Rotterdam Convention - Operation of the Prior Informed Consent Procedure for Banned or Severely Restricted Chemicals

Decision Guidance Documents

Binapacryl

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

Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Mandate

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was adopted at the Conference of Plenipotentiaries held in Rotterdam on 10 and 11 of September 1998. The Rotterdam Convention entered into force on 24 February 2004.

At its 6th session, held in Rome on 12-16 July 1999, the Intergovernmental Negotiating Committee adopted a decision guidance document for binapacryl (Decision INC-6/3) with the effect that this chemical became subject to the interim PIC procedure.

At its first meeting, held in Geneva 20 to 24 September 2004, the Conference of the Parties agreed to include binapacryl in Annex III of the Rotterdam Convention, with the effect that this chemical became subject to the PIC procedure.

The present decision guidance document for binapacryl was communicated to the Designated National Authorities on 1 February 2005 with the request that they submit a response concerning the future import of these two chemicals to the Secretariat in in accordance with Article 7 and 10 of the Rotterdam Convention.

Purpose of the Decision Guidance Document

For each chemical included in Annex III of the Rotterdam Convention a decision guidance document has been approved by the Conference of the Parties. Decision guidance documents are sent to all Parties with a request that they provide a decision regarding future import of the chemical.

The decision guidance document is prepared by the Chemical Review Committee (CRC). The CRC is a group of government designated experts established in line with Article 18 of the Convention, that evaluates candidate chemicals for possible inclusion in the Convention. The decision guidance document reflects the information provided by two or more Parties in support of the national regulatory actions to ban or severely restrict the chemical. It is not intended as the only source of information on a chemical nor is it updated or revised following its adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical as well as others that have not banned or severely restricted it. Such risk evaluations or information on alternative risk mitigation measures submitted by Parties may be found on the Rotterdam Convention web-site.

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website (www.pic.int).

Information on the chemical may also be available from other sources.

Disclaimer

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 any 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 in this document.

While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) disclaim any responsibility for omissions or any consequences that may flow therefrom. Neither FAO or UNEP 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 this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

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

<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
µg	Microgram
a.i.	active ingredient
ACGIH	American Conference of Governmental Industrial Hygienists
ADI	acceptable daily intake
ADP	adenosine diphosphate
ATP	adenosine triphosphate
BBA	Biologische Bundesanstalt für Land- und Forstwirtschaft
b.p.	boiling point
Bw	body weight
°C	degree Celsius (centigrade)
CA	Chemicals Association
CCPR	Codex Committee on Pesticide Residues
CHO	Chinese hamster ovary
D	Dust
EC	Emulsifiable concentrates
EC50	Effect concentration, 50%
ED50	Effect dose, 50%
EHC	Environmental Health Criteria
ERL	Extraneous residue limit
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	Gram
GAP	Good agricultural practice
GL	Guideline level
GR	Granules
ha	Hectare
i.m.	Intramuscular
i.p.	Intraperitoneal
IARC	International Agency for Research on Cancer
IC50	Inhibition concentration, 50%;

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT	
IPCS	International Programme on Chemical Safety
IRPTC	International Register of Potentially Toxic Chemicals
IUPAC	International Union of Pure and Applied Chemistry
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 1000)
kg	Kilogram
Koc	Organic carbon-water partition coefficient
l	Litre
LC_{50}	Lethal concentration, 50%
LD_{50}	Lethal dose, 50%
LOAEL	Lowest observed adverse effect level
LD_{LO}	Lowest lethal dose
LOEL	lowest observed effect level
m	Metre
m.p.	melting point
mg	Milligram
ml	Millilitre
mPa	MilliPascal
MRL	maximum residue limit
MTD	maximum tolerated dose
NCI	National Cancer Institute
ng	Nanogram
NIOSH	National Institute of Occupational Safety and Health
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
OP	organophosphorus pesticide
PHI	pre-harvest interval
PIC	prior informed consent
Pow	octanol-water partition coefficient
POP	persistent organic pollutant
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).
RfD	reference dose for chronic oral exposure
SBC	secretariat for the Basel Convention
SC	Soluble concentrate
SG	water soluble granules

