

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

DECISION GUIDANCE DOCUMENTS

Methamidophos

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



United Nations Environment Programme



Food and Agriculture Organization
of the United Nations

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Food and Agriculture Organization of the United Nations
United Nations Environment Programme
Rome - Geneva 1991; amended 1996

DISCLAIMER

The inclusion of these chemicals in the Prior Informed Consent Procedure is based on reports 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 (IRPT) 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 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 |
| \ll | much less than |
| \leq | less than or equal to |
| $>$ | greater than |
| \geq | 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**

Methamidophos

Published: Octo

| | |
|------------------------------|--|
| Common Name | Methamidophos |
| Other names/ Synonyms | Metamidophos |
| CAS-No. | 10265-92-6 |
| Use | Systemic insecticide with contact and stomach action to control chewing and sucking insects |
| Trade Names | Monitor, Tamaron, Filitox, Tamanox, Tam, Patrole, Metamidofos E Methamidophos 60 WSC: Methedrin 60; Morithion; Red Star Alloran |
| Formulation Types | Soluble and emulsifiable concentrates in various concentrations of active ingredient |
| Basic Manufacturers | Bayer, Chevron Chemical Co., Cia-Shen Co., Crystal Chemical Inter- America, Agro-Chems Mfg., Jiangmen, Jin Hung Fine Chemical Co., Linghu P.F., Mobay Productos OSA, Quimica Estrella S.A.C.I.e.I., Sanonda, Suzhou P.F., Taiwan Giant Industrial Co |

Reasons for Inclusion in the PIC Procedure

Formulations of the substance which exceed 600 g a.i./l are included because of their acute classification and concern as to their impact on human health under conditions of use in developing countries (Fifth meeting of the Joint Expert Group).

There are several reports that the agricultural use of methamidophos causes health problems (Hong Kong, Korea). In the USA, methamidophos ranked second in percentage of cases displaying life-threatening symptoms among occupational Poison Control Center cases. (see Annex 1).

In a study conducted by US-EPA regarding acute worker exposure risk assessment under conditions of use in Indonesia for chemicals of concern, a MOE-value (NOEL/Anticipated Exposure Level) of 100 was estimated for methamidophos. EPA generally considers a MOE of lower than 100 to present unacceptable risk. (FAO Jakarta, 1996)

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

Hazard Classification by International Organisms

| | | | | |
|-------------|--|--------------|---|----------|
| WHO | Technical product.: Ib (highly hazardous), classification based on oral to | | | |
| (WHO, 1996) | Classification of formulations | | | |
| | oral toxicity | | dermal toxicity | |
| | LD ₅₀ : 30 mg/kg bw (see Ann. 1) | | LD ₅₀ : 50 mg/kg bw (see Ann. 1) | |
| formulation | a.i. (%) | Hazard class | a.i. (%) | Hazard |
| liquid | >10 >1 | Ib II | >10 >1 | Ib II |
| solid | There are no solid formulations of methamidophos | | | |
| EPA | Category 1 (highly toxic) | | | |
| EU | T+ (very toxic) | | | |
| IARC | not classified | | | |

Protective Measures That Have Been Applied Concerning the Chemi

Measures to Reduce Exposures

- Personal** WHO recommends that for the health and welfare of workers and the general pop the handling and application of methamidophos should be entrusted only to comp supervised and well-trained applicators who must follow adequate safety measur use the chemical according to good application practices. Regularly exposed v should receive appropriate monitoring and health evaluations. (IPCS, 1993)
- Protection** Protective clothing as indicated in the *FAO Guidelines for Personal Protection Working with Pesticides in Tropical Climates* (FAO, 1990) is required; a respirator also be worn by mixers and when spraying tall crops. The use of flaggers sho avoided; if used, they require full protective clothing, including a respirator. All equ and protective clothing should be washed thoroughly after use; clothing sho laundered separately from family clothing.
Unprotected workers should be kept out of treated areas for 48 hours. (FAO 1990)
- Application** The manufacture, formulation, agricultural use and disposal of methamidophos shc carefully managed to minimize contamination of the environment. To minimize risks individuals, a 48-hour interval between spraying and re-entry into any sprayed : recommended. Pre-harvest intervals have been set in many countries. These in vary from 3 to 90 days (most falling within 14-21 days), depending on the crop, har technique and the country.
In view of the high toxicity of methamidophos, this agent should not be consid hand-applied ULV spraying practices. (IPCS, 1993; FAO, 1995)

