# TEST REPORT: 7191091230-CHM14-01-LY

Date: 25 JUL 2014 Tel: +65 68851323 Fax: +65 67784301

Client's Ref: - Email: Yang.LI@tuv-sud-psb.sg





## 1. GENERAL

### 1.1 STUDY TITLE

Primary skin irritation study of ART-$H_2O$ Solution (Stock 1300ppm) in rabbits

### 1.2 TEST ITEM IDENTIFICATION (AS DECLARED BY SPONSOR)

| | | |
|---|---|---|
| Test Item Name | : | ART-$H_2O$ Solution (Stock 1300ppm) |
| Lot No | : | 2014A-L001-180614-001 |
| Sterilization Condition | : | NA |
| Quantity | : | 2 Litre |
| Date Of Manufacture | : | 18 April 2014 |

#### 1.2.1 Material Composition and purity

| | | |
|---|---|---|
| Composition | : | NA |
| Purity | : | NA |
| Homogeneity | : | NA |
| Density | : | NA |
| pH | : | NA |

#### 1.2.2 Physical Features / Properties

| | | |
|---|---|---|
| State | : | Liquid, transparent. |

### 1.3 SAMPLE RECEIVED DATE

03 Jul 2014

### 1.4 REFERENCE ITEM IDENTIFICATION

Water for injection was used as negative control item.

## 2. CLIENT

AquaRes Technology Pte. Ltd.
9 Chin Bee Avenue
Singapore 619933

## 3. TESTING FACILITY, TESTING SITES AND STAFF

### 3.1 TESTING FACILITY

Chemical and Materials
Testing Services
TÜV SÜD PSB Pte Ltd
No 1 Science Park Drive
Singapore 118221

### 3.2 STAFF

| | |
|---|---|
| Study Director | Ms Li Yang |
| Study Personnel | Mr Lin Xi |
| The above staffs are located at | Chemical and Materials<br>Testing Services<br>TÜV SÜD PSB Pte Ltd<br>No 1 Science Park Drive<br>Singapore 118221 |

## 4. STUDY SCHEDULE AND GUIDELINES

### 4.1 STUDY SCHEDULE

| | |
|---|---|
| Experimental commencement date | 16 Jul 2014 |
| Experimental completion date | 25 Jul 2014 |

### 4.2 STUDY GUIDELINES

4.2.1 OECD Guideline for Testing of Chemicals 404: Acute Dermal Irritation/Corrosion. Adopted on 24th April 2002.

## 5. MATERIAL AND METHODS

### 5.1 PRE-TREATMENT OF SAMPLE

As required by client, the sample was diluted from 1300 ppm to 35 ppm by adding 1 ml of original sample into 36.143 ml of ultra pure water before dosing.

## 5.2 TEST ANIMALS

| | |
|---|---|
| Species | Rabbit |
| Strain | New Zealand White |
| Microbiological status | Conventional healthy |
| Age | Young adult |
| Sex | Male |
| Number | 3 |
| Source | InVivos Pte Ltd<br>9 Perahu Road,<br>Lim Chu Kang,<br>Singapore 718793 |
| Animal Holding Facility | Animal Holding Unit<br>TÜV SÜD PSB Pte Ltd<br>No 1 Science Park Drive<br>Singapore 118221 |
| Housing Condition | Conventional rabbit cage system |
| Temperature | 17 - 23°C |
| Humidity | 30 - 70% |
| Food | Altromin Maintenance Diet #2123 Fortified |
| Water | Tap water |
| Animal ID | 7191091230-01-1<br>7191091230-01-2<br>7191091230-01-3 |

## 5.3 TEST CONDITIONS

### 5.3.1. Preparation of test animals

5.3.1.1 The test animals were acclimatised for at least 5 days before the test was conducted.

5.3.1.2 Fur on the back of each test animal, on both sides of the spine, approximately 10 x 15 cm was clipped within 24 hours before application.

### 5.3.2 Application of test and control substances

5.3.2.1 The diluted sample was used as test substance. Water for injection was used as negative control substance. Test substance and negative control substance were applied to the test system by direct contact.

5.3.2.2 2.5 cm x 2.5 cm gauze patch was saturated by 0.5 ml of test substance or negative control substance, and used for topical application.

5.3.2.3 One patch of test substance and one patch of negative control substance were applied on the clipped area on the back of each animal. The application sites were covered by occlusive bandage for 4 hrs.

