

OPERATION OF THE PRIOR INFORMED
CONSENT PROCEDURE FOR BANNED
OR SEVERELY RESTRICTED CHEMICALS
IN INTERNATIONAL TRADE

DECISION GUIDANCE DOCUMENTS

Phosphamidon

JOINT FAO/UNEP PROGRAMME
FOR THE OPERATION OF
PRIOR INFORMED CONSENT



UNEP

United Nations Environment Programme



Food and Agriculture Organization
of the United Nations

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Food and Agriculture Organization of the United Nations
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DISCLAIMER

The inclusion of these chemicals in the Prior Informed Consent Procedure is based on reports of control action submitted to the United Nations Environment Programme (UNEP) by participating countries, and which are presently listed in the UNEP-International Register of Potentially Toxic Chemicals (IRPTC) database on Prior Informed Consent. While recognizing that these reports from countries are subject to confirmation, the FAO/UNEP Joint Working Group of Experts on Prior Informed Consent has recommended that these chemicals be included in the Procedure. The status of these chemicals will be reconsidered on the basis of such new notifications as may be made by participating countries from time to time.

The use of trade names in this document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included here.

This document is intended to serve as a guide and to assist authorities in making a sound decision on whether to continue to import, or to prohibit import, of these chemicals because of health or environmental reasons. While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may flow therefrom. Neither FAO or UNEP, nor any member of the FAO/UNEP Joint Group of Experts shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of these chemicals.

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ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

(N.B. : chemical elements and pesticides are not included in this list)

ADI	acceptable daily intake
ai	active ingredient
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CCPR	Codex Committee on Pesticide Residues
DNA	Designated National Authority
EC	emulsion concentrate
EEC	European Economic Community
EPA	U.S. Environmental Protection Agency
ERL	extraneous residue limit
FAO	Food and Agriculture Organization of the United Nations
g	gram
µg	microgram
GAP	good agricultural practice
GL	guideline level
ha	hectare
IARC	International Agency for Research on Cancer
i.m.	intramuscular
i.p.	intraperitoneal
IPCS	International Programme on Chemical Safety
IRPTC	International Register of Potentially Toxic Chemicals
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)

k	kilo- (x 10 ³)
kg	kilogram
l	litre
LC ₅₀	lethal concentration, 50%
LD ₅₀	lethal dose, median
m	metre
mg	milligram
ml	millilitre
m.p.	melting point
MRL	Maximum Residue Limit.
MTD	maximum tolerated dose
ng	nanogram
NOEL	no-observed-effect level
NOAEL	no-observed-adverse-effect level
NS	Not Stated
OP	organophosphorus pesticide
PHI	pre-harvest interval
ppb	parts per billion
ppm	parts per million (Used only in reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).
ppt	parts per trillion
sp gr	specific gravity
STEL	Short Term Exposure Limit
TADI	Temporary Acceptable Daily Intake
TLV	Threshold Limit Value
TMDI	theoretical maximum daily intake
TMRL	Temporary Maximum Residue Limit
TWA	Time Weighted Average
UNEP	United Nations Environment Programme
WHO	World Health Organization

WP	wettable powder
wt	weight
<	less than
<<	much less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

**PIC Decision Guidance Document for acutely hazardous pesticides
of concern to human health under conditions of use in developing countries**

Phosphamidon

Published: June 97

Common Name	Phosphamidon
Other names/ Synonyms	Phosphamidone
CAS-No.	13171-21-6 (mixture, (E) and (Z) isomers) 23783-98-4 ((Z)-isomer) 297-99-4 ((E)-isomer)
Use	Pesticide (acaricide, insecticide): Systemic insecticide with strong stomach action and slight contact action
Trade Names	Dimecron, D-Cron, Phosron, Pillarcron, Umecron. Discontinued names: Dixon, Apamidon, Swat
Formulation Types	Soluble liquid (200, 500 or 1000 g/l); suspension concentrate; emulsifiable concentrate, ULV liquid; 10% granules
Basic Manufacturers	United Phosphorus (India), Bharat Pulverising Mills (India), Hindustan Ciba Geigy Ltd. (India), Hui Kwang (Taiwan)

Reasons for Inclusion in the PIC Procedure

Formulations of the substance which exceed 1000 g a.i./l are included because of their acute hazard classification and concern as to their impact on human health under conditions of use in developing countries. (Fifth meeting of the FAO/UNEP Joint Expert Group).

