: SYXK(粵)2016-0156. 飼養環境: 溫度範圍(°C): 20~26, 相對濕度(%): 40~70. 飼料由北京華阜康生物科技股份有限公司提供, 自由飲水.
3. 主要儀器與試劑 : 電子台秤 QDW-B-V003, 分析天平 QDW-B-V001, 熒光素鈉, 無菌生理鹽水.

二. 方法

1. 檢測依據 : <消毒技術規範> (衛生部 2002 年版) 第二部分-2.3.4.
2. 試驗方法 : (1) 試驗前 24h, 檢查每隻新西蘭兔的雙眼是否有異常現象(使用 2% 熒光素鈉), 如發現異常應淘汰該兔.
(2) 吸收受試樣品 0.1mL 滴於結膜囊中, 另一側以生理鹽水作為正常對照.
(3) 滴入受試物後, 將眼被動閉合 4s, 30s 後用生理鹽水沖洗. 於滴眼後 1h, 24h, 48h, 72h, 7d, 14d 和 21d 肉眼觀察新西蘭兔結膜, 虹膜和角膜損傷和恢復情況. 如果 72h 未出現刺激反應, 或第 7d 或 14d, 眼刺激反應完全恢復, 即可提前終止試驗.
3. 結果評價 : 以給受試物後動物角膜, 虹膜或結膜各自在 24h, 48h 和 72h 觀察時點的刺激反應積分的均值和恢復時間評價.
按表 1-1 對新西蘭兔眼角膜, 虹膜和結膜的急性眼刺激反應進行評分, 並分別計算每隻動物在三個不同觀察時間(24h, 48h 和 72h)角膜損害, 虹膜損害, 結膜充血和結膜水腫四個方面的“平均評分”(及每隻動物的 24h, 48h 和 72h 評分之和除以觀察數 3). 分別一動物眼角膜, 虹膜和結膜充血, 水腫的平均評分和恢復時間進行, 按表 1-2, 表 1-3 眼刺激反應分級標準判定受試物對眼的刺激強度.



ATTESTATION REPORT

Date: 2019-09-11

Page 3 of 6

No.: T01607-12

表 1-1 家兔急性眼刺激反應的評分標準		
眼損害表現		評分
角膜損傷:		
無潰傷形成或混濁		0
散在或彌漫性混濁, 虹膜清晰可見		1
半透明區易分辨, 虹膜模糊不清		2
出現灰白色半透明區, 虹膜細節不清瞳孔大小勉強可見		3
角膜不透明, 混濁, 虹膜無法辨識		4
虹膜損傷:		
正常		0
皺摺明顯加深, 充血, 腫脹, 角膜周圍有中度充血, 瞳孔對光仍有反應		1
出血, 肉眼可見破壞, 或瞳孔對光無反應		2
結膜(臉結膜, 球結膜)充血:		
血管正常		0
血管充血呈鮮紅色		1
血管充血呈深紅色, 血管不易分辨		2
彌漫性充血呈紫紅色		3
結膜(臉結膜, 球結膜)水腫:		
無水腫		0
輕微水腫 (包括瞬膜)		1
明顯水腫, 伴有部分眼瞼外翻		2
水腫致眼瞼近半閉合		3
水腫致眼瞼近大半閉合		4
表 1-2 眼刺激性反應分級標準		
可逆性損傷	無刺激性	3 隻動物的平均評分: 角膜損傷<1, 虹膜損害<1, 結膜充血<2 和結膜水腫<2 或 3 隻動物中至少有 2 隻動物的平均評分符合上述標準. 另外 1 隻動物的刺激反應在 21d 內完全恢復.
	輕刺激性	3 隻動物中有 2 隻動物的平均評分: 角膜損傷≥1, 虹膜損害≥1, 結膜充血≥2 和結膜水腫≥2, 且 7d 內全部動物的刺激反應完全恢復.
	刺激性**	3 隻動物中有 2 隻動物的平均評分: 角



