TEST REPORT : 7191086530-02-CHM14-LY

Date: 22 MAY 2014 Tel: +65 68851323 Fax: +65 67784301

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1. GENERAL

1.1 STUDY TITLE

Acute Oral Toxicity Study of Spick (Ready to Use) in Rats

1.2 TEST ITEM IDENTIFICATION (AS DECLARED BY SPONSOR)

Test item name	:	Spick (Ready to Use)
Lot No.	:	510421
Sterilization condition	:	Not provided
Quantity	:	200 ml
Date of manufacture	:	15 April 2014
Expiry date	:	14 October 2015

1.2.1 Composition / purity

Composition	:	320 mg/L of active chlorine
Homogeneity	:	Not provided
Purity	:	Not provided

1.2.2 Physical features / properties

Colour / state	:	Liquid disinfectant
Density	:	Not provided
pH	:	Not provided
Solubility	:	Soluble

1.3 REFERENCE ITEM IDENTIFICATION

No reference item was used in this study.

2. CLIENT

Vetpharm Laboratories (s) Pte Ltd
Blk 27 Tuas Avenue 13,
#01-25,
Singapore 638993

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	Dr Hu Jin Mr Lin Xi Dr Li Baihong
The above staffs are located at	Chemical and Materials Testing Services TÜV SÜD PSB Pte Ltd No 1 Science Park Drive Singapore 118221

4. STUDY SCHEDULE AND GUIDELINES

4.1 STUDY SCHEDULE

Experimental commencement date	02 May 2014
Experimental completion date	22 May 2014

4.2 STUDY GUIDELINES

4.2.1 OECD Guideline For Testing of Chemicals 423: Acute Oral Toxicity- Acute Toxic Class Method, adopted on 17th December 2001

4.2.2 Globally Harmonized System of Classification and Labelling of Chemicals (GHS), fourth revised edition, United Nations, New York and Geneva, 2011, Part 3 Health Hazards, Chapter 3.1: Acute Toxicity.

5. MATERIAL AND METHODS

5.1 PRE-TREATMENT OF TEST ITEM

The test item was used for dosing without pre-treatment.

5.2 PREPARATION OF TEST SUBSTANCE

The density of test item was measured as 1.003 g/ml. The test item was used as test substance. A single dose was administered orally to each animal using gavage feeding needle.

5.3 TEST ANIMALS

Species	Rats
Strain	SD
Microbiological status	Murine Pathogen Free (MPF)
Age	8 weeks old
Sex	Female
Number	6
Source	InVivos Pte Ltd 9 Perahu Road, Lim Chu Kang, Singapore 718793
Animal Holding Facility	Animal Holding Unit TÜV SÜD PSB Pte Ltd No 1 Science Park Drive Singapore 118221
Housing Condition	OptiMICE Caging System
Temperature	19 - 25ºC
Humidity	30 - 70%
Food	Altromin Maintenance Diet #1324
Water	Tap water

5.4 TEST CONDITIONS

5.4.1. Preparation of test animals

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

5.4.1.2 The test animals were fasted overnight before dosing. Feed, but not water was withheld. The animals were weighed prior to dosing. The test substance was then administered by gavage feeding needle at a starting dose level of 2000 mg/kg body weight based on the body weight of each test animal.

5.4.2 Rationale of selection of starting dose

According to OECD Guideline for the testing of Chemicals 423, the limit dose of 2000 mg/kg is used for the test item which the toxicity or mortality is not expected. Thus, starting dose of 2000 mg/kg was selected according to the requirement of sponsor and the information provided by the sponsor.

5.4.3 Details of administration

Administration route	Oral route by gavage
Dose level	2000 mg/kg body weight
Dose Interval	Single dose

The details of dose for each animal are as follows:

Group	Animal ID	Dosing date	Body weight (g)	Dose (mg)
Group 1	7191086530-02-G1-1	07 May 2014	190	380
	7191086530-02-G1-2		192	384
	7191086530-02-G1-3		208	416

Group	Animal ID	Dosing date	Body weight (g)	Dose (mg)
Group 2	7191086530-02-G2-1	08 May 2014	186	370
	7191086530-02-G2-2		208	420
	7191086530-02-G2-3		204	410

5.4.4 Feed and water frequency

Animals were fasted overnight before dosing. Feed, but not water was withheld.

Feed was given 3 hours after dosing and throughout the observation period. Feed was given in the chamber in the cage.

Water was given *ad libitum* during dosing and observation period. Water was given through plastic bottle.

5.4.5 Observation, body weight measurement and necropsy

The observation was conducted on each animal during the first 30 minutes, 1, 2 and 4 hours, and daily thereafter to 14 days.

The body weight of each animal was measured once a week.

On the termination day, all the test animals were euthanized by CO_2 inhalation. Gross necropsy was conducted on each test animal.

6. TEST RESULTS

6.1 OBSERVATION OF EACH TEST ANIMAL

Group	Animal ID	Observation during 14-day period
Group 1	7191086530-02-G1-1	No adverse effects observed
	7191086530-02-G1-2	No adverse effects observed
	7191086530-02-G1-3	No adverse effects observed

Group	Animal ID	Observation during 14-day period
Group 2	7191086530-02-G2-1	No adverse effects observed
	7191086530-02-G2-2	No adverse effects observed
	7191086530-02-G2-3	No adverse effects observed

6.2 BODY WEIGHT (BW, IN GRAM) AND BODY WEIGHT CHANGES (CHANGE, IN GRAM) OF EACH ANIMAL

Group	Animal ID	BW before dosing (07 May 14)	BW on Day 7 (14 May 14)	BW on Day 14 (21 May 14)
Group 1	7191086530-02-G1-1	190	230 Change: +40	230 Change: 0
	7191086530-02-G1-2	192	222 Change: +30	220 Change: -2
	7191086530-02-G1-3	208	228 Change: +20	228 Change: 0

Group	Animal ID	BW before dosing (08 May 14)	BW on Day 7 (15 May 14)	BW on Day 14 (22 May 14)
Group 2	7191086530-02-G2-1	186	232 Change: +46	226 Change: -6
	7191086530-02-G2-2	208	234 Change: +26	242 Change: +8
	7191086530-02-G2-3	204	228 Change: +24	234 Change: +6

6.3 DEATH PRIOR TO ENDPOINT

No animals died before the endpoint, i.e. 14 days after dosing.

6.4 ONSET OF TOXICITY AND REVERSAL

No toxicity effect was observed in all animals.

6.5 NECROPSY FINDINGS

No finding was observed.

7. DISCUSSION

Based on the above study,

a) No animal died during the study.

b) No adverse effects observed in all animals during the study.

c) No significant body weight loss was observed during the study.

d) No abnormality was observed in all animals during necropsy.

8. CONCLUSION

Based on the above results and Global Harmonised Classification System (GHS) for acute toxicity hazard categories, the acute oral toxicity of the test item - Spick (Ready to Use), Lot Number: 510421, is considered as Category 5 or unclassified; based on OECD Guideline 423, the LD_{50} cut-off value of the test item - Spick (Ready to Use), Lot Number: 510421, is 5000 mg/kg body weight or unclassified.

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
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PSB Singapore

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July 2011