Regulatory measures

Although the chemical has been included in the PIC procedure because it is a highly toxic pesticide 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 regarding methamidophos have been reported by Indonesia, Samoa and Sri Lanka (Annex 2).

Liquid formulations with 40% or more methamidophos are restricted in the United States to use by certified applicators.

Not all of the reports have been determined to be of control actions which conform with the FAO/WHO definitions of banned or severely restricted for health or environmental reasons. However, all reports provided here since the FAO/WHO 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

Indonesia and Samoa have indicated alternatives to methamidophos (see Annex 2). Alternative has been reported in literature. (Gips, 1990)

It is essential that before a country considers substituting any of the reported alternatives, it ensure 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), classifies the chemical in:

| | |
|-------------------------|--|
| Hazard Class 6.1 | poisonous substance |
| Packing Group 2: | substances and preparations presenting a serious risk of poisoning (formulations containing 15 - 100 % active material) |
| Packing Group 3: | harmful substances and preparations presenting a relatively low risk of poisoning (solid formulations containing 3-15% active material and liquid formulations containing 1.5-15 % active material) |

Waste Disposal

All waste and contaminated material associated with this chemical should be considered hazardous

The material should be destroyed by incineration in a special, high temperature chemical incineration facility.

See *FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks and The Prevention of 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 | MRL's (Maximum residue limits in mg/kg) in specified products (<i>FAO/WHO, 1996</i>) | 0.01-5 |
| | JMPR_ADI (acceptable daily intake) in mg/kg diet (<i>JMPR, 1995</i>) | 0.004 |

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 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 small 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. (*IPCS, 1986*)

Comment [JK1]:

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 | Colourless crystals with a melting point 44.5 °C (pure material); Tec methamidophos (about 73%) is in the form of yellowish to colourless c with melting point below 40 °C. |
| 1.2 | Formula | C ₂ H ₈ NO ₂ PS |
| | Chemical Name | O,S-dimethyl phosphoramidothioate (IUPAC; CAS) |
| | Chemical Type | Organophosphate |
| 1.3 | Solubility | In water > 200 g/l at 20°C, highly soluble in alcohols and ketones, sp; soluble in ether and petroleum ether |
| | logP_{ow} | -0.8 |
| 1.4 | Vapour Pressure | 4.7 mPa (25°C) |
| 1.5 | Reactivity | Decomposes on heating without boiling; stable at pH 3-8. The technical and concentrates are corrosive to steel and copper containing Incompatible with alkaline pesticides. Further information in <i>Tomlin, 1994</i> and <i>IPCS, 1993</i>) |

2 Toxicity

2.1 General

| | | |
|-------|-----------------------|---|
| 2.1.1 | Mode of action | Methamidophos affects the nervous system by inhibiting acetylcholinest an enzyme essential for normal nerve impulse transmission. |
| 2.1.2 | Uptake | Methamidophos can be absorbed following ingestion, inhalation an contact |
| 2.1.3 | Metabolism | Biotransformation in mammals results in the formation of metabolites th toxicologically insignificant (<i>IPCS, 1986; IPCS, 1993</i>) |