5.3.2.4 After exposure, the application patches and bandage were removed and the residual of the test item was removed by washing with water and careful drying.

5.3.3 Observation

The appearance of each application site was observed at 1 hr, 24 hrs, 48 hrs and 72 hrs following the removal of the patches. The erythema / eschar and oedema formation were rated in all the application sites on the animals based on the following:

| Reaction | Primary irritation score |
|---|---|
| **Erythema and eschar formation**<br>No erythema<br>Very slight erythema (barely perceptible)<br>Well-defined erythema<br>Moderate erythema<br>Severe erythema (beet-redness) to eschar formation preventing grading of erythema | <br>0<br>1<br>2<br>3<br>4 |
| **Oedema formation**<br>No oedema<br>Very slight oedema (barely perceptible)<br>Well- defined oedema (edges of area well- defined by definite raising)<br>Moderate oedema (raising approximately 1 mm)<br>Severe oedema (raised more than 1 mm and extending beyond exposure area) | <br>0<br>1<br>2<br>3<br>4 |
| **Total possible score for irritation** | 8 |
| Other adverse changes (if any) at the skin sites was recorded and reported | |

The PII was calculated and characterized by number (score) and description (response category) given in table below:

| **Mean score** | **Response category** |
|---|---|
| 0 to 0.4 | Negligible |
| 0.5 to 1.9 | Slight |
| 2 to 4.9 | Moderate |
| 5 to 8 | Severe |

5.3.4. Feed and water frequency

Feed and water were given *ad libitum* during and after exposure.
Feed was given in the chamber of the cage.
Water was given through plastic bottle.

## 6. TEST RESULTS

### 6.1 ERYTHEMA / ESCHAR (E) AND OEDEMA (O) FORMATION OF EACH ANIMAL AT EACH OBSERVATION TIMEPOINT

| Animal ID | Application site | 1 hr after exposure E/O | 24 hrs after exposure E/O | 48 hrs after exposure E/O | 72 hrs after exposure E/O | Sum of all scores at 24, 48 and 72 hrs E+O |
|---|---|---|---|---|---|---|
| 7191091230-01-1 | Test site | 0/0 | 0/0 | 0/0 | 0/0 | 0 |
| | Negative Control site | 0/0 | 0/0 | 0/0 | 0/0 | 0 |
| 7191091230-01-2 | Test site | 0/0 | 0/0 | 0/0 | 0/0 | 0 |
| | Negative Control site | 0/0 | 0/0 | 0/0 | 0/0 | 0 |
| 7191091230-01-3 | Test site | 0/0 | 0/0 | 0/0 | 0/0 | 0 |
| | Negative Control site | 0/0 | 0/0 | 0/0 | 0/0 | 0 |

### 6.2 PRIMARY IRRITATION SCORE (PIS) AND PRIMARY IRRITATION INDEX (PII)

| Animal ID | $PIS_{test}$ (Sum of all scores of the test site / 3) | $PIS_{negative\ control}$ (Sum of all scores of the negative control site / 3) | **PIS** (PIStest - PISnegative control) | **PII** (Sum of PISs of individual animals / 3) |
|---|---|---|---|---|
| 7191091230-01-1 | 0 | 0 | 0 | **0** |
| 7191091230-01-2 | 0 | 0 | 0 | |
| 7191091230-01-3 | 0 | 0 | 0 | |

### 6.3 OBSERVATION OF OTHER ADVERSE EFFECTS

No other adverse effect was observed in all the test animals during the observation period.

## 7. DISCUSSION

Based on the below results, using direct contact of the diluted sample (35 ppm) of ART-$H_2O$ Solution (Stock 1300ppm), Lot No: 2014A-L001-180614-001, no skin irritation was observed during the 72-hr observation period. The primary irritation index (PII) is 0.

## 8. CONCLUSION

Under the condition of this study, using direct contact of the diluted sample (35 ppm) of ART-$H_2O$ Solution (Stock 1300ppm), Lot No: 2014A-L001-180614-001, no skin irritation was observed during the 72-hr observation period. The skin irritation response category of the sample in rabbit is negligible.

REMARKS:

1. The above test results relate to the sample of test item as received.

**MR LIN XI**
BIOLOGIST
CHEMICAL AND MATERIALS
TESTING SERVICES

**MS LI YANG**
ASSISTANT VICE PRESIDENT
CHEMICAL AND MATERIALS
TESTING SERVICES

PSB Singapore

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July 2011