There are some reports of the agricultural use of phosphamidon causing health problems (see Annex 1). A few confirmed cases of human poisonings are also currently on record. (Ciba Geigy, 1994).

Registrars need to carefully consider the formulations currently used in each country when determining the risks of continued use of this pesticide. The toxicity of the active ingredient is high, but many formulations will fall into a much lower hazard category.

Hazard Classification by International Organisms

WHO (WHO, 1996)	Technical product.: Ia (extremely hazardous), classification based on oral toxicity				
	<i>Classification of formulations</i>				
			oral toxicity		dermal toxicity
			LD ₅₀ : 9 mg/kg bw (see Ann. 1)		LD ₅₀ : 367 mg/kg bw (see Ann. 1)
	formulation	a.i. (%)	hazard class	a.i. (%)	hazard class
	liquid	>50	Ia	>80	Ib
		>3	Ib	>3	II
solid	>20	Ib	>30	II	
	>1	II			
EPA	Category 1 (highly toxic)				
EU	T+ (very toxic), N (dangerous to the environment), mutagene Category 3				
IARC	Not evaluated by IARC				

Protective Measures That Have Been Applied Concerning the Chemical

Measures to Reduce Exposures

Personal WHO recommends that for the health and welfare of workers and the general population, the handling and application of phosphamidon should be entrusted only to competently supervised and well-trained applicators, who must follow adequate safety measures and use the chemical according to good application practices. Regularly exposed workers should receive appropriate monitoring and health evaluation.

In the USA, phosphamidon is a restricted use pesticide which can be used only by certified applicators.

(FAO, 1995; US-EPA, 1988; FAO/WHO)

Protection Protective clothing as indicated in the *FAO Guidelines for Personal Protection when Working with Pesticides in Tropical Climates (FAO, 1990)* is required; a respirator should also be worn by mixers and when spraying tall crops. The use of flaggers should be avoided; if used, they need full protective clothing including a respirator. All equipment and protective clothing should be washed thoroughly after use; clothing should be laundered separately from family clothing.

According to US-EPA, when opening the container and when mixing, protective impermeable boots, clean overalls and gloves should be worn. Mixing, if not mechanical, should always be carried out with a paddle of appropriate length. When spraying tall crops or during aerial application, a face mask should be worn, as well as an impermeable hat, clothing, boots and gloves. All protective clothing should be washed immediately after use, including the inside of gloves (US-EPA, 1988).

Application The manufacture, formulation, agricultural use and disposal of phosphamidon should be carefully controlled to minimize contamination of the environment. To minimize risks for all individuals, a 48-hour interval between spraying and re-entry into any sprayed area is recommended.

According to US-EPA, unprotected persons should be kept away from tall crops for four days and away from other crops for at least 24 hours (US-EPA, 1988).

Pre-harvest intervals should be established and enforced by national authorities.

In view of the high toxicity of phosphamidon, this agent should not be considered in hand-applied ULV spraying practices.

Regulatory measures

Although the chemical has been included in the PIC procedure because it is a highly toxic pesticide that is likely to cause problems under conditions of storage, transportation and use in developing countries, some countries have reported control actions that may be of interest when considering its use as a pesticide (see below).

Control actions are reported by two countries (Belize and Japan) where the substance is banned or severely restricted for use due to its toxicity. In Indonesia, the use of phosphamidon is limited until 17 June 1997.

