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MONOCROTOPHOS

DOCUMENTATION FROM HUNGARY

Note by the secretariat

1. This note contains, in the annex, the documentation provided by Hungary in conjunction with their submitted notification of final regulatory action on monocrotophos.

ANNEX

MONOCROTOPHOS IN HUNGARY

Introduction

Azodrin 40 WSC (active ingredient: 40 % monocrotophos) has been registered in Hungary in 1971. At first, its use was registered only against pests of sugarbeet, later (in 1974) the registration was extended to sunflower, *Solanum nigrum*, and, in 1975 to soybean, maize and alfalfa.

When this product first registered, it was not a practice to make preliminary wildlife toxicity tests with a pesticide or on a pest management method. Therefore, risk to wildlife posed by Azodrin 40 WSC became evident only later, when the product was widely used.

The risk to wildlife was confirmed by wildlife toxicity tests made in pilot farms and large-scale farms at the Nature and Wildlife Conservation Station (Fácánkert, Hungary) in 1976-1980. In addition, a number of reports obtained from users, hunters, and environmentalists indicated an extreme risk imposed by the formulation and its application.

Consequently, the registration for use of Azodrin 40 WSC was modified in 1982. The uses and time of application, as well as the quantity to be applied on unit area were restricted. Thus, it was allowed to use in a maximum volume of 0.75-1.0 l/ha to control the seedling pests of sugarbeet and maize grown in blocks, crops with **poorer wildlife populations**. This measure seemed, however, **could not eliminate the risk Azodrin 40 WSC posed to wildlife, only reduced it to a lower number wild birds, than before.**

Having regard to the fact that the risk to wildlife of Azodrin 40 WSC still exists in spite of the reduction of the application rate and restriction on the uses, the registration was withdrawn in 1996 in Hungary. The registration documents of the products with active ingredients belonging to this particular group have been reviewed in compliance with the ministerial communiqué 1994/20 by the Plant Protection and Agro-environmental Department of the Ministry of Agriculture and Food, published in the Official Journal of the Ministry. In compliance with Annex 11 to Ministerial Decree 6/2001 FVM, monocrotophos is on the list of banned active ingredients.

No pest management interests are hurt by the ban on the use of the product, because efficient wildlife-friendly formulations (e.g. Bancol, Dimecron 50) are available for the control of weevils (*Bothynoderes punctiventris*, *Psolidium maxillosum*, *Tanymecus dilaticollis*, *Tanymecus palliates*), which are actually managed by Azodrin 40 WSC.

Manufacturing and uses

Share of monocrotophos products in global insecticide production is about 3%, 40 % of which is made by Syngenta.

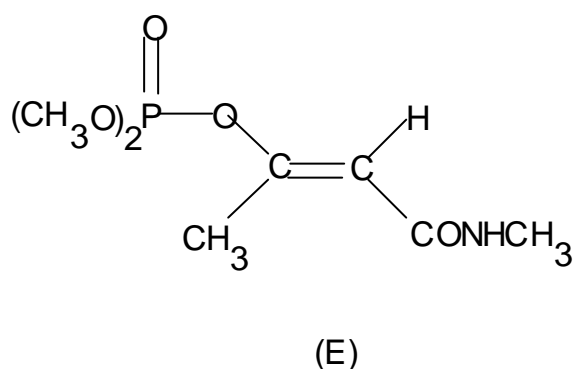
The active substance is registered for use in about 60 countries. Among them 8 countries are responsible for 60% of the global trade.

Chemical properties

CAS RN: 6923-22-4; 2157-98-4 (mixture of isomers).

Chemical name (IUPAC name): dimethyl (E)-1-methyl-2-(methylcarbamoyl)vinyl phosphate.

Structural formula:



Physical properties

Odour: mild ester odour; *colour*: colourless; (technical: not less than 74%: reddish-brown),

Physical state: hygroscopic crystals (technical: semi-solid)

Stability: decomposes > 38 °C, thermal run-away reactions can occur >55 °C.

Hydrolysis: 96 d (pH 5), 66 d (pH 7), 17 d (pH 9); unstable in short-chain alcohols.

