



# 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

### MUCUS MEMBRANE IRRITATION OF PSAP

### “POTASSIUM SALT OF ACTIVE PHOSPHOROUS” IN NEW ZEALAND WHITE RABBITS

(Guideline: Gaitode Committee Recommendations Central Insecticide Board,  
Ministry of India)

### 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**

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**Tel No.: +91 9711623080**

**Fax: +91 11 22235111**

**Project No. : 201817**  
**Report No. : IIRT/TOX/125**  
**Date : 06/07/2018**



TEST : PSAP "POTASSIUM SALT OF ACTIVE  
 COMPOUND : PHOSPHOROUS" ISHA AGRO INDIA  
 SPONSORED : MUCUS MEMBRANE IRRITATION IN NEW ZEALAND WHITE  
 STUDY : RABBITS 201817  
 PROJECT NO. : IIRT/TOX/125



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**GLP STATEMENT OF COMPLIANCE**

I, undersigned hereby declare that **Project No.-201817/Report No. IIRT/TOX/125** entitled **Mucus Membrane Irritation of PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS" in New Zealand White Rabbits** was performed in accordance 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 *Gaitode Committee Recommendations Central Insecticide Board, Ministry of India*.

**Acute Mucus Membrane Irritation**, 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.

**Mr. Shahnawaz Ahmed**

**06/07/2018**

**Study Director**

**Signature**

**Date**


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**STATEMENT BY TEST FACILITY MANAGEMENT:**

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

I, undersigned, take overall responsibility for the reliability of the work described in the report with compliance of Good laboratory Practice.

  
N.N. Mishra  
Laboratory In-charge



06/07/2018

-----  
Date



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### **QUALITY ASSURANCE STATEMENT**

This Project No.-201817/Report No. IIRT/TOX/125 entitled Mucus Membrane Irritation of PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS" in New Zealand White Rabbits with Guideline for testing of chemicals 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 schedule of this study were as follows:

Standard Test Method Compliance Audit	: 08/06/2018
Animal Preparation	: 10/06/2018
Test Material Preparation	: 15/06/2018
Application of test compound	: 15/06/2018
Assessment of Response	: 15/06/2018 to 29/06/2018
Draft Report Audit	: 04/07/2018
Signature Final Report Audit	: 06/07/2018
Evaluation specific to this study	

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



**Date: 06/07/2018**

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### STUDY INFORMATION

PROJECT NUMBER : 201817  
REPORTNUMBER : IIRT/TOX/125  
STUDYTITLE : Mucus Membrane Irritation of  
PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS"  
in New Zealand White Rabbits  
SPONSOR : ISHA AGRO INDIA

TESTING LABORATORY : INSTITUTE FOR INDUSTRIAL RESEARCH &  
TOXICOLOGY  
F-209, UPSIDC, MG ROAD, GHAZIABAD  
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**STUDY PERSONNEL**

Study Director : Mr. Shahnawaz Ahmed, M.Sc. Toxicology  
Study Personnel : Ms. Anjali Sharma, M. Pharm, Pharmacology  
Histopathology & Veterinarian : Dr. Naresh Chandra, M. V. Sc. Pathology

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**STUDY PERSONNEL**

Study Director : Mr. Shahnawaz Ahmed, M.Sc. Toxicology  
Study Personnel : Ms. Anjali Sharma, M. Pharm, Pharmacology  
Histopathology & Veterinarian : Dr. Naresh Chandra, M. V. Sc. Pathology



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**SUMMARY**

The Mucus Membrane irritation toxicity PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS" was conducted in New Zealand White Rabbit as per the Guideline- *Gaitode Committee Recommendations Central Insecticide Board , Ministry of India* at Institute for Industrial Research & Toxicology, Ghaziabad. The study was conducted stepwise as follows-

PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS" was tested for its mucous membrane irritation potential in New Zealand rabbit as per the guidelines

The test article (0.1g) was introduced into the Vaginal mucosal membrane was evaluated at 24, 48, 72, 96 hours and 7<sup>th</sup> day after treatment according Draize method.

Slight to moderate erythema and oedema of vaginal mucous membranes was observed in treated rabbits at 24 hours after application and persisted up to 96 hours Vaginal mucous membranes appeared normal on day 7<sup>th</sup> after treatment. No other sign of toxicity were seen in any of the treatment animals.

Based on the average irritation index (2.14) PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS" moderately irritating to mucus membrane to rabbit

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**INTRODUCTION**

**OBJECTIVE**

The objective of Mucous Membrane irritation study was to evaluate the possible irritation potential of PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS" when instilled in the vagina of rabbit. This study provides a rational basis of risk assessment in man.

**Regulatory References**

The study was carried out as per the guidelines laid down by „Gaitonde committee Recommendation Central insecticide Board ,Ministry of Agriculture, Government of INDIA;

**MATERIAL AND METHODS**

**TEST ARTICLE**

- 1. Study title : Acute Mucus Membrane Irritation study in New Zealand white rabbit
- 2. Test compound : PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS"
- 3. Batch No. : 001
- 4. Mfg Date : Jan, 2018
- 5. Exp. Date : Dec, 2021
- 6. Phosphorus as P<sub>2</sub>O<sub>5</sub> : 40.62%
- 7. Potash as K<sub>2</sub>O : 40.76%
- 8. Sponsored by : ISHA AGRO INDIA

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### **HUSBANDRY**

- Environmental conditions : Air conditioned rooms with 10-15 air changes per hour, temperature between  $20 \pm 3^{\circ}\text{C}$ , relative humidity 50-60% and illumination cycle set to 12 hours artificial fluorescent light and 12 hours dark.
- Accommodation : Animals were housed individually in stainless steel cages provided with stainless steel mesh bottom and facilities for food and water bottle.
- Diet : Pelleted feed supplied by Krishna Valley Agro. Tech LLP, B7/8, first floor, double store, Ramesh Agar, New Delhi-110015(India).
- Water : Community tap water passed through 'Aqua Guard on line water filter', was kept in glass bottles, *ad Librium*

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## **PREPARATION AND TREATMENT OF ANIMALS**

### **SELECTION OF SPECIES:**

The albino rabbit is the preferable laboratory animal and only healthy young adult animals are used.