Not all of the reports have been determined to be of control actions which conform with the FAO/UNEP definitions of banned or severely restricted for health or environmental reasons. However, all reports are provided here since the FAO/UNEP Joint Expert Group on Prior Informed Consent decided that the substance should be included in the PIC procedure due to its potential to cause problems under conditions of use in developing countries regardless of the number of qualifying actions.

For further information on the control actions provided in Annex 2, contact the Designated National Authorities (Annex 3) in the country reporting the control action.

Alternatives

There are no alternatives indicated by countries reporting control actions. Alternatives have been reported in literature (Gips, 1990).

It is essential that before a country considers substituting any of the reported alternatives, it ensures that the use is relevant to its national needs. A first step may be to contact the DNA in the country where the alternative has been reported (see addresses of DNAs in Annex 3). It will then be necessary to determine the compatibility with national crop protection practices.

Packaging and Labelling

Follow *FAO Revised Guidelines on Good Labelling Practice for Pesticides* (FAO, 1995).

The United Nations Committee of Experts on the Transportation of Dangerous Goods (*IPCS, 1993*) classifies the chemical in:

Hazard Class 6.1 poisonous substance

Packing Group 2: substances and preparations presenting a serious risk of poisoning

Waste Disposal

All waste and contaminated material associated with this chemical should be considered hazardous waste. The material should be destroyed by incineration in a special, high temperature chemical incinerator facility.

See *FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks* and *The Pesticide Storage and Stock Control Manual* (FAO,1996).

It should be noted that the methods recommended in literature are often not suitable in a specific country. High temperature incinerators or secure landfills may not be available.

Exposure Limits

	Type of limit	Value
Food	MRLs (Maximum residue limits in mg/kg) in specified products (<i>FAO/WHO, 1996</i>)	0.05 – 0.5
	JMPR ADI (acceptable daily intake) in mg/kg diet (<i>JMPR, 1986</i>)	0.0005

First Aid

Early symptoms of poisoning may include excessive sweating, headache, weakness, giddiness, nausea, vomiting, hypersalivation, stomach pains, blurred vision and slurred speech. If these symptoms occur, the person should remove contaminated clothes, wash the affected skin with soap and water and flush with large quantities of water. If in the event of collapse artificial resuscitation is used, vomit may contain toxic amounts of the substance. In case of ingestion, the stomach should be emptied as soon as possible by careful gastric lavage. Do not induce vomiting if the formulation contained hydrocarbon solvents.

Persons who have been poisoned (accidentally or otherwise) must be transported immediately to a hospital and put under the surveillance of properly trained medical staff.

Antidotes are atropine sulphate and pralidoxime chloride.

General surveillance and cardiac monitoring must be maintained for at least 14 days (*FAO/WHO*).

Annexes

- Annex 1 Further Information on the Substance
- Annex 2 Details on Reported Control Actions
- Annex 3 List of Designated National Authorities
- Annex 4 References

Annex 1 - Further Information on the Substance

1 Chemical and Physical Properties

1.1	Identity	Technical phosphamidon is a pale yellow to colourless oily liquid with a faint odour. It consists of a mixture of (Z)-isomer and (E)-isomer in the approximate proportion of 70:30.
1.2	Formula	C ₁₀ H ₁₉ ClNO ₅ P
	Chemical Name	2-chloro-2-diethylcarbamoyl-1-methylvinyl dimethyl phosphate (IUPAC)
	Chemical Type	Organophosphate
1.3	Solubility	Miscible with water and soluble in most organic solvents except paraffins.
	logP_{ow}	0.79
1.4	Vapour Pressure	2.2 mPa 25° C
1.6	Reactivity	Rapidly hydrolysed by alkalis. It is corrosive to iron, tinplate and aluminium. The substance decomposes on heating or on burning, producing highly toxic fumes. Further information in <i>Tomlin</i> ; 121; 123; 122; 119; 154

2 Toxicity

2.1 General

2.1.1	Mode of action	Phosphamidon affects the nervous system by inhibiting acetylcholinesterase, an enzyme essential for normal nerve impulse transmission. An impurity of the technical product, gamma-chlorphosphamidon, inhibits mammalian cholinesterase 10 to 20 times more than pure phosphamidon (121).
2.1.2	Uptake	Phosphamidon may be readily absorbed from the gastrointestinal tract, through the skin and by inhalation of spray mists and dusts.
2.1.3	Metabolism	In mammals, phosphamidon is metabolized mostly to polar non-toxic breakdown products.

