मिसिल संख्या/ F. No. 26-08/2026-CIR-I (Part-I)(E-193277)
भारत सरकार/ Government of India
कृषि एवं किसान कल्याण मंत्रालय/ Ministry of Agriculture & Farmers' Welfare
कृषि एवं किसान कल्याण विभाग/ Department of Agriculture & Farmers Welfare
वनस्पति संरक्षण ,संगरोध एवं संग्रह निदेशालय/ Directorate of Plant Protection, Quarantine and Storage
एन .एच ,4-.फरीदाबाद ,हरियाणा/ N. H. IV., Faridabad (Haryana)
Website:-www.ppqs.gov.in, E-mail:- cibsecy@nic.in

Dated: .06.2026

PUBLIC NOTICE

Subject: Consideration of Health Monitoring Study Protocol for Toxicological Scrutiny of Applications under Household Category under the Insecticides Act, 1968, for Streamlining and Expediting the Scrutiny Process-reg.

Reference is invited to the decision taken by the Registration Committee vide Agenda item No.10.51 of 472nd RC meeting held on 26.05.2026 which is reproduced as under:-

"The RC deliberated the agenda and considered the proposed Health Monitoring Study Protocol as placed at Annexure-10.51.1, for adoption and implementation by the Sectt. of CIB&RC for streamlining and expediting the scrutiny process, henceforth these protocol may be used for simultaneous study initiation, hence reduce the total study generation tenure. A public notice shall be issued with these protocols for wide use."

2. This public is notice is issued for general awareness and information to all stakeholders.

This issues with the approval of Secretary, CIB&RC.

Encl: as above

Digitally signed by Sangeeta Meena
Date: 30-06-2026 14:37:02

(Sangeeta Meena)
Section Officer, CIB&RC

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Annexure-10.52.1

Health Monitoring Study Protocol for Household Insecticide Products

1. GENERAL INFORMATION:

S. No.	Test Product Details	Details
1.	Name of Product	
2.	Type of Formulation (in case of new formulation type, please give brief details)	
3.	Batch No.	
4.	Date of Manufacturing	
5.	Date of Expiry	

2. TOXICOLOGICAL INFORMATION OF THE PRODUCT:

2.1 Summary of GLP Studies

Name of Laboratory:

S. No.	Test	Animal	GLP Study No.	Result	GHS classification
1.	Acute Oral toxicity				
2.	Acute Dermal toxicity				
3.	Acute Inhalation toxicity				
4.	Eye Irritation				
5.	Skin Irritation				
6.	Skin Sensitization				

2.2 Handling of product or attach MSDS of product

S. No.	Parameter	Details
1.	Precautions	
2.	First Aid	
2.1	Eye Contact	

2.2	Skin Contact	
2.3	Ingestion	
2.4	Inhalation	
3.	Symptoms	
4.	Note to Physician	

3. STUDY DETAILS

3.1 Objective

The objective of the study is to assess the safety of household insecticide product (Name) on household inhabitants for a period of 30.

The study should be conducted under the supervision of a Registered Medical Practitioner. An individual informed consent must be obtained in writing for participation in the study.

3.2 Ethical Committee Approval

The study should be initiated after obtaining approval from the Institutional Ethics Committee of Laboratory.

3.3 Protocol

S. No.	Parameters	Details
1.	Location	
2.	No. of inhabitants*	30 inhabitants, selected randomly
3.	Inhabitants age	adults (both males and females)
4.	Age Group	18-60
5.	Exposure duration/day (frequency, quantity used, room size, ventilation, re-entry time)	
5.	Direction for Use	As per label & leaflet

*Only healthy individuals should be allowed to participate in study. Persons who have severe respiratory illness, allergy, children, elderly (>60), and pregnant/ lactating women may be excluded from the study as per decision of clinician. Details of each volunteer to be recorded as per Medical Case History Form (**Annexure I**)