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT	
SL	soluble concentrate
SMR	standardized mortality ratio
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
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
VOC	volatile organic compound
WHO	World Health Organization
WP	wettable powder
Wt	Weight

PIC - Decision guidance document for a banned or severely restricted chemical

Binapacryl

Published: 1 September 1999
Reissued: 1 February 2005

Common name	Binapacryl (ISO)
Other names/ synonyms	2-*sec*-butyl-4,6-dinitrophenyl 3-methylcrotonate (IUPAC); 2-(1-methylpropyl)-4,6-dinitrophenyl-3-methyl-2-butenoate (CA).
CAS No.	485-31-4
Use category	Pesticide
Use	Binapacryl is used as a fungicide and miticide.
Trade names	Ambox, Acricid, Dapacryl, Endosan, Hoe 2784, Morocid, Morrocid, Niagara 9044
Formulation types	Emulsifiable concentrates (EC), wettable powders (WP).
Basic manufacturer	Hoechst (up to 1987). Currently no production or identifiable manufacturer.

Reasons for inclusion in the PIC procedure

Binapacryl is included in the PIC procedure as a pesticide. Inclusion was recommended at the eighth meeting of the FAO/UNEP Joint Group of Experts on Prior Informed Consent following detailed discussions during the sixth and seventh meetings. It is included in the procedure on the basis of the control actions reported by a number of Governments.

Summary of control actions (see Annex 2 for details)

Control actions were reported by 9 countries and the European Union. In 7 countries (Angola, Cyprus, India, Kuwait, Pakistan, Slovenia and Thailand) and in the European Union binapacryl was reported as banned. In 2 countries (Austria and New Zealand) the substance was reported as withdrawn by the producer. No remaining uses were reported. All countries listed concern about the effects of binapacryl on human health as a primary reason for the control actions.

Hazard classification by Organization

<table>
<tr><td>WHO

(WHO,1996)</td><td colspan="5">Technical product: Class II (moderately hazardous),classification based on an oral LD_{50} of 421 mg/kg bw.</td></tr>
<tr><td></td><td colspan="5">Classification of formulations</td></tr>
<tr><td></td><td></td><td colspan="2">oral toxicity</td><td colspan="2">dermal toxicity</td></tr>
<tr><td></td><td></td><td colspan="2">LD_{50}: 58 mg/kg bw (see Ann. 1)</td><td colspan="2">LD_{50}: 750 mg/kg bw (see Ann. 1)</td></tr>
<tr><td></td><td>Formulation</td><td>a.i. (%)</td><td>Hazard class</td><td>a.i. (%)</td><td>Hazard class</td></tr>
<tr><td></td><td>Solid</td><td>>10
<10</td><td>II
III</td><td>>70
<70</td><td>II
III</td></tr>
<tr><td>USEPA</td><td colspan="5">Not classified.</td></tr>
<tr><td>EU</td><td colspan="5">Toxic, teratogen cat.2. (T: R61 (Repr. Cat. 2); Xn: R21/22) (classification in accordance with Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances).</td></tr>
<tr><td>IARC</td><td colspan="5">Not classified.</td></tr>
</table>

Protective measures that have been applied concerning the chemical

Measures to reduce exposure

For the health and welfare of workers and the general public, the handling and application of the substance 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 evaluations. Protective clothing as indicated in the *FAO Guidelines for Personal Protection when Working with Pesticides in Tropical Climates* (1990) is required.

Packaging and labelling

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

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard class 6.1	Poisonous substance.
Packing group 3	Harmful substances and preparations presenting a relatively low risk of poisoning. (IPCS/CEC, 1993)

Alternatives

India indicated specific alternatives (see Annex 2).

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 designated national authority in the country where the alternative has been reported (see addresses of designated national authorities in Annex 3). It would then be necessary to determine the compatibility with national crop protection practices.

Waste disposal

Waste should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal and any guidelines thereunder (SBC, 1994).

See the FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks (1995) and The Pesticide Storage and Stock Control Manual (1996).