2.2 Known Effects on Human Health

2.2.1 Acute Toxicity

Symptoms of poisoning The organophosphate insecticides are cholinesterase-inhibitors. The highly toxic by all routes of exposure. When inhaled, the first effect usually respiratory and may include bloody or runny nose, coughing, discomfort, difficult or short breath and wheezing due to constriction or fluid in the bronchial tubes. Skin contact with organophosphates may localized sweating and involuntary muscle contractions. Eye contact 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, 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 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 Respiratory failure or cardiac arrest may cause death.
- 2.2.2 **Short and long term exposure** *Some organophosphates may cause delayed symptoms beginning weeks after an acute exposure that may or may not have produced immediate symptoms. In such cases, numbness, tingling, weakness and cramping appear in the lower limbs and progress to incoordination and paralysis. Improvement may occur over months or years, but some residual impairment will remain.*
- Repeated exposure through inhalation, ingestion or through skin gradually lead to signs and symptoms of inhibition of cholinesterase activity. Excessive human exposure to methamidophos may cause demyelinating neuropathy. (IPCS, 1993)
- 2.2.3 **Epidemiological studies** no data available
- 2.3 Toxicity studies with laboratory animals and *in vitro* systems**
- 2.3.1 **Acute Toxicity** (Tomlin, 1994; IPCS, 1993; FAO/WHO, 1993)
- oral** LD₅₀ (a.i.; mg/kg b.w.): 10-50; in different test species
- dermal** LD₅₀ (a.i.; mg/kg b.w.): 50-110 ; in different test species.
- inhalation** LC₅₀ (a.i.; mg/m³ air- exposure 4 hrs) 162 ; (rat)
- irritation** Moderate erythema and oedema were observed in skin tests on the ear. The chemical is also irritating to the eye.
- 2.3.2 **Short and long term exposure** The following levels were published as not to cause any toxicological effects: rat: 0.1 mg/kg bw/day; dog: 0.06 mg/kg bw/day; chicken 0.3 mg/kg bw/day (IPCS, 1993)
- A long-term study (500 days) on the effects of low doses of methamidophos on mice was conducted. Mice given 0.03 mg methamidophos/kg body weight still showed significant effects (reduced number of muscarinic receptors in brain), which can be valued as an important influence on the central nervous system. (Tigges, 1994)
- 2.3.4 **Effects on reproduction** In reproductive studies, several parameters were affected at relative low levels. (IPCS, 1993)
- 2.3.5 **Mutagenicity** Methamidophos was found to be non-mutagenic in bacterial and *in vitro* assays. (IPCS, 1993)
- 2.3.6 **Carcinogenicity** There were no indications of oncogenicity in a mouse oncogenicity study and a long-term toxicity/oncogenicity study on rats.

3 Exposure

- 3.1 **Food** Use of methamidophos may result in low level residues; but there should be no health hazards if preharvest intervals are observed. (IPCS, 1993)
- Since 1987 in Hong Kong, there have been numerous cases of poisoning following the consumption of green leafy vegetables imported from China. In Shenzhen, where the bulk of these vegetables originates, it is strongly suspected that methamidophos has been used by some farmers and that the sprayed vegetables have been harvested too early before the residues have dissipated.

levels have fallen to safe levels. (Chan, 1994)

In the US, methamidophos was found at unacceptable levels in preschool diets in a 1989 study. The average intake as a percentage of the ADI was 5.763%. Between 63%-97.6% of 1-5 year olds were estimated to be receiving average daily exposures above the ADI (NRDC, 1989).

- 3.2 Occupational** Higher occupational exposure (mainly through inhalation and dermal absorption) may occur in the case of accidents or as a result of insecticide handling.
- There are several reports on methamidophos indicating it may cause health problems during occupational use. In the US, methamidophos was the third-highest among 28 pesticides on measures of occupational health. Methamidophos had the third-highest ratio of handler poisonings per application in California when exposures in mixtures were included, a second-highest overall for field workers. Methamidophos ranked second in percentage of cases displaying symptoms or life-threatening symptoms among occupational Poison Control Center cases. (US-EPA, 1996)
- In China, 27 provinces reported a total of 48,377 poisoning cases, including 3,204 fatalities in 1995. 15,300 of these cases were caused by insecticide agricultural use and not by accidents or improper use. More than 50% of these 15,000 cases were attributed to parathion, methamidophos, and omethoate (Shuyang Chen, Peipei Yao, 1996; Chan, 1996).*
- 3.3 Environment** The population is not generally exposed to methamidophos in air or water
- 3.4 Accidental Poisoning** Accidental poisoning with methamidophos may occur due to insecticide handling.