3.4 Clinical Observation & Methods

The below mentioned parameter to be carried out on each volunteer during the study:

Observation	Annexure No.	Frequency/Time point
Clinical observation	Annexure II	Pre-exposure (Day -1or 0) Exposure Days: Days 2, 5, 30 Post-exposure: Day 30+6 (6 days after the completion of exposure)
Eye examination	Annexure III	
Clinical Pathology Haematology	Annexure IV	

Biochemistry	Annexure V	
Urinalysis	Annexure VI	
Nerve conduction tests*	Annexure VII	Pre-exposure (Day 0) Exposure Days: Days 5, 30 Post-exposure: Day 30+6 (6 days after the completion of exposure)

*Conducted on at least ten volunteers of both sexes, selected randomly

4. REPORTING

The clinical findings of all the individual should be reported. The post-exposure values of individual volunteers should be compared with their respective pre-exposure values to assess the effect of the test item.

The report should include below details:

i. Study details, objectives, study design and exposure conditions
ii. Certificate of authenticity signed by the scientists involved and supervising the Registered Medical Practitioner
iii. Ethics Committee approval details and informed consent documentation
iv. Description of exposure characterization (quantity of product used, frequency of application, environmental conditions and duration of exposure)
v. Summary of findings including statistical evaluation, interpretation and conclusion by the supervising physician
vi. Clinical Case History recordings of the Registered Medical Practitioner on the health of each volunteer as per respective formats
vii. Ophthalmological examination record, Haematology, biochemistry, urinalysis and nerve conduction test results
viii. Adverse event and serious adverse event reports if any, including medical management provided.
ix. Documentation of any study deviations and study stopping criteria, if applicable.
x. Statement of compliance with Good Clinical Practice (GCP) and data confidentiality requirements.

ANNEXURE I: MEDICAL CASE HISTORY FORM

Medical history of all volunteers should be recorded before participation in study.

Study No. : Volunteer No. :

Name : Age :

Gender : Occupation :

Present Address :

Past History

I	Illness*	No/Yes
II	Poisoning	No/Yes
III	Allergy	No/Yes

*If under any medication details should be provided

Family History

1	Allergy	No/Yes
2	Psychological Disorders	No/Yes

3	Haemorrhagic Disorders	No/Yes

PERSONAL HISTORY

Ablutions (Washing/Bathing/Cloth changing)	Good	
	Fair	
	Poor	
Personal Habits	Smoking	
	Alcohol	
	Other addictions	

HISTORY OF RECENT EXPOSURE (IF ANY)

Product	Method of use	Date(s) of exposure	Exposure duration

ANNEXURE II:CLINICAL OBSERVATIONS

A clinician will examine all the participants on scheduled days and record the data.

Study No. : Volunteer No. :

Name : Age :

Gender : Occupation :

Observations	Pre-exposure day	Exposure days			Post-exposure day
	0	2	5	30	30+6
A. VITAL SIGNS					
Pulse rate					
Respiratory rate/minute					
Depth of respiration					
Temperature (□F)					
Chest tightness					
B. GENERAL					
Weakness					
Fatigue					
Sleep					
Urination					
Sweating					
C.GASTROINTESTINAL					
Nausea					
Vomiting					
Appetite					
Taste					
Abdomen pain					
Diarrhoea					
Siallorrhoea					
D. NEUROMUSCULAR					
Headache					
Dizziness					
Irritability					
Neuro Muscular Pains					
Twitchings					
Tremors					
Convulsions					
Paraesthesia					
Hallucinations					
Unconsciousness					
E. CARDIORESPIRATORY					
Nasal discharge					
Wheeze					
Cough					
Expectoration					

Tightness of chest					
Dyspnoea					
Palpitation					
Heart conservation					

Cyanosis					
Tachycardia					
F. PSYCHOLOGICAL					
Temperament					
Judgement					
Nervousness/Restlessness					
Insomnia					
G. SKIN					
Dermal reaction/ irritation/allergic reaction					
H. OTHER CONDITIONS					
Any other Clinical /Medical conditions					
Signature of Medical Officer/Physician with Date					

