IIRT
Institute for Industrial Research & Toxicology
औद्योगिक अनुसंधान एवं विष विज्ञान संस्थान
Registration No. 1303/C/CPCSEA (Ministry of Environment & Forests, Government of India)
License No.: 01/2015 (Food and Drug Administration, UP)
AN ISO 9001 : 2015, ISO 14001 : 2015, ISO 45001 : 2018 Certified Organization
GLP Certified, NABL (ISO/IEC 17025) Accredited

# ACUTE ORAL TOXICITY OF PSAP "POTASSIUM SALT OF ACTIVE PHOSPHORUS" IN WISTAR ALBINO RATS

(Guideline: OECD-423 Acute Oral Toxicity)

**SPONSORED BY**

**ISHA AGRO INDIA**

**OFFICE NO 05, B-101, MALATI COMPLEX,**

**4/129, IDEAL COLONY, PAUD ROAD,**

**KOTHRUD PUNE- 411038, INDIA**

**TESTING LABORATORY**

**INSTITUTE FOR INDUSTRIAL RESEARCH & TOXICOLOGY**

**F-209, UPSIDC, MG ROAD, GHAZIABAD-201302**

**Email: info@toxicityindia.org**

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**Tel No.: +91 9711623080**

**Fax: +91 11 22235111**

| | | |
|---|---|---|
| **Project No.** | : | 201817 |
| **Report No** | : | IIRT/TOX/121 |
| **Date** | : | 21/06/2018 |

## CONTENTS

# GLP COMPLIANCE STATEMENT

I, undersigned hereby declare that **Project No.-201817/ Report No. IIRT/TOX/121 entitled Acute Oral Toxicity of PSAP "Potassium Salt of Active Phosphorus" in Wistar Albino Rats** was performed in accordance with the standard with the standard operating procedures of *Toxicology Department, Institute for Industrial Research & Toxicology,* as well as the approved study plan.

I hereby attest the authenticity of the study and guarantee that this report represents a true and accurate record of results obtained and shall not be reproduced except in full, without the written approval of the Sponsor.

The study was conducted to meet the requirements of the **OECD Guideline No. 423 for testing of chemicals. "Acute Oral Toxicity", Section-4: Health Effects (Adopted: 17th Dec, 2001)** in compliance with the principles of Good Laboratory Practices (G.L.P.).

All original raw data including documentation, the draft report, a copy of the final report and the representative test item are archived in the archives at **Toxicology Department, Institute For Industrial Research & Toxicology.** There were no known circumstances that may have affected the quality or integrity of the study.

The sponsor is responsible for necessary evaluations of the test item concerning the chemicals purity, identity, stability and other required data.

The chemical analysis of the test item **PSAP "Potassium Salt of Active Phosphorus"** was carried out by the sponsor.

| **Dr. Pawan Kumar** | | 21/06/2018 |
|---|---|---|
| Study Director | Signature | Date |

| | |
|---|---|
| **TEST COMPOUND** | **: PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"** |
| **SPONSORED BY** | **: ISHA AGRO INDIA** |
| **STUDY** | **: ACUTE ORAL TOXICITY IN WISTAR ALBINO RAT** |
| **PROJECT** | **: 201817** |

## STATEMENT BY TEST FACILITY MANAGEMENT

Management of the test facility has made available all the resources to the Study Director which was necessary for conduct of the present study in compliance with the principles of GLP.

I, the undersigned, take overall responsibility for the reliability of the work described in the report

**N.N. Mishra**
**Laboratory In-charge**

21/06/2018
---
**Date**

## STUDY INFORMATION

**PROJECT NO.** : 201817

**REPORT NO.** : IIRT/TOX/121

**STUDY TITLE** : **Acute Oral Toxicity of PSAP "Potassium Salt of Active Phosphorus" in Wistar Albino Rats** (OECD Guideline No. 423 Acute Oral Toxicity, Section-4: Health Effects (Adopted: 17th Dec, 2001)

**SPONSOR** : **ISHA AGRO INDIA**
**OFFICE NO 05, B-101, MALATI COMPLEX, 4/129, IDEAL COLONY, PAUD ROAD, KOTHRUD PUNE- 411038, INDIA**