4 Effects on the Environment

4.1 Fate

- 4.1.1 Persistence** The half-life in soil is a few days. Degradation products are CO₂, mercaptan, dimethyl disulfide and dimethyl sulfide.
- 4.1.2 Bioconcentration** On the basis of data on the solubility of methamidophos, bioaccumulation would not be expected to occur.
(Tomlin, 1994; IPCS, 1993)

4.2 Ecotoxicity

- 4.2.1 Fish** LC₅₀ 96 h: 25 - 100 mg/l (rainbow trout, goldfish, carp)
- 4.2.2 Aquatic invertebrates** EC₅₀ 48 h : 0.27 mg/l (Daphnia)
- 4.2.3 Birds** Oral LD₅₀: 8 - 50 mg/kg bw (mallard duck, Japanese quail, hen)
- 4.2.4 Bees** Toxic to bees (Tomlin, 1994; IPCS, 1993)

Annex 2 - Details on reported control actions

INDONESIA

| | |
|-----------------|---|
| Effective: | 1996 |
| Control Action: | Registration no longer permitted. Stocks can be used only until 12/10/1999. |

| | |
|---------------------|--|
| Uses still allowed: | None. |
| Reasons: | Induces harmful effects on human beings and the environment. |

KUWAIT

| | |
|---------------------|----------------------------------|
| Effective: | 1980 |
| Control Action: | The substance is banned for use. |
| Uses still allowed: | No remaining uses are allowed. |
| Reasons: | |

SAMOA

| | |
|---------------------|--|
| Effective: | 1995 |
| Control Action: | Registration declined 84/1992. Review declined 26/5/1994; Notification PIC 27/7/11 |
| Uses still allowed: | None. |
| Reasons: | Significant health hazard to users. |

SRI LANKA

| | |
|---------------------|--|
| Effective: | 1995 |
| Control Action: | Severely restricted. The import of methamidophos formulations higher than 600 been prohibited since July 1995. |
| Uses still allowed: | |
| Reasons | |

Annex 3 - List of Designated National Authorities

INDONESIA

| | | |
|--|---------------|------------|
| P | Phone | 62 (21) 78 |
| Chairman | | 78 |
| Direktorat Bina Perlindungan Tanaman Pesticide Committee, Jln. AUP. Pasar Minggu 12520 Jakarta | Fax | 6 |
| | Telex | |
| | e-mail | |
| CP | Phone | 021 5 |
| Bapedal Offices , Ms. Masnellyarti Hilman | Fax | 021 57 |
| Arthaloka Building, 11th Floor, Jl. Jend Sudirman No. 2 Jakarta Pusat | Telex | 62 21 5 |
| | e-mail | |

KUWAIT

| | | |
|---|---------------|--------------|
| P | Phone | (965) 24 |
| Public Authority for Agriculture Affairs & Fish Resources Plant Wealth Department, Safat 13075 Kuwait P.O. Box 21422 | Fax | |
| | Telex | |
| | e-mail | |
| CP | Phone | (965) 24 |
| The Secretary General | | 24568 |
| Environment Protection Council , Safat 13104 Kuwait P.O. Box 24395 | Fax | (965) 24 |
| | Telex | 46408 EP CNC |
| | e-mail | |

SAMOA

| | | |
|---|---------------|---------|
| P | Phone | (685) . |
| Director | Fax | (685) . |
| Ministry of Agriculture, Forests, Fisheries and Meteorology , Apia P.O. Box 1874 | e-mail | |

SRI LANKA

| | | |
|---|---------------|---------|
| P | Phone | 94 (08) |
| Registrar of Pesticides | Fax | 94 (08) |
| Pesticides Registration Office , Getambe | Telex | |
| Peradeniya P.O. BOX 49 | e-mail | |

Annex 4 - References

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

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