ANNEXURE III: OPHTHALMOLOGICAL EXAMINATION

Study No. : Volunteer No. :

Name : Age :

Gender : Occupation :

Observations	Pre-Exposure Day	Exposure Days			Post Exposure Day
	0	2	5	30	30+6
DV – Right Eye					
DV – Left Eye					
NV – Right Eye					
NV – Left Eye					
Colour Vision – BE					
Fields – BE					
Fundus – BE					
Myosis					
Lacrimation					
Double vision					
Blurred vision					
Signature of Medical Practitioner with Date					

ANNEXURE IV: HAEMATOLOGY EXAMINATION*

Below mentioned parameters will be analysed

Days	WBC	RBC	Hb	HCT	MCV	MCH	MCHC	PLT	N	L	M	E	Bas	RC	PT	APTT	ESR
	(10^3/µL)	(10^6/µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	(10^3/µL)	(%)	(%)	(%)	(%)	(%)	(%)	(Sec)	(Sec)	(mm/ hour)
0																	
2																	
5																	
30																	
30+6																	

*Detailed methodology and instruments used must be provided

WBC - White Blood Corpuscles, RBC - Red Blood Corpuscles, Hb - Haemoglobin, HCT - Hematocrit, MCV - Mean Corpuscular volume, MCH - Mean Corpuscular Hemoglobin, MCHC - Mean Corpuscular Hemoglobin Concentration, PLT - Platelet, N- Neutrophils, L - Lymphocytes, M - Monocytes, E - Eosinophils, Bas - Basophils, RC - Reticulocyte Count, PT - Prothrombin Time, APTT - Activated Partial Thromboplastin Time, ESR - Erythrocyte Sedimentation Rate.

ANNEXURE V: BIOCHEMISTRY EXAMINATION*

The plasma to be separated and below mentioned parameters to be analyzed

Days	GLU	BU	CRE	CHOL	TBI	TGL	TP	ALB	GLOB	ALB/GLO ratio	ALP	AST	ALT	CA	PHOS	Na	K	Cl
	(mg/ dL)	(mg /dL)	(mg/ dL)	(mg/dL)	(mg/ dL)	(mg/ dL)	(g/ dL)	(g/dL)	(g/dL)	calculated	(U/L)	(U/L)	(U/L)	(mg/dL)	(mg/dL)	(mmol/L)	(mmol/L)	(mmol/L)
0																		
2																		
5																		
30																		
30+6																		

*Detailed methodology and instruments used must be provided

GLU - Glucose, BU - Blood urea, CRE - Creatinine, CHOL - Total Cholesterol, TBI - Total bilirubin, TGL - Triglycerides, TP - Total protein, ALB - Albumin, GLOB – Globulin (calculated), ALB/GLO
- Albumin- Globulin ratio (calculated), ALP - Alkaline phosphatase, AST - Aspartate aminotransferase, ALT - Alanine aminotransferase, CA - Calcium, PHOS - Phosphorous, Na - Sodium, K - Potassium, Cl – Chloride.

ANNEXURE VI: URINE ANALYSIS*

Urine (random) samples to be collected in labeled, clean and sterile containers with wide mouth, protected by tightly fitting lids and subjected to qualitative analysis and microscopic examination.

Days	Physical							Chemical									Microscopic					
	Volume (mL)	Colour	Appearance	SG	pH	Sediment	Protein (mg/dL)	Glucose (mg/dL)	Serum CRE (mg/dL)	Bilirubin	Bile Salts	Bile Pigments	Uro-bilinogen	Ketone (mg/dL)	Blood	Nitrite	Leucocytes	WBC	RBC	E	Casts	Crystals	Organisms
0																							
2																							
5																							
30																							
30 + 6																							

*Detailed methodology and instruments used must

be provided SG-specific gravity;

WBC - White Blood

Corpuscles; RBC - Red

Blood Corpuscles;

E – Epithelial cells

CRE- Creatinine

ANNEXURE VII: NERVE CONDUCTION TEST

Detailed methodology and instruments used must be provided.