**TESTING LABORATORY** : **INSTITUTE FOR INDUSTRIAL RESEARCH & TOXICOLOGY**
**F-209, UPSIDC, MG ROAD, GHAZIABAD**
**E-mail: info@toxicityindia.org**
**Website: www.toxicityindia.org**
**Tel No.: +91 9711623080**
**Fax: +91 11 22235111**

**INSTITUTE FOR INDUSTRIAL RESEARCH & TOXICOLOGY,**

| | |
|---|---|
| **TEST COMPOUND** | **: PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"** |
| **SPONSORED BY** | **: ISHA AGRO INDIA** |
| **STUDY** | **: ACUTE ORAL TOXICITY IN WISTAR ALBINO RAT** |
| **PROJECT** | **: 201817** |

# QUALITY ASSURANCE STATEMENT

This **Project No.- 201817/ Report No. IIRT/TOX/121** entitled **Acute Oral Toxicity of PSAP "Potassium Salt of Active Phosphorus" in Wistar Albino Rats** (OECD Guideline No. 423) was subjected to inspections by the Quality Assurance Unit.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed. In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and as per scheduled of this study.

| | | |
|---|---|---|
| Standard Test Method Compliance Audit | : | 21/05/2018 |
| Animal Preparation | : | 21/05/2018 |
| Test Material Preparation | : | 22/05/2018 |
| Application of test compound | : | 22/05/2018 |
| Assessment of Response | : | 22/05/2018 to 04/06/2018 |
| Draft Report Audit | : | 11/06/2018 |

QUALITY ASSURANCE OFFICER IIRT * Ghaziabad * QA

**Quality Assurance Officer**
**(Ms. Shalini Mishra)**

Date: 21/06/2018

## STUDY PERSONNEL

| | | |
|---|---|---|
| **Study Director** | : | Dr. Amit k. Pal, Ph.D. Toxicology |
| **Study Personnel** | : | Ms. Anjali sharma, M. Sc. Toxicology |
| **Histopathology & Veterinarian** | : | Dr. Naresh Chandra, M. V. Sc. Pathology |

# SUMMARY

The acute oral toxicity study of **PSAP "Potassium Salt of Active Phosphorus" in Wistar Albino Rats** was conducted on Wistar albino rats. The study was conducted under the OECD Guideline-423 for testing of chemicals.

The healthy wistar albino rats of body weight 200±20 gm were selected for study after acclimatization to standard laboratory condition and divided into test compound group each having three animals. The study was conducted stepwise as follow:

**Starting Dose 300 mg/kg Body Weight:**

**Step I: 300 mg/kg body weight**

The test compound was administered orally at the dose level of 300 mg/kg body weight (dose volume 10 ml/kg) to three female rats. The treated animals were closely observed for clinical signs of intoxication during first four hours of test compound administration. Thereafter, all the animals were observed periodically at one hour interval for 24 hrs and twice daily for a period of 14 days. The necropsy was performed on all animals at the termination of the study.

The test compound **PSAP "Potassium Salt of Active Phosphorus" in Wistar Albino Rats** did not find any clinical signs/intoxication and mortality throughout the 14 days of observation at the tested dose level 300 mg/kg body weight. The necropsy finding did not reveal any gross pathological changes at the tested dose level. Furthermore, no gross pathological change was observed in vehicle control group.

**Step II: 2000 mg/kg Body Weight**

The test compound was administered orally at the dose level of 2000 mg/kg body weight (dose volume 10ml/kg) to three female rats. The treated animals were closely observed for clinical signs of intoxication during first four hours of test compound administration. Thereafter, all the animals were observed periodically at one hour interval for 24 hrs and twice daily for a period of 14 days. The necropsy was performed on all animals at the termination of the study.

The test compound **PSAP "Potassium Salt of Active Phosphorus" in Wistar Albino Rats** did not find any clinical signs/intoxication and mortality throughout the 14 days of observation at the tested dose level 2000 mg/kg body weight.

The necropsy finding did not reveal any gross pathological changes at the tested dose level.

