Toxicology and Bio Evaluation Service Center (TBES)
National Science and Technology Development Agency (NSTDA)
111 Thailand Science Park (TSP), Phahonyothin Road, Khlong Nueng, Khlong Luang, Pathum Thani 12120, Thailand
Tel : +66 2564-7000 ext. 71701-4 E-mail: sales.tbes@nstda.or.th

Test Report

Report No.:	20-012-EYI
Customer:	Actiwa Swiss (Thailand) Co., Ltd.
Address:	12 On nut 17 Alley, Lane 15, Suan Luang, Suan Luang Bangkok 10250
Date of Receipt:	8 July 2020
Date of Analysis:	18 August 2020 – 27 August 2020
Test Method:	*In vitro* eye irritation test (OECD 492)
Number of test item(s):	1

Performed and reported by:
(sign/date)

Paninee C. 2020.09.01

Paninee Chetprayoon, Ph.D.
Researcher

Reviewed by:
(sign/date)

Rawiwan Maniratanachote 2020.09.01

Rawiwan Maniratachote, Ph.D.
Principal Researcher

Approved by:
(sign/date)

L. Krasachol 2020-09-01

Ladawan Krasachol, Ph.D.
Executive Vice President for President
National Science and Technology Development Agency

Remarks :

1. The validity of the test results is strictly limited to the specific samples and the corresponding testing conditions and devices used: no further extrapolation or interpolation of the result is to be inferred.
2.
3. Making reference of Toxicology and Bio Evaluation Service Center or the unit of the public made only in accordance with instruction given by the director of Toxicology and Bio Evaluation Service Center.
4. Toxicology and Bio Evaluation Service Center will not be responsible for any damage directly any reference to our written report or results such as usage of the experimental results for designing products and/or any other purposes.
5. Having any questions about this report, please contact us within 7 working days after the report was received.

Details of Test sample

No.	Sample Name	Sample Code	Attribute
1	SteriPlant	SteriP	Clear Solution

1. Test method principle

In vitro eye irritation test

In vitro eye irritation test is the reconstructed human Corneal epithelium; RhCE with physical and biological characteristics which is similar to the human corneal epithelium, The test has the validity that has been accepted accepted by the European Center for the Validation of Alternative Methods (ECVAM). The test was performed based on the OECD Test Guideline (TG) No. 492 by evaluating the Test substance from the percentage of tissue viability. The test can identify the substance was not to be classified as an irritant to eyes or No UN GHS category. However, the test method cannot be used to determine the severity level (Category 1 or 2) of a substance that produced a positive test result. Therefore, it needs to be interpreted the result in conjunction with the other tests to determine the UN GHS category of the substance.

2. Objective

2.1 To test for eye irritation in according to the OECD TG 492 method of SteriPlant sample.

3. Details of test substance

Test chemical	Chemical identification	Physical appearance	Purity/concentration	Treatment prior to testing	Storage condition
PBS (Negative control)	Dulbecco's phosphate-buffered saline	Clear liquid	N/A	None	RT
Ethanol (Positive control)	C_2H_5OH (CAS no. 64-17-5)	Clear liquid	≥ 99.8%	None	RT
SteriP	N/A	Clear liquid	N/A	None	RT

RT. Room temperature

4. Test procedure

Sample Preparation

- No

Test method

- RhCE to be exposed in test substance with volume of 50 µL for 60 second
- Sample in Negative Control (NC) to be tested with PBS volume of 50 µL for 60 second
- Sample in Positive Control (PC) to be tested with ethanol volume of 50 µL
- Sample was washed and incubated RhCE in a cell culture cabinet for 24 hrs.
- RhCE viability was measured by WST-8 assay

- Repeated the test for 3 times (tissues)

The criteria for result interpretation

The evaluation of the eye irritation test by using RhCE was based on the United Nations Globally Harmonized System (UN GHS) of the chemical substance used in the eye Irritation Test. The test was made in vivo and the mean tissue viability was greater than 40% since compared with the control group showed negative results (NC) which were classified as No category or non-irritating. In case the mean of tissue viability was less than or equal to 40%, it was classified as a positive group or irritant, but were not classified the severity level (Category 1 or 2) as shown in the following table

In vitro result	Prediction
Mean tissue viability > 40 %	No category (non-irritant)
Mean tissue viability ≤ 40 %	Category 1 or 2 (irritant)

5. Test result

Table 1. Percentage of RhCE viability in the eye Irritation Test from SteriPlant as sample group has shown the mean from 3 times test as follow

Sample	Tissue viability (%)			Mean	SD	Result interpretation
	Tissue 1	Tissue 2	Tissue 3			
NC	99.57	104.40	96.03	100.00	4.20	N/A
PC	4.20	6.47	3.94	4.87	1.39	Irritant
SteriP	102.52	106.99	109.30	106.27	3.45	Non-irritant

6. Conclusion

From the eye irritation test in SteriPlant in according to OECD TG method and RhCE Tissue Interpretation Criteria showed the SteriPlant samples were classified as No category or were not likely to cause eye irritation (non-irritant).

7. Reference

(1) OECD (2019), OECD Guideline for the Testing of Chemicals No. 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labeling for eye irritation or serious eye damage.