### **PREPARATION OF ANIMALS:**

Vaginal mucosa of each animal selected for study was examined on previous day of testing for presence of irritation or discharge if any. Animal showing no irritation or vaginal discharge were selected for the study.

### **Test procedure**

The test item (0.1 g) was introduced into the upper half of vaginal vault of each of six animals by means of syringe the rabbits were fixed in rabbit holder during the application.

### **DOSE LEVEL:**

A dose of 0.1g of test substance was applied into the vagina of the rabbits.

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**OBSERVATION**

The vaginal mucosa of each rabbit was examined at 24 ,48 and 72 hours after the instillation and the local irritation was evaluated following method of Dramatize J. H\*(1965).Further observations were not necessary as no irritation was observed up to 72 hours.

**Clinical sign**

Animals were also observed for sign of intoxication during the observation

**Scale for scoring local irritation**

*A. Erythema and Eschar formation*

OBSERVATION	SCORE
No erythema	0
Very slight erythema( barely perceptible)	1
Well define erythema	2
Moderate to Severe erythema	3
Severe erythema (beet redness) or slight Escher formation injury in depth. (Maximum erythema)	4

*B. Oedema Formation*

OBSERVATION	SCORE
No Oedema	0
Very Slight Oedema (barely precipitable )	1
Slight Oedema (Slight swelling of Vulvar lips)	2
Moderate Oedema (Moderate swelling of Vulvur lips)	3
Sever Oedema ( Sever swelling of Vulver lips with proturation)	4
<b>Maximum Possible Oedema</b>	

\*DARAIZE,J. H Appraisal of the safety of Chemical in foods, Drugs and Cosmetics :pp 46-59 Asso. Of food and Drug Officials of the United States ,Topeka, Kanas ,1965

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**RESULTS**

**OCCULAR IRRITATION**

Local irritation of individual animal is presented in table.

The test article caused very slight erythema or vaginal mucous membrane in four rabbits at 24 hours after application. All treated animals recovered after 48 hours. No edema was observed in any of the animals.

Based on the average irritation index (0.165) PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS" is classified as slightly irritating to Mucous membrane in Rabbits.

**CLINICAL SIGNS**

Throughout the study no clinical sign of intoxication were observed in any of the rabbit.

**TABLE- 1-GRADING OF OCULAR LESIONS**

**Individual Animal Mucous Membrane Irritation Score**

Rabbit No.	Sex	24 Hours		72 Hours	
		E	Oe	E	Oe
201817-1	F	1	0	0	0
201817-2	F	0	0	0	0
201817-3	F	1	0	0	0
201817-4	F	1	0	0	0
201817-5	F	0	0	0	0
201817-6	F	1	0	0	0
Total		4	0	0	0
Mean		0.66	0	0	0
Grand Total		0.66			

**Clinical Sign**

Sex	Animal No.	Time After Treatment		
		Hours		
		24	48	72
Females	201817-1	N	N	N
	201817-2	N	N	N
	201817-3	N	N	N
	201817-4	N	N	N
	201817-5	N	N	N
	201817-6	N	N	N



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### CONCLUSION

Based on above findings, it can be concluded that the test compound **PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS"** Sponsored By Isha Agro India, Office No 05, B-101, Malati Complex, 4/129, Ideal Colony, Paud Road, Kothrud Pune - 411038, India. Causes very slight erythema at 24 hours when applied to the vaginal mucus membrane of the New Zealand White rabbits at the dose level of 0.1 mg.

Based on the average irritation index **PSAP "POTASSIUM SALT OF ACTIVE PHOSPHOROUS"** (0.165) is classified as slightly irritating to mucus membrane in Rabbit.

A handwritten signature in blue ink, reading 'Shahnawaz Ahmed', is written over a circular official stamp of the Institute for Industrial Research &amp; Toxicology.

**Mr. Shahnawaz Ahmed**  
**Study Director**

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**CERTIFICATE OF ANALYSIS**



**Institute for Industrial Research & Toxicology**

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**CERTIFICATE OF ANALYSIS**

<b>NAME AND ADDRESS OF THE MANUFACTURE/SPONSOR</b> M/s. Isha Agro India Office No. 05, Malti Complex, 4/121, Ideal Colony, Poud Road - Pune, Maharashtra, India. <b>[SAMPLE NOT DRAWN BY IIRT™]</b> Mfd. By: As above	Report No.	IIRT/1819/1370	Date	07-06-2018
	Party Ref.	-	Date	-
	Product Name	Potassium Salt of Active Phosphorus		
	Trade Name	PSAP		
	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.

*Am*  
28-06-2018

Reported by:  
Sign/date

*Sushant*  
28-06-2018

Reviewed by:  
Sign/date

*Am*  
28-06-2018

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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GLP CERTIFICATION



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**

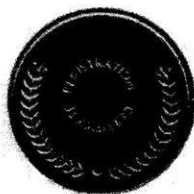
**OECD Principles of Good Laboratory Practice**

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



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

*Startford Ray*

Certification Manager



Centre For Global Accreditation  
Accreditation No. AB-14/001

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e-mail: [qsainternational@yahoo.co.uk](mailto:qsainternational@yahoo.co.uk)

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