**Confirmatory Test: 2000 mg/kg Body Weight**

After 72 hrs, the result of step-third was found no mortality and toxic sign & symptoms observed, The test compound was administered orally at the dose level of 2000 mg/kg body weight (dose volume 10ml/kg body wt.) to three female rats (OECD-423 guidelines) under same test condition.

The treated animals were closely observed for clinical signs of intoxication during first four hours of test compound administration.

Thereafter, all the animals were observed periodically at one hour interval for 24 hrs and twice daily for a period of 14 days. The necropsy was performed on all animals at the termination of the study.

The test compound administered at the dose level of 2000 mg/kg body weight did not produce any mortality and toxic clinical sign throughout the period of 14 days.

Necropsy was conducted at the end of the study (15$^{th}$ day) on all the animals which did not reveal any gross pathological changes.

The body weight of test group was observed on day 0 (pretreatment) did not show any significant change as compared with day 7$^{th}$, and 15$^{th}$ (post treatment) Presented in **Table-1.**

**CONCLUSION**

Finally, it is concluded that the test compound **PSAP "Potassium Salt of Active Phosphorus" in Wistar Albino Rats** sponsored by Isha Agro India, Office No 05, B-101, Malati Complex, 4/129, Ideal Colony, Paud Road, Kothrud Pune- 411038, India for acute oral toxicity study under the guideline OECD-423 may be harmful if swallowed and $LD_{50}$ is greater than 2000 mg/kg body weight. According to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), it comes under Category-5 (> 2000 to 5000 < mg/kg body weight).

# INTRODUCTION

## OBJECTIVES:

The study was conducted with the following objectives:

- To find out clinical signs of acute oral toxicity of **PSAP "Potassium Salt of Active Phosphorus"** in Wistar albino rats.
- To find out mortality, necropsy finding and gross pathological changes in wistar albino rats.
- To find out Globally Harmonized Classification System category of test compound **PSAP "Potassium Salt of Active Phosphorus"**
- To find out cut-off $LD_{50}$ of test compound **PSAP "Potassium Salt of Active Phosphorus"**
- To provide dosage regimen for establishing sub-acute studies.

## REGULATORY REFERENCES:

**Test Guidelines**

- The study was conducted in compliance with the modification OECD Guidelines for Testing of Chemicals (No. 423, Section 4: Health Effects) on conduct of "Acute Oral Toxicity" (Adopted: 17$^{th}$ Dec, 2001).

# MATERIAL AND METHODS

## TEST ARTICLE

| | | |
|---|---|---|
| **Study title** | : | Acute Oral Toxicity in Wistar Albino Rats |
| **Test compound** | : | **PSAP "Potassium Salt of Active Phosphorus"** |
| **Batch No.** | : | 001 |
| **Mfg Date** | : | Jan. 2018 |
| **Exp. Date** | : | Dec. 2021 |
| **Phosphorus as $P_2O_5$** | : | 40.62% |
| **Potash as $K_2O$** | : | 40.76% |
| **Sponsored by** | : | **Isha Agro India** |

- The sponsor shall be responsible for the test sample and its characterization.

## TEST SYSTEM

| | | | |
|---|---|---|---|
| Species | | : | Albino rat |
| Strain | | : | Wistar |
| Source | | : | Institute for Industrial Research & Toxicology |
| Age | | : | 8 to 12 weeks |
| Sex | | : | Female, nulliparous and non pregnant. |
| Body weight range | | : | 200±20g |
| Identification | | : | By cage tag and corresponding colour body marking |
| No. of animals per dose group | | : | Three (3 females)/step |
| No. of Steps | Step I | : | 300 mg/kg body wt. 2000 |
| | Step II | : | mg/kg body wt. |
| Confirmatory test | | : | 2000 mg/kg body wt. |

10. Acclimatization : One week in experimental room after veterinary examination.

11. Randomization : After acclimation and veterinary examination randomly selected in groups of three females.

12. Nutritional conditions : Fasted overnight prior to treatment. Food was offered three hours after dosing.

**HUSBANDRY**

1. Environmental conditions : Air conditioned rooms with 10-15 air changes per hour, Temperature between 22 ± 3 $^{0}$C, relative humidity 50-60% and illumination cycle set to 12 hours artificial fluorescent light and 12 hours dark.