Wear protective clothing and respiratory equipment suitable for toxic materials. Sweep, scoop or pick up spilled material. Vacuuming or wet sweeping may be used to avoid dust dispersal. Do not flush to surface water or sanitary sewer system. Dispose of empty containers in a sanitary landfill or by incineration.

It should be noted that the methods recommended in literature are often not suitable in a specific country. High temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies.

Exposure limits

	Type of limit	Value
Food	MRLs (Maximum Residue Limits in mg/kg) in specified products *(FAO/WHO, 1983).*	MRL withdrawn.
	JMPR ADI (Acceptable Daily Intake) in mg/kg diet *(FAO/WHO, 1983).*	ADI withdrawn.

First aid

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

Eyes: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower lids.

Skin: Flush skin with plenty of soap and water for at least 15 minutes before removing contaminated clothing and shoes. Seek medical attention immediately.

Ingestion: Do not induce vomiting. Have the victim rinse his or her mouth and then drink 2-4 cupfuls of water, and seek medical advice.

Inhalation: Remove from exposure into fresh air immediately.

Annexes

Annex 1 - Further information on the substance

1 Chemical and physical properties

1.1	Identity	Pale yellow to brownish crystals.
1.2	Formula	$C_{15}H_{18}N_2O_6$
	Chemical name	2-(1-methylpropyl)-4-,6-dinitrophenyl-3-methyl-2-butenoate (CA)
	Chemical type	Nitrophenol
1.3	Solubility	Solubility in water is low to moderate (11%) in ethanol, but exceeds 50 percent in heavy aromatic naphta and acetone (*Spencer, 1982*).
	$\log K_{ow}$	4.75 (estimate) (*USEPA, 1987*)
1.4	Vapour pressure	13 mPa at 60 °C *(Worthing and Walker, 1987)*
1.5	Melting point	66-67 °C (*Weast, 1989*)
1.6	Reactivity	It is readily hydrolized by strong acids or dilute alkalis; a small degree of hydrolysis will occur in water after prolonged contact. Decomposes slowly by UV irradiation *(Worthing and Walker, 1987; RSC, 1983).*

2 Toxicity

2.1 General

2.1.1	Mode of action	Binapacryl is a dinitrophenol and acts by uncoupling or inhibiting oxidative phosphorylation, which basically prevents the formation of the high-energy phosphate molecule, adenosine triphosphate (ATP) *(Ware, 1997)*. The basic mechanism of toxicity is stimulation of oxidative metabolism in cell mitochondria by interference with the normal coupling of carbohydrate oxidation to phosphorylation (ADP to ATP). Increased oxidative metabolism leads to hyperthermia, tachycardia and dehydration and in time depletes carbohydrate and fat stores.
2.1.2	Uptake	Most nitrophenols and nitrocresols are well absorbed from the gastrointestinal tract through the skin, and by the lungs when fine droplets are inhaled. Fatal poisonings have occurred as a result of dermal contamination (*Morgan, 1989*).
2.1.3	Metabolism	Nitrophenols and nitrocresols undergo some biotransformation in humans, mainly reduction (one nitro group to an amino group) and conjugation at the phenolic site. Although nitrophenols and metabolites appear consistently in the urine of poisoned individuals, hepatic excretion is probably the main route of disposition. Elimination is slow: residence half-life in humans is 5-14 days. Blood and tissue concentrations tend to increase progressively if an individual is substantially exposed on successive days *(Morgan, 1989)*.

2.2 Known effects on human health

2.2.1 Acute toxicity

Symptoms of poisoning

Nitroaromatic compounds are highly toxic to humans and animals. Nitrophenols and nitrocresols are toxic to the liver, kidney and nervous system. Most severe poisonings from absorption of these compounds have occurred in workers working in hot environments. Hyperthermia and direct action on the brain cause cerebral oedema, manifesting clinically as a toxic psychosis and sometimes as convulsions. Liver parenchyma and renal tubules show degenerative changes. Albuminuria, pyuria, hematuria and azotemia are prominent signs of renal injury (*Morgan, 1989*).