Solubility: in water 100% (20 °C), in methanol 100%, acetone 70%, n-octanol 25%, toluene 6 % (all at 20 °C), sparingly soluble in kerosene and diesel oil.

Agricultural assessment

Efficacy: of the monocrotophos-containing insecticides, Azodrin 40 WSC (Shell, UK; Agrokémia Szövetkezet, Hungary) was registered, with a rate of 0.75-1.0 l/ha, to control *Bothynoderes*

punctiventris, *Psallidium maxillosum*, *Tanyemecus dilaticollis*, *Tanyemecus palliatus* in emerging sugarbeet and maize grown in blocks if applied within 30 days of the sowing date.

Nuvacron 40 WSC (Ciba-Geigy AG, Switzerland; Nitrokémia Ipartelepek, Hungary) with the same active ingredient was registered in sugarbeet against *Aphis fabae*, *Bothynoderes punctiventris*, *Chaetocnema tibialis*, *Pegomya betae*, *Lixus scabricollis* (rate: 0.75-1.25 l/ha), *Psallidium maxillosum* (rate: 1.0-1.25 l/ha), *Scrobipalpa ocelatella* (rate: 1.5 l/ha), *Mamestra brassicae* (rate: 1.5-2.5 l/ha) and spider mites (*Tetranychus urticae*) (rate: 1.5-2.0 l/ha). In maize it was registered with a rate of 0.75-1.25 l/ha and 1.5 l/ha against *Tanyemecus dilaticollis* and *Oscinella frit*, resp. In maize and soybeans, the following rates were registered to control different pests: larvae of noctuids 1.5-2.0 l/ha, spider mites 1.5-2.0 l/ha, while in sunflower and soybeans 1.75-1.25 l/ha was registered against *Tanyemecus* spp., *Psallidium maxillosum* and *Sitona* spp. For the control of *Leptinotarsa decemlineata*, 2.4-2.8 l/ha was registered in *Solanum nigrum*. Both products were authorized for only large-scale farms use.

Biological efficacy of the products was good against the above pests. They were especially good in controlling high population of *Bothynoderes punctiventris*, *Psallidium maxillosum*, *Tanyemecus dilaticollis*, *Tanyemecus palliatus* established during the period of plant emergence.

Monocrotophos was registered in the following crops: sugarbeet, sunflower, *Solanum nigrum*, maize, soybean, alfalfa

Toxicological assessment

Acute toxicity

Monocrotophos is a systemic organophosphorus compound of acaricide and insecticide effect. It is highly toxic to mammals and birds. Monocrotophos is a cholinesterase inhibitor of direct effect. Highly toxic if swallowed, inhaled or absorbed through the skin. In case of direct contact or inhalation, the effects emerge with delay.

Symptoms: excessive sweating, weakness, nausea, vomit, stomach complaints, diarrhoea, excessive mucous secretion, dim sight, narrow pupils, arrhythmia.

Effects on the nervous system: headache, giddiness, muscle activity disturbances (tongue, eye, respiratory muscles), jerk, spasm, paralysis of extremities and respiratory muscles, in many cases involuntary urination and defecation, psychosis, coma, death due to respiratory disturbances.

Chronic toxicity:

The substance may cause delayed neuropathy. Sensory and reflex disturbances may break out. It has no teratogenic, mutagenic, and carcinogenic effect. Chromosome aberrations were observed in the peripheral lymphocytes in humans.

Metabolism:

The substance is of quick metabolism and passage, there is no accumulation. In mammals, 60-65% is excreted within 24 hours, especially with urine.

Toxicity

Oral acute LD₅₀: 17-18 mg/kg (male rats)

Oral acute LD₅₀: 20 mg/kg (female rats)

Dermal LD₅₀: 126 mg/kg (male rats)

Dermal LD₅₀: 112 mg/kg (female rats)

Dermal LD₅₀: 354 mg/kg (rabbits)

LC₅₀ (4 h): 0.08 mg/l (rats)

ADI: 0-0.0006 mg/kg bw

NOEL (2y) (estimated by WHO, JMPR, 1972): for rats 0.5 mg/kg diet (0.025 mg/kg daily); for dogs 0.5 mg/kg diet (0.0125 mg/kg daily)

EU hazard symbols: T+, N

R24-28-50/53

S1/2-23-36/37-45-60-61

Conclusion for public health:

Monocrotophos has no human teratogenic, mutagenic, carcinogenic effects.