Study No. : Volunteer No. :

Name : Age :

Gender : Occupation :

1. Right/Left Median (Motor): Thenar Muscles: Surf. Ele.

Wrist..... Elbow.....Supraclavicular.....Amp.....
Latency..... msec..... msec..... msec m.v.
Distancy .....cm ..... cm cm
Conduction velocity ..... metres/sec. (Wrist to elbow)
Conduction velocity ..... metres/sec. (Elbow to supraclavicular region)

2. Right/Left Ulnar (Motor): Hypothenar muscles: Surf. Ele.

Wrist..... Elbow..... Supraclavicular.....Amp.....
Latency..... msec.....msec..... msec m.v.
Distancy .....cm ..... cm…cm
Conduction velocity .....metres/sec (Wrist to elbow)
Conduction velocity .....metres/sec (Elbow to supraclavicular region)

3. Right/Left Lateral Popliteal: Ext. Dig. BR.: Surf. Ele.

Ankle..... Knee.....Amp.....
Latency..... msec.....msec..... msec m.v.
Distance .....cm ..... cm cm
Conduction velocity .....metres/sec.

4. Right/Left Sural nerve (Antidromic-Sensory): Needle Ele.

Amplitude.....uv
Latency.....msec
Distance.....cm

Conduction velocity ..... m/sec

5. Right/Left Median (Orthodromic Sensory)

Stimulation- digital nerves-index finger Recording at wrist: Needle Ele./Surf. Ele. Amplitude .....uv.
Latency.....msec

6. Right/Left Ulnar (Orthodromic Sensory)

Stimulation-digital nerves-
index finger Recording at
wrist: Needle Ele./Surf. Ele.
Amplitude .....uv.
Latency .....msec

7. Right/Left Facial nerve

Muscles Latency. Amplitude
Distance Orb. oris .....msec..... mv/uv cm
Frontails ..... msec ..... mv/uv cm
Orb. oculi .....msec..... mv/uv..... cm

8. Needle Electromyography

(i). Fibrillations..... Fasciculations .....Insertional activity .....
Mystonic .....Interference pattern .....Amplitude of motor units .....

(ii). Fibrillations ..... Fasciculations ..... Insertional activity.....
Mystonic .....Interference pattern .....Amplitude of motor units .....

(iii). Fibrillations .....Fasciculations .....Insertional activity.....
Mystonic .....Interference pattern.....Amplitude of motor units .....

9. Blink response study

Needle electrode (Conc.): Right Orb. Occuli.
Stimulation.....
Latency.....
Early Response..... msec.
Late Response ..... msec.

10. Conclusion and interpretation of results by clinician

NOTE:

The following requirements shall be read as integral to the Health Monitoring Study Protocol:

1. A structured Adverse Event Monitoring and Reporting system shall be implemented. All adverse events shall be recorded, and any Serious Adverse Event (SAE) shall be reported immediately and within 24 hours to the Ethics Committee and the competent authority.
2. Study stopping/termination criteria shall be predefined. The study shall be halted if moderate or severe toxicity is observed or if continuation is deemed unsafe by the supervising clinician.
3. The study shall be conducted under the supervision of a Registered Medical Practitioner, and all clinical observations and interpretation of medical investigations shall be carried out and authenticated by the physician.
4. The study shall comply with Good Clinical Practice (GCP) principles.
5. Confidentiality of participant data and record retention shall be ensured as per applicable ethical and regulatory requirements.

This Health Monitoring Study Protocol for household insecticide products is intended to serve as a general guiding framework. Based on the specific characteristics of the product and the study context, appropriate refinements or modifications may be considered on a case-to-case basis, as deemed necessary.