2. Accommodation : Groups of three animals of similar sex in polypropylene cages with stainless steel grill top, facilities for food and water bottle, and bedding of clean paddy husk.

3. Diet : Pelleted feed supplied by Pranav agro Industries Ltd., B7/6 Ramesh Nagar, Delhi, India

4. Water : Aqua Guard filter water was kept in PVC bottles, *ad libitum*

## DOSE LEVELS AND JUSTIFICATION

Dose level was selected by the step wise manure: 300 & 2000 mg/kg body weight, as per OECD-423 guideline for testing of chemicals.

## STUDY DESIGN:

The toxicity of the test compound following oral administration was assessed. Three female rats were used per step for each dose level. The rats were observed for incidence of mortality and signs of intoxication for 14 days after the administration of test article.

**TABLE 1: STUDY DESIGN**

| Steps | Dose (mg/kg b. wt.) | Wistar albino Female rats |
|---|---|---|
| | | No. of animals per step |
| **Step I** | 300 | 3 |
| **Step II** | 2000 | 3 |
| **Confirmatory test** | 2000 | 3 |

## DOSE PREPARATION

Dose preparation of the test article **PSAP "Potassium Salt of Active Phosphorus"** was done freshly, few minutes prior to dosing.

## ADMINISTRATION OF TEST COMPOUND:

The test compound was administered by oral route with the help of oral cannula at the dose volume of 10 ml/kg body weight.

# OBSERVATIONS:

## BODY WEIGHT:

The body weight of all the animals was observed weekly on day 0 (pre treatment), 7th and 14th (post treatment).

## MORTALITY:

The test compound was administered at different dose level in wistar albino rats observed for mortality at the time interval of 30 minutes, 1hr, 2hrs, 4 hrs, and 6hrs time interval on the day of test compound administration and thereafter twice a day for 14 days.

## CLINICAL SIGNS

The treated animals were closely observed for clinical signs of intoxication, first 4 hours and every 1 hrs interval for 24 hrs after dosing and thereafter twice a day for 14 days. All the rats were observed at least twice daily to observe any clinical signs or behavioral changes. These observations included changes in skin and fur, in the eyes and mucous membranes, respiratory, circulatory, central nervous and autonomic nervous systems, somatomotor activity and behavioral changes. The following clinical signs were observed in rats to characterize the various systemic studies: Salivation, lacrimation, pale mucous membrane, diarrheal feaces, hunched posture, scratching, polyuria, hypoactivity etc. The clinical sign will be graded as 0 = Normal, + = Mild, ++= Moderate, +++ =High and ++++ = Severe.

## NECROPSY:

Necropsy was carried out on all the animals which died during the study or surviving animals were sacrificed at the end of the study to observe any gross pathological changes.

## ARCHIVE

The raw data and other material, sample of the test substance and the study report are being retained for two year at Institute for Industrial Research & Toxicology, Ghaziabad on completion of the study.

# RESULTS

## BODY WEIGHT

Wistar albino rats treated with the test compound **PSAP "Potassium Salt of Active Phosphorus"** at the dose level of 300 and 2000 mg/kg body weight showed normal gain in body weight on day $7^{th}$ and $14^{th}$ (post treatment) presented in Table-2.

## CLINICAL SIGNS

No clinical signs were recorded at the dose level of 300 and 2000 mg/kg body weight throughout the period of observation.

## MORTALITY

No mortality recorded in any of the Wistar albino rats after administration of the test compound at the dose level of 300 and 2000 mg/kg body weight throughout the period of observation.