Occupational health and safety assesment:

Occupational exposition limits: TLV-TWA: 0.25 mg/m³

Environmental assesment:**Ecotoxicology**

Highly toxic to birds and bees, moderately toxic to aquatic organisms (fish, crustacea, etc.)

Environmental fate

The substance does not accumulate in the soil. Its half life in the soil (with sunlight) is less than 7 days, at 25 °C, pH=9: 14-21 days, in darkness about 30 days.

Data on acute (p.o. LD₅₀; ALD) and subchronic (LC₅₀) toxicity of monocrotophos and Azodrin 40 WSC on wild species*Acute oral toxicity of monocrotophos (p.o. LD₅₀)*

California quail	0,76 mg/kg
Bobwhite quail	0,94 mg/kg
Canada goose	1,58 mg/kg
European starling	3,3 mg/kg
Mallard ducks	4,76 mg/kg

Azodrin 40 WSC (a.i. 40 % monocrotophos)

<i>Phasianus colchicus</i>	ALD value lower than 1 mg/kg
<i>Lepus europeus</i>	ALD value 55 mg/kg

LC₅₀ of 8-day dietary tests of Azodrin 40 WSC:

<i>Phasianus colchicus</i>	29 ppm
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According to the determined acute and subchronic toxicity data, both monocrotophos and Azodrin 40 WSC are extremely toxic to wild species.

TER_a value (theoretical exposure rate)

The value of TER_a of different wild species in various crops, based on data of LD₅₀ of Azodrin 40 WSC related to monocrotophos:

	Alfalfa	Sugarbeet	Maize
California quail	0.081	0.076	0.870
Mallard duck	0.410	0.384	4.407
Pheasant	0.086	0.081	0.926

It is clear from the obtained values that they all are much below 10 indicating that application of the active ingredient poses risk independently from the crops.

Effect of monocrotophos and its clinical symptoms on pheasants

Similarly to the organophosphate derivatives, monocrotophos is well absorbed from the digestive canal through the respiratory epithelium and the skin. Reaching the circulatory system, the poison acts by inhibiting the acetylcholinesterase enzyme, leading to muscarine, nicotine and central nerve system types of symptoms. The muscarine-like action takes place at the postganglionic nerve ends and causes mainly the accelerated activity of glands and smooth muscles. Accordingly, the following symptoms appear in the poisoned animals: salivating, vomit, diarrhoea, abdominal pains, lachrymation, sweating, frequent urination and dyspnoea (bronchus spasm). Pupils are greatly narrowed and sight disturbance develops.

The nicotine-like action develops at the motor nerve ends and results in fascicular jerks, myasthenia and paralysis in the striated muscles.

The effect on the central nerve system is first stimulating then paralyzing. Accordingly, the following symptoms appear in the poisoned animals: tremble, uncoordinated movement, generalized eclampsia, then coma. In addition, chronic cardiac weakness and pulmonary oedema may also develop in the poisoned animals. Death is caused by respiratory paralysis.

Severity of poisoning is mainly determined by the quantity of the active ingredient reaching the pheasant's organism. It is influenced by several factors in the various treatments: mode and time of the application of the product, weather conditions, treated crops and growth stage.

The observed clinical symptoms are typical for the organophosphates: frightened and alarmed movement, head jerk, salivating, frequent swallowing of saliva, motion reminding eventual regurgitation, "penguin posture", unbalanced, unsteady walking, trembling stand. Death is preceded by abasia, tremble, muscle jerk and generalised eclampsia. Symptoms appear 0.5-6 hours after spraying. In addition to animals' death, the more severe effect is that the poisoning is prolonged (lasts 6-12 days) preventing the animals' feeding, egg laying, hatching and causes progeny deficiency. The animals inhibited in hiding and escaping have no chance for surviving.