Neutropenia has occurred in humans following heavy exposure to dinitrophenol. Cataracts occur in laboratory animals given nitrophenols, and have occurred in humans, both as a result of ill-advised medicinal use and as a consequence of occupational exposure. Cataract formation is sometimes accompanied by glaucoma *(Morgan, 1989)*.

Yellow staining of skin and hair often signifies contacts with a nitroaromatic chemical. Staining of the sclerae and urine indicates absorption of potentially toxic amounts. Profuse sweating, headache, thirst, fever, confusion, malaise and lassitude are common early symptoms of poisoning. Warm, flushed skin, tachycardia and tachypnea indicate a serious degree of poisoning. Restlessness, apprehension, anxiety, manic behaviour or unconsciousness reflect cerebral injury. Convulsions signify an immediate life-threatening intoxication. Laboured breathing and cyanosis are consequences of stimulated metabolism and tissue anoxia. Weight loss occurs in persons continually exposed to relatively low doses of nitrophenols or nitrocresols *(Morgan, 1989)*.

2.2.2 Short and long- term exposure

There are no short and long-term exposure studies on effects on human health related only to binapacryl.

2.2.3 Epidemio-logical studies

There are no epidemiological studies on effects on human health related only to binapacryl.

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

2.3.1 Acute Toxicity

oral	LD_{50} (mg/kg): 58–200 (different test species), *(Gaines, 1969); (Spencer, 1982)*.
Dermal	LD_{50} (a.i.; mg/kg): 720 in rats *(World review of pest control, 1970),* LD_{50} (mg/kg): 750 in rabbits (*Spencer, 1982).*
Inhalation	Inhalation may result in toxic effects on humans *(Sax, 1975).*
irritation	Except in a few sensitive individuals, it is only moderately irritating to the skin and mucous membranes.

2.3.2	Short and long-term exposure	Six-month studies with rats fed with binapacryl concentrations up to 500 ppm in the diet showed pathological alterations at concentrations higher than 200 ppm *(Worthing and Walker, 1987).*
2.3.3	Long-term exposure	Rats were fed with a diet containing binapacryl up to 200-500 mg/kg and dogs with a diet containing 20-50 mg/kg for two years. No effect on morbidity or mortality due to binapacryl was found *(Worthing and Walker, 1987)*.
2.3.4	Effects on reproduction	In a multigeneration study on binapacryl in rats the reproductive performance, as measured by the indices of mating, pregnancy, fertility, parturition and lactation, was not influenced by feeding with the substance *(Kennedy and Calandra., 1965)*. In rat studies, where three generations were fed with a diet containing up to 60 ppb binapacryl, no effect on reproduction could be observed *(FAO/WHO, 1983).*
2.3.5	Embryo-toxicity and teratogenicity	In groups of 11-12 pregnant female New Zealand rabbits, which received binapacryl by gavage, there were no statistically significant differences between control and treated groups with respect to mean values of *corpora lutea*, implantations, live and dead foetuses, early and late resorptions or live foetal weight. Placenta weight was slightly decreased in the 5.0 mg/kg bw group, but the difference was not toxicologically relevant because all other findings were normal. Foetuses with externally visible malformations were one in the control and one in the 5.0 mg/kg bw group *(FAO/WHO, 1983)*.
2.3.6	Mutagenicity	Binapacryl was positive in *Salmonella typhimurium* TA100 without metabolic activation *(RSC, 1987)*.
2.3.7	Carcino-genicity	Rats administered 500 mg/kg in diet for 2 years and dogs receiving 50 mg/kg in diet for 2 years showed no ill effects *(Worthing and Walker, 1987)*.

3 Exposure

3.1	Occupational	Two workers developed headache, nausea, vomiting, abdominal pain, diarrhoea, and breathing difficulties after spraying tomatoes with binapacryl for 2 hours. Fever, weak pulse, and tremor were noted later. Recovery was complete within a week (*Hayes, 1982*).