2.2 Known Effects on Human Health

2.2.1 Acute Toxicity

Symptoms of poisoning	The organophosphate insecticides are cholinesterase-inhibitors. They are highly toxic by all routes of exposure. When inhaled, the first effects are usually respiratory and may include a bloody or runny nose, coughing, chest discomfort, difficult or short breath and wheezing due to constriction or excess fluid in the bronchial tubes. Skin contact with organophosphates may cause localized sweating and involuntary muscle contractions. Eye contact will cause pain, bleeding, tears, pupil constriction and blurred vision. Following exposure by any route, other systemic effects may begin within a few minutes or be delayed for up to 12 hours. These may include pallor,
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nausea, vomiting, diarrhoea, abdominal cramps, headache, dizziness, eye pain, blurred vision, constriction or dilation of the pupils, tears, salivation, sweating and confusion. Severe poisoning will affect the central nervous system, producing incoordination, slurred speech, loss of reflexes, weakness, fatigue, involuntary muscle contractions, twitching, tremors of the tongue or eyelids, and eventually paralysis of the body extremities and the respiratory muscles. In severe cases there may also be involuntary defecation or urination, psychosis, irregular heart beat, unconsciousness, convulsions and coma. Respiratory failure or cardiac arrest may cause death.

- 2.2.2 **Short and long term exposure** A group of thirty-two people which was exposed to a phosphamidon spraying of 550 g/ha experienced conjunctival irritation and inhibition of plasmacholinesterase from 0 up to over 50% with complete recovery in 9 days.
- A study with hens showed that phosphamidon did not induce delayed neurotoxicity (JMPR, 1986).
- 2.2.3 **Epidemiological studies** No data available

2.3 Toxicity studies with laboratory animals and *in vitro* systems

2.3.1 Acute Toxicity

oral	LD ₅₀ (a.i., mg/kg b.w.): 9.1-17 in different test species
dermal	LD ₅₀ (a.i., mg/kg b.w.): 367-530 in different test species
inhalation	LC ₅₀ (a.i., mg/m ³ air- exposure 4 hrs) 33 - 180
irritation	slight skin and moderate eye irritation

2.3.2 Short-term exposure

NOEL	rat:	0.1 mg/kg bw/day
	dogs:	0.1 mg/kg bw/day
	mouse	0.15 mg/kg bw/day

(*Gunther, 1971, BBA 1996*)

Daily oral doses above 1.3 mg/kg bw results in symptoms of poisoning

2.3.3 Long term exposure

NOEL	rat:	0.05 mg/kg bw/day
	mouse	0.1 mg/kg bw/day
	dog:	0.1 mg/kg bw/day

(*JMPR, 1986; BBA, 1996*)

In a two-year study on rats with dietary concentrations from 0.2 to 80 ppm, the NOAEL was 0.05 mg/kg bw (JMPR, 1986).

2.3.4 Effects on reproduction

In a three-generation test of reproduction, parental generations were unaffected and there were no pathological changes in the tissues. Reproductive performance was normal. There were no significant differences in the number of new-born (*Hayes, 1990*).

Effects on litter size and pup viability were seen in a rat multigeneration study at maternally toxic dose levels, Phosphamidon was devoid of a teratogenic potential (*JMPR, 1986*).

- 2.3.5 **Mutagenicity** In the mutagenicity studies, phosphamidon was negative in a number of *in vitro* test systems, except for one test on chromosome aberrations. Several *in vivo* tests on chromosome anomalies have been carried out in rodents. Reports submitted to WHO showed negative or questionable results, whereas literature data showed a positive effect (*JMPR, 1986*).
- 2.3.6 **Carcinogenicity** Carcinogenicity studies in rats were negative (*JMPR, 1986*).