ATTESTATION REPORT

Date: 2019-09-11

Page 4 of 6

No.: T01607-12

		膜損傷≥1, 虹膜損害≥1, 結膜充血≥2和結膜水腫≥2, 且 21d 內全部動物的刺激反應完全恢復.	
不可逆性損傷	腐蝕性***	至少有一隻動物的角膜, 虹膜或結膜的刺激反應在 21d 的觀察期內未完全恢復或和在 3 隻動物中有 2 隻動物的平均評分: 角膜損害≥3; 虹膜損害≥1.5.	
注: 完全恢復是指動物的眼刺激反應評分: 角膜損害=0, 虹膜損害=0, 結膜充血=0 或 1, 結膜水腫=0 或 1.			
**刺激性: 接觸受試物後所產生的可逆性炎性反應.			
***腐蝕性: 接觸受試物後所產生的不可逆性組織損傷.			
表 1-3 眼刺激性反應分級標準			
<u>平均評分</u>	<u>動物數(隻)</u>	<u>恢復時間(d)*</u>	<u>損傷類型</u>
角膜損害<1; 虹膜損害<1; 結膜充血<2; 結膜水腫<2	≥2	≤21	無刺激性
角膜損害≥1; 虹膜損害≥1; 結膜充血≥2; 結膜水腫≥2	≥2	≤7	輕刺激
		≤21	刺激性
角膜損害≥3; 虹膜損害≥1.5	≥2		腐蝕性**
角膜損害≥1; 虹膜損害≥1; 結膜充血≥2; 結膜水腫≥2	≥1	>21	
*恢復時間: 為動物刺激反應評分恢復至角膜損害=0, 虹膜損害=0, 結膜充血=0 或 1, 結膜水腫=0 或 1 的時間.			
**腐蝕性: 至少有 1 隻動物於 21d 尚存在角膜黏連或血管翳, 也可判為腐蝕性.			



ATTESTATION REPORT

Date: 2019-09-11

Page 5 of 6

No.: T01607-12

三. 檢測結果

眼刺激反應評分表											
動物 信息	損傷 表現	1h		24h		48h		72h		平均積分*	
		樣品	對照	樣品	對照	樣品	對照	樣品	對照	樣品	對照
2.1583 kg	角膜 損傷	0	0	0	0	0	0	0	0	0	0
	虹膜 損傷	0	0	0	0	0	0	0	0	0	0
	結膜 充血	1	0	1	0	0	0	0	0	0.33	0
	結膜 水腫	1	0	0	0	0	0	0	0	0	0
2.1728 kg	角膜 損傷	0	0	0	0	0	0	0	0	0	0
	虹膜 損傷	0	0	0	0	0	0	0	0	0	0
	結膜 充血	1	0	1	0	0	0	0	0	0.33	0
	結膜 水腫	1	0	0	0	0	0	0	0	0	0
2.1439 kg	角膜 損傷	1	0	1	0	1	0	0	0	0.66	0
	虹膜 損傷	0	0	0	0	0	0	0	0	0	0
	結膜 充血	1	0	1	0	1	0	1	0	1	0
	結膜 水腫	1	0	1	0	1	0	0	0	0.66	0
*平均積分系指 24h, 48h, 72h 評分之和除以觀察時間段數 3.											
動物的角膜積分全部為 0.66, 虹膜積分分別為 0, 結膜充血積分分別為 1, 結膜水腫積分分別為 0.66, 且所有動物的角膜, 虹膜, 結膜積分在 3 天內降至 0.											
是否有其他眼刺激反應: 否.											

四. 結論

受試物對新西蘭兔的眼刺激性為無刺激性.



ATTESTATION REPORT

Date: 2019-09-11
No.: T01607-12

Page 6 of 6

Product Photo



***** **END OF REPORT** *****

Certification of Translation

Ectranslator Translations Services, a translation company in China, is competent to translate from Simplified Chinese into English, and certify that the translation of "Acute Eye Irritation Test of GERMAGIC DISINFECTANT SPRAY" is true and accurate to the best of our abilities.



Name of the Director: 聂晶 (Nie Jing)

Signature: 聂晶

Address: No. 21-302, Lane 1799, Yinchun Rd
Shanghai, China 201111

Tel: 0086-21-51036356

Fax: 0086-21-51597023

Email: sales@ectranslator.com



ATTESTATION REPORT

Date: Sept 11, 2019
No.: T01607-12

Page 1 of 6

Applicant : Chiaphua Industries Ltd.
Unit A, 2/F, Chiaphua Industries Building, Nos 8-10 Siu Lek Yuen Road, Sha Tin, New Territories, Hong Kong

Description of sample(s) : Product name in English: THYME DISINFECTANT SPRAY
Product name in Chinese: 百里香消毒噴劑
Model no.: GMTHYME; 1/128THYME
Brand name: GERMAGIC; 菌魔力, 霾菌滅
Quantity submitted: 4 bottles

Date Sample(s) received : March 18, 2019

Date Testing : Mar 18, 2019 to Jun 28, 2019

Investigation requested : Acute Eye Irritation Test

Conclusion : Refer to Test Summary.