## NECROPSY FINDING

### EXTERNAL

i. **Skin-** Normal

ii. **All external orifices-** Normal

### B. INTERNAL

**i. Subcutaneous-** No change was observed.

**ii. Superficial and deep lymph nodes-** No change in mesenteric lymph node.

## ABDOMINAL CAVITY

i. **Opening and general examination-** In the abdominal cavity all the organs were present in normal position.

ii. **Spleen-** Normal up to highest tested dose level 2000 mg/kg b.wt.

iii. **Digestive system-** No gross changes were observed in stomach and intestine upto highest tested dose level 2000 mg/kg b.wt.

iv. **Liver and biliary ducts-** No gross pathological changes were observed

v. **Excretory system-** No gross pathological changes were observed upto highest tested dose level 2000 mg/kg b.wt.

vi. **Adrenal -** Observed Normal.

vii. **Female genital organs** – Showed normal colour, consistency and no inflammatory changes upto highest tested dose level 2000 mg/kg b.wt.

## 2. THORACIC CAVITY

i. **Opening and general examination-** It was observed normal, no change was observed in presence of fluid, volume of fluid, colour etc. upto the highest tested dose level 2000 mg/kg b. wt.

ii. **Lungs-** Lung was observed highly congested at the highest tested dose level 2000 mg/kg body weight.

iii. **Heart-** No changes were observed in colour and consistency upto the highest tested dose level 2000 mg/kg b. wt.

iv. **Thyroid-** Normal in shape, size and surface upto the highest tested dose level 2000 mg/kg b. wt.

## 3. CRANIAL CAVITY

**Brain-** Normal in shape and size.

TEST : PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"
COMPOUND : ISHA AGRO INDIA
SPONSORED BY : ACUTE ORAL TOXICITY IN WISTAR ALBINO
STUDY RAT
PROJECT : 201817

## TABLE – 2

## SUMMARY OF BODY WEIGHT (gm)

| Steps | Animal No. | Day 0 | Day 7 | % Gain/loss | Day 14 | % Gain/loss |
|---|---|---|---|---|---|---|
| Step I: 300 mg/kg b. wt. | 201817 - 01 | 201 | 204 | 1.49 | 208 | 3.48 |
| | 201817 - 02 | 196 | 200 | 2.04 | 202 | 3.06 |
| | 201817 - 03 | 203 | 205 | 0.99 | 208 | 2.46 |

| Steps | Animal ID | Day 0 | Day 7 | % Gain/loss | Day 14 | % Gain/loss |
|---|---|---|---|---|---|---|
| Step II: 2000 mg/kg b. wt. | 201817 - 04 | 197 | 201 | 2.03 | 206 | 4.57 |
| | 201817 -05 | 189 | 193 | 2.12 | 200 | 5.82 |
| | 201817-06 | 201 | 205 | 1.99 | 209 | 3.98 |
| Confirmatory test: 2000 mg/kg b. wt. | 201817 -07 | 204 | 207 | 1.47 | 209 | 2.45 |
| | 201817 -08 | 201 | 205 | 1.99 | 207 | 2.99 |
| | 201817-09 | 207 | 209 | 0.97 | 211 | 1.93 |

TEST : PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"
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STUDY RAT
PROJECT : 201817

## TABLE-3

## CLINICAL SIGNS AND MORTALITY

**Step I: 300 mg/kg body weight** **Sex: Female Rats**

| Parameters | Incidence of Clinical Signs Observed after Dosing on | | | | | | | | | | | | | | | | | | Mortality |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day 0 | | | | | DAY | | | | | | | | | | | | | |
| | Min | Hour | | | | | | | | | | | | | | | | | |
| | 30 | 1 | 2 | 4 | 6 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | Total |
| Mortality | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0/3 |
| Clinical Signs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

0 = No clinical sign (Normal)
\+ = Mild
++ = Moderate
+++ = High
++++ = Severe

TEST : PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"
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STUDY RAT
PROJECT : 201817

## TABLE- 3 (Continued)

## CLINICAL SIGNS AND MORTALITY

**Step II: 2000 mg/kg body weight** **Sex: Female Rats**

| Parameters | Incidence of Clinical Signs Observed after Dosing on | | | | | | | | | | | | | | | | | | Mortality |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day 0 | | | | | DAY | | | | | | | | | | | | | |
| | Min | Hour | | | | | | | | | | | | | | | | | |
| | 30 | 1 | 2 | 4 | 6 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | Total |
| Mortality | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0/3 |
| Clinical Signs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