3 Exposure

- 3.1 **Food** No data available.
- 3.2 **Occupational** Evaporation at 20° C is negligible; a harmful concentration of airborne particles can, however, quickly be reached when dispersed.
One case of poisoning has been reported in which the only recognized exposure was through the uprooting and cutting of shrubs that had been sprayed with phosphamidon 2 weeks before. The 50-year-old man had worked without gloves for only 1 day. In the afternoon following exposure, he suffered dizziness, repeated severe vomiting, and eventually collapsed. When brought to the hospital, he was sweating and showed excessive lacrimation. After minimum treatment, the patient regained full consciousness in a few hours, regained full strength after 2 days and recovered completely. (*Hayes, 1991; IPCS, 1993*)
- 3.3 **Environment** No data available.
- 3.4 **Accidental Poisoning** Two workers were accidentally drenched in 50% phosphamidon and six others suffered soaked feet and splashes to the arms, hands and clothing when a pipe burst. The workers immediately washed with soap and water. They suffered short-term gastric pain, headache and eye irritation; none required an antidote and all returned to work (*Hayes aaaaaa*).

4 Effects on the Environment

- 4.1 **Fate**
- 4.1.1 **Persistence** Phosphamidon is not persistent.
- 4.1.2 **Bioconcentration** Phosphamidon does not bioconcentrate.
- 4.2 **Ecotoxicity**
- 4.2.1 **Fish** LC₅₀-96 hr (rainbow trout, Guppy, Bluegill, Channel Catfish, Carp): 3.2 - 600 mg/l (*121; 120*)
- 4.2.2 **Aquatic invertebrates** EC₅₀ (daphnia) : 0.01 – 0.022 mg/l (*Ciba Geigy, 1994*)
- 4.2.3 **Birds** LD₅₀-oral (5 different species): 2 - 26 mg/kg bw. The substance can be lethal by dermal exposure. Available information indicates that delayed mortality of birds occurs after application of phosphamidon (*121; 120*)
- 4.2.4 **Bees** Phosphamidon is highly toxic to bees. LD₅₀: 0.17 - 0.32 µg/bee. It belongs to the group of substances most toxic to bees (*Delaplane, 1995*).

Annex 2 - Details on reported control actions

BELIZE	
Effective	1985
Control Action	The substance is banned for use.
Uses still allowed	No remaining uses are allowed.
Reasons	Highly toxic.
INDONESIA	
Effective	1996
Control Action	Decree of the Minister of Agriculture N.473/Kpts/TP.270/6/96, dated 17 June 1996: the discontinuance of the registration of phosphamidon was stipulated. The owner of phosphamidon has been given a time period of one year for using up the stocks after the date of the decree.
Uses still allowed	
Reasons	
JAPAN	
Effective	1955
Control Action	Severe Restrictions; uses other than those specified by Cabinet Order are prohibited; no use has been designated.
Uses still allowed	Scientific research by authorized researcher.
Reasons	Very strong toxicity.

Annex 3 - List of Designated National Authorities

BELIZE**C**

Sanitation Engineer
Ministry of Health Public Health Bureau
Belize City

Phone**Fax****Tele****e-mail****P**

The Secretary
Pesticides Control Board Department of Agriculture, Mr Mario
Central Farm Cayo

Phone501-92-2640 /
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102 Foreign Bz

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C Industrial and consumer product chemicals

Phosphamidon - Cas No: 13171-21-6; 23783-98-4; 297-99-4

CP Pesticides

P Pesticides, industrial and consumer product chemicals

Annex 4 - References

The information on phosphamidon given in this DGD is mainly based on documents published by WHO, FAO and the International Programme on Chemical Safety (IPCS). If important information from other sources has been used, these references are noted in the text. The following list also includes other publications containing useful information.

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