Summary of results obtained during studying toxicity to wildlife of Azodrin 40 WSC

In addition to the acute and subchronic studies, wildlife toxicity tests were made in pilot farms and large-scale farms with Azodrin 40 WSC (40% monocrotophos) as well as with Dimecron 50 (50% fosfamidon) and Bancol 50 WP (50% bensultap) which can be efficiently used for the control of *Bothynoderes punctiventris*, *Psallidium maxillosum*, *Tanymecus dilaticollis*, *Tanymecus palliates*.

Pilot farm tests:

1) Azodrin 40 WSC damaged both the pheasant chickens and the adult animals in alfalfa, sugarbeet, and oilseed rape of high density. The product caused prolonged illness to the majority of the animals and caused deaths of a part of them (Tables 1 and 2).

2) Comparative toxicity study of Azodrin 40 WSC-Azodrin ULV and Dimecron 50-Dimecron 25 ULV to pheasant chickens (10 weeks) and adults in alfalfa. Under the experimental conditions, in the rate recommended for use (2,0 l/ha) Azodrin 40 WSC caused prolonged illness to 86,7 % of the pheasant chickens, inhibited the development and caused 6,3 % mortality. Among the adult pheasants, 71 % of the animal was diseased, with no death.

- Dimecron 50 (rate: 1,5 l/ha) caused illness to only 6% of pheasant chickens with no death, while to 7 % of adults, with no death.

- Bancol 50 WP (rate: 1,0 kg/ha and 3,0 kg/ha) caused neither clinical symptoms showing health injury, nor deaths in young pheasants (6-8 weeks) in alfalfa. Increase of bodyweights of the animals was similar to that of the control group.

- Wildlife toxicity of Azodrin 40 WSC was also studied in emerging maize of low crop density because there is a slighter possibility for exposition than in crops with high density. In a pilot farm study made in maize with adult pheasants (rate: 1,3 l/ha), 30 % of the animals were diseased with 1,5 % mortality.

Table 1. Clinical symptoms and mortality caused by Azodrin 40 WSC on pheasants in pilot farm studies (alfalfa, sugarbeet, and oilseed rape).

Treated crops	Rate (l/ha)	Age of pheasants	Morbidity (rate of diseased animals)	Mortality (rate of death)
Alfalfa	2.0	10 weeks	86.7 % (60:52)	6.7 % (60: 4)
	6.0	10 weeks	90.0 % (20:18)	25.0 % (20: 5)
Alfalfa	2.0	Adult	71.4 % (21:15)	0.0 % (21: 0)
	6.0	Adult	85.7 % (7:6)	14.3 % (7:1)
Sugarbeet	2.5	10 weeks	92.5 % (37:40)	60.0 % (24:40)
	5.0	10 weeks	95.0 % (20:19)	95.0 % (20:19)
Oilseed rape	2.0	5 months	73.3 % (30:22)	0.0 % (30: 0)

Table 2. Clinical symptoms caused by Azodrin 40 WSC-Azodrin ULV, Dimecron 50-Dimecron 25 ULV on pheasants in pilot farm studies in alfalfa

Product	Rate (l/ha)	Clinical symptoms	
		chicken	adult
Azodrin 40 WSC	2.0	52/60 (86%)	15/21 (71%)
Azodrin 40 WSC	6.0	18/20 (90%)	6/7 (86%)
Azodrin ULV	2.0	50/60 (83%)	16/21 (76%)
Azodrin ULV	6.0	19/20 (95%)	6/7 (86%)
Dimecron 50	1.5	4/60 (6%)	1/21 (5%)
Dimecron 50	4.5	8/20 (40%)	1/7 (14%)
Dimecron 25 ULV	3.0	4/60 (6%)	1/21 (5%)
Dimecron 25 ULV	9.0	9/20 (45%)	1/7 (14%)

Table 3. Mortality caused by Azodrin 40 WSC on pheasants in pilot farm studies in alfalfa