0 = No clinical sign (Normal)
\+ = Mild
++ = Moderate
+++ = High
++++ = Severe

TEST : PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"
COMPOUND : ISHA AGRO INDIA
SPONSORED BY : ACUTE ORAL TOXICITY IN WISTAR ALBINO
STUDY RAT
PROJECT : 201817

## TABLE-3 (Continued)
## CLINICAL SIGNS AND MORTALITY

**Confirmatory test: 2000 mg/kg body weight** **Sex: Female Rats**

| Parameters | Incidence of Clinical Signs Observed after Dosing on | | | | | | | | | | | | | | | | | | Mortality |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day 0 | | | | | DAY | | | | | | | | | | | | | |
| | Min | Hour | | | | | | | | | | | | | | | | | |
| | 30 | 1 | 2 | 4 | 6 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | Total |
| Mortality | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0/3 |
| Clinical Signs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

0 = No clinical sign (Normal)
\+ = Mild
++ = Moderate
+++ = High
++++ = Severe

TEST : PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"
COMPOUND : ISHA AGRO INDIA
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STUDY RAT
PROJECT : 201817

## TABLE – 4

### Summary of necropsy findings

### Fate: Terminal Sacrifice

| S. No. | Finding | Female Rats | | |
|---|---|---|---|---|
| | | Dose (mg/kg b. wt.) | | |
| | | Step I: 300 | Step II: 2000 | Confirmatory test: 2000 |
| 1 | Terminal Sacrifice | 3/3 | 3/3 | 3/3 |
| 2 | Abnormality detected | 0/3 | 0/3 | 0/3 |
| 3 | Mortalities | 0/3 | 0/3 | 0/3 |

TEST : PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"
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STUDY RAT
PROJECT : 201817

## TABLE- 5

## INDIVIDUAL ANIMAL FATE & Gross Findings

**Step I: 300 mg/kg body weight**

| Animal No. | Sex | Fate | Time | Gross Findings |
|---|---|---|---|---|
| 201817-01 | Female | TS | Day 15 | NAD |
| 201817-02 | Female | TS | Day 15 | NAD |
| 201817-03 | Female | TS | Day 15 | NAD |

**Step II: 2000 mg/kg body weight**

| Animal No. | Sex | Fate | Time | Gross Findings |
|---|---|---|---|---|
| 201817 -04 | Female | TS | Day 15 | NAD |
| 201817 -05 | Female | TS | Day 15 | NAD |
| 201817 -06 | Female | TS | Day 15 | NAD |

**Confirmatory test: 2000 mg/kg body weight**

| Animal No. | Sex | Fate | Time | Gross Findings |
|---|---|---|---|---|
| 201817-07 | Female | TS | Day 15 | NAD |
| 201817 -08 | Female | TS | Day 15 | NAD |
| 201817-09 | Female | TS | Day 15 | NAD |

Day 0 is the day of dose administration.
TS- Terminal Sacrifice
NAD- No Abnormality Detected

| | |
|---|---|
| **TEST** | **: PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"** |
| **COMPOUND** | **: ISHA AGRO INDIA** |
| **SPONSORED BY** | **: ACUTE ORAL TOXICITY IN WISTAR ALBINO** |
| **STUDY** | **RAT** |
| **PROJECT** | **: 201817** |

## CONCLUSION

Based on the results obtained from present investigation, it can be concluded that test compound **PSAP "Potassium Salt of Active Phosphorus" in Wistar Albino Rats** sponsored by Isha Agro India, Office No 05, B-101, Malati Complex, 4/129, Ideal Colony, Paud Road, Kothrud Pune- 411038, India for acute oral toxicity study under the guideline OECD-423 may be harmful if swallowed and $LD_{50}$ is greater than 2000 mg/kg body weight. According to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), it comes under Category-5 (> 2000 to 5000 < mg/kg body weight).

