

**OnePCR**  
[Lot No.: MB10370015]

**OECD 203**

**FINAL REPORT**

**Client:** TAQKEY Science  
**Testing Institution:** SGS Taiwan Ltd.  
**Report No. :** UB/2013/80653A-02  
**Report Date:** 2013/09/26

- Note:**
1. The content of this report is invalid if it is not presented as the entire report.
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  3. The results shown in this test report refer only to the article(s) tested.

**STUDY SCHEDULE**  
***OECD 203***  
**OnePCR**

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Report No.: UB/2013/80653A-02

Test article registration date: 2013/08/16

Experimental starting date: 2013/08/19

Experimental completion date : 2013/08/24

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## Testing Institution

**Name:** SGS TAIWAN LTD.

**Address:** No. 38, Wu Chyuan 7<sup>th</sup> Rd., New Taipei Industrial Park, Wu Ku Dist., New Taipei

City 24890, Taiwan (R. O. C.)

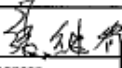
## Client / Sponsor

**Name:** TAOKEY Science

**Address:** 1F., No. 60, Jiabei 2<sup>nd</sup> St., Zhunan Township, Miaoli County 350

## TEST ARTICLE INFORMATION

### INFORMATION FOR TEST ARTICLE / CONTROL ARTICLE

Sponsor Company Name	TAQKEY Science	
Sponsor Address	1F., No.60, Jiabei 2nd St., Zhunan Township, Miaoli County 350	
Contract study item	<input checked="" type="checkbox"/> Base on the contract <input type="checkbox"/> Others	
Name of Test article/ Control article	OnePCR	
Batch/Lot number	<input checked="" type="checkbox"/> Base on the specific number on the package : <u>MB10370015</u> <input type="checkbox"/> Base on the date on the package : _____ <input type="checkbox"/> Base on the arrived date <input type="checkbox"/> Others : _____	
Specification & Amount	1125ul / vial* 6 vials (e.g.10ml / bottle * 6 bottles)	
Retention amount (Note 2)	The amount of the same lot is sufficient for <input type="checkbox"/> One test <input checked="" type="checkbox"/> Two test (for retention)	
External features	External features: <input checked="" type="checkbox"/> liquid <input type="checkbox"/> powder <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> Other	Color : <u>blue</u>
Major components & Purity	Major components: <u>water</u>	Purity: <u>up to 90%</u>
Solvent and solubility	N/A	
Storage condition	<input type="checkbox"/> Room temperature <input checked="" type="checkbox"/> 4°C <input type="checkbox"/> Dry <input checked="" type="checkbox"/> Light sensitive <input type="checkbox"/> Others	
Expiration date(Note 3)	<input checked="" type="checkbox"/> Date: <u>2014 / 03 / 20</u> (YYYY/MM/DD) or <input type="checkbox"/> Period : _____ year _____ month _____ day	
Attachment(Note 4)	<input type="checkbox"/> Certificate of Analysis <input type="checkbox"/> Material Safety Data Sheet <input type="checkbox"/> Stability Test Result <input type="checkbox"/> Other : _____ <input checked="" type="checkbox"/> No attachment (Note4)	
Sterilization	Has been sterilized <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO (If Yes, please select the following item) Methods <input type="checkbox"/> EO sterilization <input type="checkbox"/> Gamma sterilization <input type="checkbox"/> Steam sterilization <input type="checkbox"/> Other	
Categorization of devices (The column is only for device used)	1. <input type="checkbox"/> Contact with intact skin or mucosa (cumulative contact duration) <input type="checkbox"/> Short-term (no greater than 4 hr) <input type="checkbox"/> Long-term (exceeding 4 hr) Maximum duration is _____ hrs 2. <input type="checkbox"/> Implanted device	
Specific requirement (Note 5)	N/A	
Sponsor Signature/ Date :	 2013.08.14	
<small>Note 1. Above all information is disclosure by the sponsor.            Note 2. If the sponsor doesn't provide the retention of test article/control article, the retention of a reserved test article/control article from each batch of test article /control article is the responsibility of the Sponsor.            Note 3. If the effective period is less than 5 years, the test article/control article will be retained till the expiry date. If the effective period is longer than 5 years, the test article/control article will be retained for 5 years only.            Note 4. Determination and documentation of identity, strength, purity, stability, composition, method of synthesis, fabrication, derivation or other characteristics of the test article/control article are the responsibility of the Sponsor.            Note 5. The test article/control article which has been destroyed or cutting will be discarded after the end of experiment. For retention or return of the kind of test article/control article, please indicate in the "special requirement". The human intake suggests or dose requested by the sponsor also can fill in the "special requirement". Note treatment method after test if the test article need to be retreated            Note 6. The code number of test article is the same as the report number.            Note 7. Note 'N/A' if not applicable. Do not leave blank.</small>		

版次：3.1 試驗-對照物質資料表 Information for test article-control article  
 發行日期：2013.06.14

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SIGNATURE OF STUDY PERSONNEL  
OnePCR  
Fish, Acute Toxicity Test

Study Director:

*Peggy Peng*

\_\_\_\_\_  
Peggy Peng / SGS Taiwan Ltd.