Remark(s) : Report content refers to SCTR No.: 2019SP1434R01a

Lee Mei Yu, Amy
Certification Officer
For and on behalf of
The Hong Kong Certification Centre Ltd



ATTESTATION REPORT

Date: Sept 11, 2019

Page 2 of 6

No.: T01607-12

Test Summary

1. Acute Eye Irritation Test.

I. MATERIALS

1. Test sample : The stock solution of the sample submitted for test.
2. Animals : Three healthy, adult female common class New Zealand rabbits, weighing 2~3kg each. Each rabbit was raised in an individual cage. The animals were acclimatized in the animal quarantine room for 3 days before the experiment. The rabbits were provided by Huadongxinhua experimental animal farm, Huadu district, Guangzhou. Animal production license number: SCXK (Guangdong) 2014-0023, Animal Certificate No.44007600006301. The license number of using laboratory animals in the center is SYXK (Guangdong) 2016-0156. Feeding environment: Temperature range (°C): 20-26, relative humidity (%): 40-70. Feed is provided by Beijing Huafukang biotechnology Co., Ltd. The rabbits were given ad-litum access to water.
3. Main instruments and reagents : Electronic platform balance QDW-B-V003, Analytical balance QDW-B-V001, sodium fluorescein, Sterile normal saline.

II. Methods:

1. Test basis : *Technical Standards for Disinfection* (Ministry of Health, 2002 Edition) – 2.3.4
2. Test method : (1) At 24 hours before the test, each New Zealand rabbit's eyes were checked for abnormalities (using 2% sodium fluorescein). If abnormalities were found, the rabbit should be excluded.
(2) Drop 0.1mL of the test sample into the conjunctival sac of one eye, and drop normal saline into the other eye as the normal control.
(3) After dropping the test substance, the eyes were passively closed for 4 seconds, then rinsed with normal saline after an additional 30 seconds. Injury and recovery of conjunctiva, iris and cornea of New Zealand rabbits were observed with naked eyes at 1h, 24h, 48h, 72h, 7d, 14d and 21d after eye drop. If no irritation reaction was observed at 72h, or the eye irritation recovers on the 7th or 14th day, the test can be terminated early.
3. Results evaluation : The irritation was evaluated using the mean irritation reaction score of cornea, iris or conjunctiva at 24h, 48h and 72h respectively, and the mean time to recover.

The acute eye irritation reactions of cornea, iris and conjunctiva of New Zealand rabbits were scored according to Table 1-1. And the "average scores" of cornea damage, iris damage, conjunctival injection and conjunctival swelling in three observation time points (24h, 48h and 72h)



of each animal were calculated respectively (and the sum of the scores at 24h, 48h and 72h of each animal was divided by 3, i.e., times of observation). The average score and recovery time of the cornea, iris and conjunctival injection and swelling of animal eyes were recorded, respectively. The irritation intensity of the test sample to the eye should be judged according to eye irritation grading standard reactions in Table 1-2 and Table 1-3.

ATTESTATION REPORT

Date: Sept 11, 2019

Page 3 of 6

No.: T01607-12

Table 1-1 Scoring Criteria for Acute Ocular Irritation Reaction in Rabbits	
<u>Manifestations of Ocular damage</u>	<u>score</u>
Corneal injury:	
No ulceration or opacity	0
Scattered or diffuse areas of opacity (details of iris clearly visible)	1
Easily discernible translucent areas of opacity (details of iris slightly obscured)	2
Areas of opacity, no details of iris visible, size of pupil barely discernible	3
Complete corneal opacity, iris not discernible	4
Iris injury:	
Normal	0
Markedly deepened folds, congestion, swelling, moderate circumcorneal injection, pupil is still light reactive	1
Bleeding, visible damage to the naked eye, or pupil is unresponsive to light	2
Conjunctival injection (palpebral conjunctiva, bulbar conjunctiva):	
Blood vessels are normal.	0
Blood vessels are congested, bright red	1
Diffuse congestion, purplish red	3
Conjunctiva (palpebral conjunctiva, bulbar conjunctiva) swelling:	
No swelling.	0
Slight swelling (including nictitating membrane)	1
Obvious swelling with partial eversion of lids	2
Swelling with lids about half closed	3
Swelling with lids about half closed to completely closed	4



Table 1-2 Eye irritation response classification criteria		
Reversible damage	No irritation	Average score of 3 animals: Corneal damage < 1, iris damage < 1, Conjunctival injection < 2, conjunctival swelling < 2; or average scores of at least 2 of 3 animals meet the above criteria. The irritation reaction of the other animal should be completely recovered within 21 days.
	Mild irritation	Average score of 2 of 3 animals: Corneal damage ≥ 1, iris damage ≥ 1, conjunctival injection ≥ 2 and conjunctival swelling ≥ 2, and the irritation reaction of all animals should be completely recovered within 7 days.