4 Effects on the environment

4.1	Fate	If released to soil, binapacryl may undergo slow hydrolysis in basic soils *(RSC, 1983; Goring et al., 1975).* If released to water, binapacryl is expected to undergo slow hydrolysis to dinoseb under basic conditions *(RSC, 1983).* Binapacryl is known to slowly decompose under the influence of UV light *(RSC, 1983)* and it may undergo photolysis in the atmosphere. An estimated rate constant for the gas-phase reaction of binapacryl with photochemically produced hydroxyl radicals leads to an estimated half-life of 4.63 hours in the ambient atmosphere *(Goring et al., 1975).*
4.1.1	Persistence	Binapacryl, a dinitrophenol ester, probably hydrolyzes to form free phenol, identical in structure to the herbicide dinoseb. Only after such a transformation might there be some potential for leaching *(McBride et al.).*

4.1.2	Bioconcentration	Based on an estimated log octanol/water partition coefficient of 4.75, a calculated bioconcentration factor of 2400 can be calculated for binapacryl using an appropriate regression equation. The magnitude of this value indicates that binapacryl may significantly bioconcentrate in fish and aquatic organisms *(Lyman et al., 1982).*

4.2 Ecotoxicity

4.2.1	Fish	Binapacryl is highly toxic to fish ; (LC_{50} : 0.04 – 0.06 mg/l) (*Mayer and Ellersieck, 1986*).
4.2.2	Aquatic invertebrates	Binapacryl is toxic to aquatic organisms. *Asellus brevicaudus* (96 hours) 29 μg/l at 16 °C as the technical material (*Mayer and Ellersieck, 1986)*.
4.2.3	Birds	There are no studies on effects on birds related only to binapacryl.
4.2.4	Bees	Not toxic to bees (*Spencer, 1982).*

Annex 2 - Details on reported control actions

ANGOLA

Effective:	1990
Control action:	Banned for use. No remaining uses allowed.
Reasons:	Banned for use in agriculture for toxicological reasons.
Alternatives:	Presently not known.

AUSTRIA

Effective:	1993
Control action:	Voluntarily withdrawn by manufacturer since July 1991. All uses banned as of 01.01.93.
Reasons:	High acute human toxicity (probable oral lethal dose 5-50 mg/kg; for a 70 kg person: between 7 drops and 1 teaspoon).
Alternatives:	Many alternatives for designated purposes.

CYPRUS

Effective:	1987
Control action:	Banned for all use as a pesticide. No remaining uses allowed.
Reasons:	Risk associated with birth defects and male sterility.

EUROPEAN UNION

Effective:	1990
Control action:	The placing on the market and the use of all plant protection products containing binapacryl as an active ingredient is prohibited.
Reasons:	Binapacryl is likely to give rise to harmful effects on human and animal health (close chemical relationship to dinoseb). The chemical showed mutagenic effects in animal testing. Binapacryl has been classified by the EC as a category 2 reproductive toxin (probably causing developmental damage to humans).

(Member States of the European Union are: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom.)

INDIA

Effective:	1975
Control action:	Refused registration.
Reasons:	Since it is moderately irritant to eyes and its effective and safer substitutes are available.
Alternatives:	Dicofol, Dinocap, Tridemorph.

KUWAIT

Effective:	1975
Control action:	Banned for use as a pesticide. No remaining uses allowed.
Reasons:	Action was taken because safe alternatives are available.

NEW ZEALAND

Effective:	1986
Control action:	Voluntary withdrawal of all products, registrations cancelled. No uses allowed.
Reasons:	Human health reasons (teratogenicity and possible carcinogen).

PAKISTAN

Effective:	1990
Control action:	Prohibited. No remaining uses allowed.

SLOVENIA

Effective:	1997
Control action:	Banned for use in agriculture.
Reasons:	This chemical was banned from the use in agriculture due to the effect of its toxic properties to human health and the environment according to the opinion given by the Commission on Poisons.

THAILAND

Effective:	1995
Control action:	All use categories have been banned.
Reasons:	Possibly carcinogenic and teratogenic in test animals.

Annex 3 – List of designated national authorities

ANGOLA

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Le Coordinateur
Programme national de la protection des plantes
Ministère de l'Agriculture, Cabinet technique
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CP DNA Industrial chemicals and pesticides
P DNA Pesticides
C DNA Industrial chemicals

Annex 4 - References

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