\_\_\_\_\_  
Date Completed

Deputy of

Facility Manager:

*Amy Li*

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Amy Liu / SGS Taiwan Ltd.

*2013.10.11*

\_\_\_\_\_  
Date Completed



## ARCHIVING

All the study-related the final report will be kept in the archives room of SGS (TAIWAN) LTD for 3 years. Agent authorized by the sponsor can apply for the review according to SGS procedures.

Archives Room Address:

No. 38, Wu Chyuan 7<sup>th</sup> Rd., New Taipei Industrial Park, Wu Ku Dist., New Taipei City 24890, Taiwan

(R. O. C.)

## ABSTRACT

The study was to evaluate the test article, “OnePCR”, for its acute aquatic toxicity. The fish were exposed to the test substance preferably for a period of 96 hours. Mortalities were recorded at 24, 48, 72 and 96 hours and the concentrations which would kill 50 per cent of the fish (LC50), were determined where possible.

In the study, the mortality in the controls was 0 per cent at the end of the test. Furthermore, there was no any mortality in the group of fish that were exposed to the 1 ml/L of test substance. The result of the study showed that LC50 of acute aquatic toxicity was >1 ml/L of “OnePCR”.

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## PURPOSE

This study was to assess acute toxicity of the test substance. Mortalities of *Cyprinus carpio* were recorded at 24, 48, 72 and 96 hours and the concentrations which would kill 50 per cent of the fish (LC50) were determined where possible. The experiment was performed following OECD 203.

## EXPERIMENTAL DESIGN

### A. *Cyprinus carpio* :

Total length of test fish were 2-4 cm. They can be bred and cultivated either in fish farms or in the laboratory, under disease- and parasite-controlled conditions, so that the test fish will be healthy and of known parentage.

### B. Reconstituted water (for test solution) :

Per liter of the reconstituted water, it contains: 96.0 mg NaHCO<sub>3</sub>, 123.0 mg MgSO<sub>4</sub> • 7H<sub>2</sub>O, 4.0 mg KCl, 60.0 mgCaSO<sub>4</sub> • 2H<sub>2</sub>O.

The reconstituted water has been strongly exposed to air until 48 hours before the test day.

### C. Holding of fish :

All fish must be obtained and held in the laboratory for at least 12 days before they are used for testing.

They must be held in water of the quality to be used in the test for at least seven days immediately before testing and under the following conditions:

Light: 12-16 hours photoperiod daily;

Temperature: 22 ± 2°C;

Oxygen concentration: at least 80 per cent of air saturation value;

Feeding: daily until 24 hours before the test is started.

Following a 48-hour settling-in period, mortalities are recorded and the following criteria are applied:

Mortalities of greater than 10 per cent of population in seven days: rejection of entire batch;

Mortalities of between 5 and 10 per cent of population: acclimatization continued for seven additional days;

Mortalities of less than 5 per cent of population: acceptance of batch.

### D. Water :

Good quality natural water or reconstituted water is preferred. Waters with total hardness of between 10 and 250 mg CaCO<sub>3</sub> per liter, and with a pH 6.0 to 8.5 are preferable. The reagents used for the

preparation of reconstituted water should be of analytical grade and the deionised or distilled water should be of conductivity equal to or less than  $10 \mu\text{Scm}^{-1}$ .

#### **E. Test solutions :**

Test solutions of chosen concentrations are prepared by dilution of a stock solution. The test should be carried out without adjustment of pH. If there is evidence of marked change in the pH of the tank water after addition of the test substance, it is advisable that the test be repeated, adjusting the pH of the stock solution to that of the tank water before addition of the test substance. This pH adjustment should be made in such a way that the stock solution concentration is not changed to any significant extent and that no chemical reaction or precipitation of the test substance is caused. HCl and NaOH are preferred.

#### **F. Procedure :**

1. Conditions of exposure.

Duration: 96 hours

Loading: maximum loading of 1.0 g fish/liter

Light: 16 hours photoperiod daily

Temperature:  $22 \pm 2^\circ\text{C}$

Oxygen concentration: not less than 60 per cent of the air saturation value

Feeding: none

Disturbance: disturbances that may change the behavior of the fish should be avoided

2. Number of fish

20 fish were used at each test concentration and in the controls. Each container carried 10 fish and 1.5L test solution.

