GLP TEST REPORT

Date:2022-06-21
No.: DY22040198

TEST FACILITY

STC (Dongguan) Company Limited
68 Fumin Nan Road,
Dalang, Dongguan, Guangdong,
China. (Zip code 523770)

SPONSOR

Chinchex Limited.
12F, WING FAT LOONG INDUSTRIAL BUILDING 136 WAI YIP ST, KWUN TONG HONG.

CONFIDENTIAL

STUDY TITLE

Eye Irritation Test of Chinchex bed bugs insecticide using International Organization for Standardization (ISO) 10993-23-2021 Biological evaluation of medical devices —Part 23 Tests for irritation

TEST ARTICLE NAME

Chinchex bed bugs insecticide

TEST ARTICLE IDENTIFICATION

CP-MD-4949
CSD No.: CL20220407196

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Summary

The test article, Chinchex bed bugs insecticide, was evaluated for eye irritation in rabbits. This study was conducted based on the requirements of International Organization for Standardization (ISO) 10993-23-2021 Biological evaluation of medical devices —Part 23 Tests for irritation. The test article was used directly for test.When gently compacted, instil that amount which occupies a volume of 100 µl and does not weigh more than 100 mg into the lower conjunctival sac of one eye of 3 rabbits in a group. Following instillation hold the eyelids together for approximately 1 s. The eyes of the animals were examined at 1 hour, 24 hours, 48 hours and 72 hours after dripping. If there was no appeared eye irritation at 72 h, the test could be terminated.

Under the conditions of this experiment, no appeared eye irritation was observed at 1, 24, 48 or 72 hours after contact, and the score of cornea, iris and conjunctiva was 0. The test article was judged as non-irritation.

Authorized Signatory Approval: _____

Emilly Chen

1. Introduction

1.1 Purpose

The purpose of this study was to evaluate the test article for the potential to cause eye irritation in the rabbit.

1.2 Testing Guidelines

This study was based on the requirements of the International Organization for Standardization (ISO) 10993-23-2021 Biological evaluation of medical devices —Part 23 Tests for irritation.

1.3 Dates

Test Article Received:	2022.04.18
Treatment Started:	2022.05.22
Observations Concluded:	2022.05.28

2. Identification of Test and Control Articles

The test article provided by the sponsor was identified and handled as described below:

Table 1: Test Article

Name:	Chinchex bed bugs insecticide
Size:	N/A
CAS:	N/A
Model:	N/A
Lot:	OOL12123
Initial State:	Not Sterilized
Strength, Purity and Composition:	SILICON DIOXIDE
Color:	WHITE
Physical Description of the Test Article:	DUST
Manufacture date:	2021.02
Expiration Date:	N/A

3. Test System

3.1 Test System

Species: Rabbit (Oryctolagus cuniculus)
Strain: New Zealand White
Source: Guangzhou huadu district huadongxinhua animal farm
Sex: Male
Age: Young adult
Acclimation Period: Minimum 5 days
Number of Animals: 3

3.2 Test System Management

According to International Organization for Standardization (ISO) 10993-23-2021 Biological evaluation of medical devices —Part 23 Tests for irritation.", New Zealand White rabbit is the first choice for experimental animals.

4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions conformed to STC Standard Operating Procedures. Animals were housed in groups in stainless steel or plastic suspended cages identified by a card indicating the animal numbers, test code, sex, animal code and date dosed.

The animal housing room is conventional system lab. The lab animal use permit No. SYXK(Guangdong province)2019-0159. The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 18-26℃ and the relative humidity was set to 40-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.

The light cycle was controlled (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

Food: Laboratory animal formula feed (rabbit), Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd., was provided daily.

Water: The water quality met the "Sanitary standard for drinking water" (GB5749-2006)

Food and water meet animal welfare requirements. No contaminants present in the feed and water impacted the results of this study.

4.3 Personnel

Associates involved in this study were appropriately qualified and trained.

4.4 Veterinary Care

Standard veterinary medical care was provided in this study.

4.5 IACUC

This procedure has been approved by the STC Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.

4.6 Selection

Two eyes of the animals were examined (including the use of fluorescein sodium) within 24 hours before the start of the trial. Animals with eye irritation, corneal defects and conjunctival injuries should not be used in experiments.

5. Method

5.1 Test and Control Article Preparation

The test article was used directly for test. Sodium chloride injection was used directly as negative control.

5.2 Test Procedure

Two eyes of the animals were examined (including the use of fluorescein sodium) within 24 hours before the start of the trial. Animals with eye irritation, corneal defects and conjunctival injuries should not be used in experiments. The lower eyelid of one side of the rabbit eye (right eye) was gently opened and 0.1 mL was dropped into the conjunctival capsule to passively close the upper and lower eyelids for 1 s to prevent the loss of the specimen. The other eye (left eye) was not treated as self-control.

5.3 Laboratory Observations

The eyes of the animals were examined at 1, 24, 48, 72 h after dripping. If there was no stimulus response at 72 h, the test could be terminated. Extended observation may be necessary if there are persistent lesions, in order to determine the progress of the lesions or their reversal; this need not exceed 21 d. Extended observation cannot be justified for animals with severe lesions.

6. Evaluation

Differences between the test and control eyes shall be characterized and explained in terms of the grading system given in Table 2.
If the treated eye in more than one animal shows a positive result (footnoted grades given in Table 2) at any of the observations, then the material is considered an eye irritant and further testing is not required.
If only one of three treated eyes shows a mild or moderate reaction or the reactions are equivocal, treat further animals.
When further animals have been treated, the test material is considered to be an eye irritant if more than half of the eyes treated in the test group exhibit a positive result (footnoted grades given in Table 2) at any stage of the observation.
A severe reaction in only one animal is considered sufficient to label the material as an eye irritant.