Products	Rates (l/ha)	Mortality	
		chicken	adult
Azodrin 40 WSC	2.0	4/60 (6.6%)	0/21 (0.0%)
Azodrin 40 WSC	6.0	5/20 (25.0%)	1/7 (14.3%)
Azodrin ULV	2.0	5/60 (8.3%)	1/21 (4.7%)
Azodrin ULV	6.0	5/20 (25.0%)	1/7 (14.3%)
Dimecron 50	1.5	0/60 (0.0%)	0/21 (0.0%)
Dimecron 50	4.5	1/20 (5.0%)	0/7 (0.0%)
Dimecron 25 ULV	3.0	1/60 (1.6%)	0/21 (0.0%)
Dimecron 25 ULV	9.0	2/20 (10.0%)	0/7 (0.0%)

Wildlife toxicity studies in large-scale farms

Risk by Azodrin 40 WSC was studied in small games with high population number in emerging maize (82 ha, rate: 1.3 l/ha) and in emerging sunflower (60 ha, rate: 1,5 l/ha).

- Pheasants visiting maize and sunflower crops following spraying by Azodrin 40 WSC became ill: they moved less, their reflexes slowed down, squat (if disturbed) in the field, could not fly and could be caught by man.
- Pheasant population visiting areas sprayed with Azodrin 40 WSC was greatly decreased, partly due to the direct lethal effect of Azodrin 40 WSC, partly because a high number of the toxicated animals was killed by predators.
- In addition to pheasants, Azodrin 40 WSC caused death of many other birds of small bodyweight.
- No death of field hares was observed, but 10-20 % of the adults showed clinical symptoms.

Concluding remarks

The wildlife toxicity studies made in pilot farms and large-scale farms clearly confirmed that the use of Azodrin 40 WSC significantly damaged wildlife, first of all the birds. Independently from the age, bodyweight of the animals, and the growth stage of the treated crops, the use of the product causes death to some of the animals, or prolonged poisoning to some others (6-12 days). The poisoned animals are reluctant to stimulus and cannot escape, therefore it is probable that most of them is killed by predators. Additional loss is caused by the fact that the recommended use of the product is at the time of the animals' reproduction, thus the eventually surviving poisoned animals do not feed for several days and do not sit back on the nest, etc.

In Hungary, in addition to pheasants, field hares (*Lepus europeus*) are the most important small game. In the wildlife toxicity studies made in large-scale farms, no hare death was observed, though slightly poisoned adults could be seen (3-4 kg). Therefore it is probable that Azodrin 40 WSC causes death of young hares of small bodyweight. Azodrin 40 WSC has been used in Hungary since 1971. The annually treated acreage is 50-150 000 ha.

Considering the very low population of the died animals and the unborn progeny, the estimated loss in Hungary has amounted to 5-10 million pheasants since the beginning of the use of Azodrin 40 WSC (25 years). The loss in the number of other songbirds and granivorous birds of small bodyweight may be much higher than this value. No pesticide has caused damages of this

extent in Hungary in the natural wild bird population, and the use of Azodrin 40 WSC has a significant role in the actual very low population of small games in our country.

Monocrotophos-containing insecticides were registered for use from 1971 till 1996 in Hungary. By their withdrawal, no lack in the pest management program of the concerned crops (sugarbeet, maize, sunflower, soybean and *Solanum nigrum*) appeared. For their major uses (to control *Bothynoderes punctiventris*, *Chaetocnema tibialis*, and *Tanymecus dilaticollis*), several registered organophosphates insecticides, such as Danatox 50 EC, Dimecron 50, Nurelle D 50/500 EC, Pyrinex 48 EC, Ultracid 40 WP, chlorinated hydrocarbons, e.g., Thiodan 35 EC, Thionex 35 EC, and other active ingredients, e.g. Bancol 50 WP, Padan 50 are available. Regent 80 WG will soon have the registration document, including a very efficient solution of for pest management program. In sugarbeet, maize and sunflower seed-dressing agents containing chloronicotinil have been recently registered which can be successfully applied against pests of young plants, *Bothynoderes punctiventris*, *Psalidium maxillosum*, *Tanymecus dilaticollis*, *Tanymecus palliatus* and *Chaetocnema tibialis*.

The other pests, e.g. *Aphis fabae*, *Pegomya betae*, *noctuids* and *Scrobipalpa ocelatella* can be well controlled with several registered organophosphates and with synthetic pyrethroids with less mammalian toxicity Thus, the rotation has caused no problem in this field, either (replacement of Azodrin 40 WSC).