3. Test concentrations

5 concentrations were performed and all concentration groups were duplicated. A range-finding test conducted before the definitive test enables the choice of the appropriate concentration range.

#### 4. Controls

One blank (20 fish): Each container carried 10 fish and 1.5L reconstituted water

#### 5. Observations

The fish were inspected at least after 24, 48, 72 and 96 hours. Fish were considered dead if there was no visible movement (e.g. gill movements) and if touching of the caudal peduncle produces no reaction.

Dead fish are removed when observed and mortalities are recorded. Observations at three and six hours after the start of the test are desirable. Records were made on visible abnormalities (e.g. loss of equilibrium, swimming behavior, respiratory function, pigmentation, etc.). Measurement of pH, dissolved oxygen and temperature should be carried out at least daily.

## DATA MANAGEMENT

For statistical analysis, data were analyzed using one of the software: Graphic method, Probit method, Sperman-karber methol, and Trimmed spearman-karber method. The result showed “LC50 > the highest concentration”, if the mortalities of 5 sample concentrations were less than 50%.

## RESULTS

### A. Water quality characteristics (pH, oxygen concentration, and temperature)

Table 1.1. pH of test solutions

Concentration (mL/L)		Test solution					
		0 (Control)	0.0625	0.125	0.250	0.500	1.00
pH	0 hr	8.58	8.53	8.48	8.37	8.26	8.20
	24 hr	8.56	8.53	8.48	8.35	8.10	8.09
	48 hr	8.57	8.50	8.47	8.21	8.01	7.82
	72 hr	8.53	8.42	8.40	8.17	7.88	7.53
	96 hr	8.51	8.40	8.30	8.11	7.67	7.22

Table 1.2. Oxygen concentration of test solutions

Concentration (mL/L)		Test solution					
		0 (Control)	0.0625	0.125	0.250	0.500	1.00
Oxygen concentration (mg/L)	0 hr	6.94	6.55	6.37	6.18	6.40	6.37
	24 hr	6.77	6.40	6.18	6.30	6.25	5.17
	48 hr	6.53	5.93	6.00	5.42	5.08	4.20
	72 hr	6.56	4.32	5.14	3.14	4.11	3.11
	96 hr	6.18	4.08	3.11	1.03	2.18	0.61

Table 1.3. Temperature of test solutions

Concentration (mL/L)		Test solution					
		0 (Control)	0.0625	0.125	0.250	0.500	1.00
Temperatrue (°C)	0 hr	22.4	22.3	22.5	22.4	22.9	22.3
	24 hr	23.5	22.9	23.1	23.0	22.8	22.7
	48 hr	22.1	22.5	22.2	22.1	22.3	22.4
	72 hr	23.0	23.1	22.9	23.2	23.1	22.8
	96 hr	22.1	22.5	22.2	22.5	22.4	22.1

## B. A range-finding test and definitive test

Table 2.1. Range-finding test

Concentration(mL/L)	Mortality	Number of fish	Ratio of mortality (%)
0(Control)	0	5	0
0.01	0	5	0
0.1	0	5	0

Table 2.2. Definitive test

Concentration (mL/L)	Mortality						Mortality (total)	Ratio (%)
	2 hr	6 hr	24 hr	48 hr	72 hr	96 hr		
0(Control)	0	0	0	0	0	0	0	0
	0	0	0	0	0	0		
0.0625	0	0	0	0	0	0	0	0
	0	0	0	0	0	0		
0.125	0	0	0	0	0	0	0	0
	0	0	0	0	0	0		
0.25	0	0	0	0	0	0	0	0
	0	0	0	0	0	0		
0.5	0	0	0	0	0	0	0	0
	0	0	0	0	0	0		
1.0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0		

## C. Analysis of LC50

All of the 5 concentration caused no mortality within the period of the test (LC50 > 1.0 mL/L) .

## CONCLUSION

According to the Table 2.2, all of the 5 concentrations caused no mortality within the period of the test.

The result showed that the LC50 of “OnePCR” was  $> 1.0$  mL/L.



## **DEVIATIONS AND INVESTIGATIONS**

There were no deviation and investigation during the test period of this study.

## **PROTOCOL AMENDMENTS**

There was no protocol amendment during the test period of this study.

## REFERENCES

1. OECD. 1992. Guideline for Testing of Chemicals, Test No. 203: Fish, Acute Toxicity Test.
2. U.S. Environmental Protection Agency. Methods for measuring the acute toxicity of effluents to freshwater and marine organisms. 3rd ed. EPA / 600 / 4 – 85 / 013. U.S. EPA Publication, Cincinnati, OH. 1985.

TEST ARTICLE PHOTO

## UB/2013/80653



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