Table 2 System for grading ocular lesions

Reaction	Numerical grading
1.Cornea	
Degree of opacity (most dense area)	
No opacity	0
Scattered or diffuse areas, details of iris clearly visible	1 [a]
Easily discernible translucent areas, details of iris slightly obscured	2 [a]
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 [a]
Opaque, detail of iris not visible	4 [a]
Area of cornea involved	
One-quarter (or less), not zero	0
Greater than one-quarter, but less than half	1
Greater than half, but less than three-quarters	2
Greater than three-quarters, up to whole area	3
2. Iris	
Normal	0
Folds above normal, congestion swelling, circumcorneal injection (any or all or combination of these), iris still reacting to light (sluggish reaction is positive)	1 [a]
No reaction to light, haemorrhage, gross destruction (any or all of these)	2 [a]
3. Conjunctivae	
Redness (refers to palpebral and bulbar conjunctiva excluding cornea and iris)	
Vessels normal	0
Vessels definitely injected above normal	1
More diffuse, deeper crimson red, individual vessels not easily discernible	2 [a]
Diffuse beefy red	3 [a]

Chemosis	
No swelling	0
Any swelling above normal (include nictitating membrane)	1
Obvious swelling with partial eversion of lids	2 [a]
Swelling with lids about half-closed	3 [a]
Swelling with lids about half-closed to completely closed	4 [a]
Discharge	
No discharge	0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)	1
Discharge with moistening of the lids and hairs just adjacent to lids	2
Discharge with moistening of lids and hairs, and considerable area around the eye	3
[a] Positive result.	

7. Results

All the animals were clinically normal throughout the study. Individual results of eye irritation scoring are presented in Appendix 1.

8. Conclusion

Under the conditions of this experiment, no appeared eye irritation was observed at 1, 24, 48 or 72 hours after contact, and the score of cornea, iris and conjunctiva was 0. The test article was judged as non-irritation .

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs. All of the files was storage in DGSTC MD Archiving room.

10. ISO Compliance

All procedures were compliance to ISO 17025.

11. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (2018).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices -Part 2: Animal welfare requirements (2006).

International Organization for Standardization (ISO) 10993-23 Biological evaluation of medical devices —Part 23 Tests for irritation (2021).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices -Part 12: Sample preparation and reference materials (2021).

International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories (2017).

Appendix 1 – Dermal Observations

Animal number	Weight (g)	Group	Observation		Interval (hours)			
					1h	24h	48h	72h
2022041402	2623.7	Right eye	Cornea	Degree of opacity (most dense area)	0	0	0	0
				Area of cornea involved	0	0	0	0
			Iris		0	0	0	0
			Conjunctiva	Redness	0	0	0	0
				Chemosis	0	0	0	0
				Discharge	0	0	0	0
		Left eye	Cornea	Degree of opacity (most dense area)	0	0	0	0
				Area of cornea involved	0	0	0	0
			Iris		0	0	0	0
			Conjunctiva	Redness	0	0	0	0
				Chemosis	0	0	0	0
				Discharge	0	0	0	0
2022041424	2252.1	Right eye	Cornea	Degree of opacity (most dense area)	0	0	0	0
				Area of cornea involved	0	0	0	0
			Iris		0	0	0	0
			Conjunctiva	Redness	0	0	0	0
				Chemosis	0	0	0	0
				Discharge	0	0	0	0
		Left eye	Cornea	Degree of opacity (most dense area)	0	0	0	0

				Area of cornea involved	0	0	0	0
			Iris		0	0	0	0
			Conjunctiva	Redness	0	0	0	0
				Chemosis	0	0	0	0
				Discharge	0	0	0	0
2022051212	2280.7	Right eye	Cornea	Degree of opacity (most dense area)	0	0	0	0
				Area of cornea involved	0	0	0	0
			Iris		0	0	0	0
			Conjunctiva	Redness	0	0	0	0
				Chemosis	0	0	0	0
				Discharge	0	0	0	0
		Left eye	Cornea	Degree of opacity (most dense area)	0	0	0	0
				Area of cornea involved	0	0	0	0
			Iris		0	0	0	0
			Conjunctiva	Redness	0	0	0	0
				Chemosis	0	0	0	0
				Discharge	0	0	0	0

Appendix 2 – Photograph(s) of Test Articles

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

tatement of Quality Assurance Activities

Phase Inspected	Date Inspected	Study Director Notification Date	Management Notification Date
Study Plan Review	2022.04.24	2022.04.24	2022.04.24
Onsite Inspection:Animal acclimatization	2022.05.22	2022.05.22	2022.05.22
Onsite Inspection:Test substance application 1st day	2022.05.24	2022.05.24	2022.05.24
Onsite Inspection:Observation conclude	2022.05.28	2022.05.28	2022.05.28
Study Data Review	2022.06.21	2022.06.21	2022.06.21
Final Report Review	2022.06.21	2022.06.21	2022.06.21

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58) and OECD Series on Principles of Good Laboratory Practice (GLP).

Quality Assurance Unit Representative: Jason

Jason Huang

2022.06.21
Date

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1. All samples and goods are accepted by The STC (Dongguan) Company Limited (the "Company") solely for testing and reporting in accordance with the following terms and conditions. The Company provides its services on the basis that such terms and conditions constitute express agreement between the Company and any person, firm or company requesting its services (the "Clients").

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5. The results in Report apply only to the sample as received and do not apply to the bulk, unless the sampling has been carried out by the Company and is stated as such in the Report. The Clients provide the sample's relevant information, and the Company will not be liable for or accept responsibility for the truth of the sample information.

6. When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

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12. Issuance records of the Report are available on the internet at www.stc.group. Further enquiry of validity or verification of the Reports should be addressed to the Company.