ATTESTATION REPORT

Date: Sept 11, 2019

Page 4 of 6

No.: T01607-12

	Irritation**	Average score of 2 of 3 animals: Corneal damage ≥ 1, iris damage ≥ 1, conjunctival injection ≥ 2 and conjunctival swelling ≥ 2; and the irritation reaction of all animals should be completely recovered within 21 days.
Irreversible damage	Corrosiveness**	At least irritation reaction of one animal's cornea, iris or conjunctiva did not fully recover in the observation period of 21 days or/and the average score of 2 animals out of 3 animals: Corneal damage ≥ 3; Iris damage ≥ 1.5.
Note: Complete recovery means the animal's eye irritation reaction score: Corneal injury = 0, iris injury = 0, Conjunctival injection = 0 or 1, conjunctival swelling = 0 or 1.		
**Irritation: Reversible inflammatory reaction after being exposed to the test substance.		
***Corrosiveness: Irreversible tissue damage after being exposed to the test substance.		



Table 1-3 Eye irritation response classification criteria			
<u>Average score</u>	<u>Number of animals</u>	<u>Recovery time (d)*</u>	<u>Damage type</u>
Corneal injury <1; Iris injury <1; Conjunctival injection <2; Conjunctival swelling <2	≥ 2	≤ 21	No irritation
Corneal injury ≥1; Iris injury ≥1; Conjunctival injection ≥2; Conjunctival swelling ≥2	≥ 2	≤ 7	Mildly irritating
		≤ 21	Moderate Irritating
Corneal injury ≥3; Iris injury ≥1.5	≥ 2		Corrosiveness**
Corneal injury ≥1; Iris injury ≥1; Conjunctival injection ≥2; Conjunctival swelling ≥2	≥ 1	>21	
* Recovery time: The time needed for animal irritation reaction score restoration to corneal injury =0, iris injury =0, conjunctival injection =0 or 1, conjunctival swelling=0 or 1.			
**Corrosiveness: If at least one animal still has corneal adhesion or pannus on day 21, the test substance can be judged as corrosive.			



ATTESTATION REPORT

Date: Sept 11, 2019

Page 5 of 6

No.: T01607-12

III. Test Results

Eye Irritation Reaction Scale											
Animals INFO RMA TION	Damage	1h		24h		48h		72h		Average score*	
		Sample	Control	Sample	Control	Sample	Control	Sample	Control	Sample	Control
2.1583 kg	Corneal injury	0	0	0	0	0	0	0	0	0	0
	Iris injury	0	0	0	0	0	0	0	0	0	0
	Conjunctival injection	1	0	1	0	0	0	0	0	0.33	0
	Conjunctival swelling	1	0	0	0	0	0	0	0	0	0
2.1728 kg	Corneal injury	0	0	0	0	0	0	0	0	0	0
	Iris injury	0	0	0	0	0	0	0	0	0	0
	Conjunctival injection	1	0	1	0	0	0	0	0	0.33	0
	Conjunctival swelling	1	0	0	0	0	0	0	0	0	0
2.1439 kg	Corneal injury	1	0	1	0	1	0	0	0	0.66	0
	Iris injury	0	0	0	0	0	0	0	0	0	0



ATTESTATION REPORT

Conjunctival injection	1	0	1	0	1	0	1	0	1	0	
Conjunctival swelling	1	0	1	0	1	0	0	0	0.66	0	

* The average score refers to the sum of the scores at 24h, 48h and 72h divided by 3, i.e., the number of observations.

All corneal scores of animals were 0.66, iris score was 0, conjunctival injection score was 1, conjunctival swelling score was 0.66. The scores of cornea, iris and conjunctiva for all animals dropped to 0 within 3 days.

Any other eye irritation reactions: None.

IV. Conclusions:

The test substance is non-irritating to the eyes of New Zealand rabbits.



ATTESTATION REPORT

Date: Sept 11, 2019

No.: T01607-12

Page 6 of 6

Product Photo



*****END OF REPORT*****