**Study Director**

**INSTITUTE FOR INDUSTRIAL RESEARCH & TOXICOLOGY,**

**TEST : PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS"**
**COMPOUND : ISHA AGRO INDIA**
**SPONSORED BY : ACUTE ORAL TOXICITY IN WISTAR ALBINO**
**STUDY RAT**
**PROJECT : 201817**

# CERTIFICATE OF ANALYSIS

## Institute for Industrial Research & Toxicology
## औद्योगिक अनुसंधान एवं विष विज्ञान संस्थान

Registration No. 1303/C/CPCSEA (Ministry of Environment & Forests, Government of India)
License No.: 01/2015 (Food and Drug Administration, UP)
AN ISO 9001 : 2015, ISO 14001 : 2015, ISO 45001 : 2018 Certified Organization
GLP Certified, NABL (ISO/IEC 17025) Accredited

## CERTIFICATE OF ANALYSIS

| NAME AND ADDRESS OF THE MANUFACTURE/SPONSOR | Report No. | IIRT/1819/1370 | Date | 07-06-2018 |
|---|---|---|---|---|
| M/s. Isha Agro India<br>Office No. 05, Malti Complex, 4/121, Ideal Colony, Poud Road – Pune, Maharashtra, India. | Party Ref. | - | Date | - |
| | Product Name | Potassium Salt of Active Phosphorus | | |
| "SAMPLE NOT DRAWN BY IIRT" | Trade Name | PSAP | | |
| Mfd. By:<br>As above | Sample code | - | ICS code | CHEM-1370 |
| | Sample Quantity | 200gm | Recd. Dt. | 04-04-2018 |
| | Mfg. Dt. | Jan-2018 | Exp. Dt. | Dec-2021 |
| | Batch No. | 001 | Pack cond. | Sealed |
| | Smp. Draw By | - | | |

**RESULT OF ANALYSIS AND PROTOCOLS OF TEST APPLIED**

**Description:** The material in the form of white free flowing powder, free from visible impurities.

| S.No. | Parameters | Method | Results | Unit |
|---|---|---|---|---|
| 1. | Phosphorus as P2O5 | FCO | 40.62 | % |
| 2. | Potassium as K2O | FCO | 40.76 | % |

**Note:** The above performed tests comply and confirm as per specifications.

28-06-2018
**Reported by:**
**Sign/date**

28-06-2018
**Reviewed by:**
**Sign/date**

20-06-2018
**Approved by:**
**Sign/date**

**Note:** 1) This certificate refers to only to the particular sample submitted for Testing. 2) This certificate not is produce, except in full, without the permission from the Q.M./Director of IIRT. 3) Results reported valid at the time of Testing. 4) Laboratory Standards are traceable to Nation Standard. 5) This report issued based on the Chemical Composition provided by the Sponsor.

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Email: iirtdelhi@gmail.com, info@toxicityindia.org, www.toxicityindia.org

INSTITUTE FOR INDUSTRIAL RESEARCH & TOXICOLOGY,

| | |
|---|---|
| TEST | : PSAP "POTASSIUM SALT OF ACTIVEPHOSPHORUS" |
| COMPOUND | : ISHA AGRO INDIA |
| SPONSORED BY | : ACUTE ORAL TOXICITY IN WISTAR ALBINO |
| STUDY | RAT |
| PROJECT | : 201817 |

## GLP CERTIFICATION

QSA INTERNATIONAL

# Certificate OF REGISTRATION

**This is to certify that**

## M/s Institute for Industrial Research & Toxicology

Site: F-209, UPSIDC Phase-I, MG Road, Ghaziabad (U.P.)-201010
Office: A-27, Street No-2, Madu Vihar (I.P.Extension) Delhi-110092

has been assessed and found to be conforming the requirements of the

**GLP Facility**

**OECD Principles of Good Laboratory Practice**

for the scope of

**Pre-Clinical Toxicology, Pharmacology, Analytical Chemistry & Micro Biology**

By QSA International, UK

| | |
|---|---|
| **Registration Number** | **: QSA-120326** |
| **Initial Certification Date** | **: 30 March 2012** |
| **Re-Certification Date** | **: 29 March 2018** |
| **Certification Expiry Date** | **: 28 March 2021** |

Stratford Ray

Certification Manager

Quality System Assessment International Limited
**27, Old Gloucester Street, London, WC1N3AX, ENGLAND**

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