

CONSIDERATION OF DRAFT DECISIONS GUIDANCE DOCUMENTS FOR
ETHYLENE DICHLORIDE, ETHYLENE OXIDE, MALEIC HYDRAZIDE AND
BROMACIL

Note by the secretariat

Addendum

The secretariat has the honour to submit, in the annex to the present addendum, the draft decision guidance document for the following chemical:

Chemical	CAS number	Category
Maleic hydrazide	123-33-1	Pesticide

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

Maleic hydrazide

Published:

Common name	Maleic hydrazide (ISO)
Other names/ synonyms	6-hydroxy-2H-pyridazine-3-one (IUPAC); 1,2-dihydro-3,6-pyridazinedione (CA); maleic hydrazine; maleic acid cyclic hydrazide.
CAS No.	123-33-1
Use category	Pesticide
Use	The compound is used as a herbicide and plant-growth inhibitor. It is used for the suppression of grass growth on lawns, roadside verges, embankments and amenity areas, and of growth of shrubs and trees. It is also used to inhibit sprouting in potatoes, onions and carrots in storage, to induce dormancy in citrus fruits and as a plant-growth regulator to control growth of tobacco, potatoes, onions, non-bearing citrus, beans, beets, corn, lima beans, peas, strawberries, sugar beets, garlic and tomatoes. It is used to control suckering of tobacco, for weed control and as a sugar content stabilizer in beets.
Trade names	MH, Mazide25, Regulox, Vondalhyd (<i>Tomlin, 1994</i>).
Formulation types	Soluble concentrate (SL); water soluble granules (SG) (<i>Tomlin, 1994</i>). Maleic hydrazide is available as technical grade material containing 97% minimum active ingredient and less than 1% anionic wetting agent. It is also offered for sale as emulsifiable concentrates or wettable powders for agricultural uses in form of its potassium salt or its diethanolamine salt. Products can contain small amounts of hydrazine as impurity (<i>IARC, 1974</i>).
Basic manufacturers	Drexel Chemical Company; Fair Products, Inc.; Rhône-Poulenc; Uniroyal Chemical Company, Inc.; Vitax; Elf Atochem.

Reasons for inclusion in the PIC procedure

Maleic hydrazide 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 have been reported by three countries (Austria, Denmark, Korea) and the European Union. In two countries (Austria, Denmark) maleic hydrazide was reported as banned. The control action reported by the European Union refers only to the following products: products containing, first, maleic hydrazide and its salts, other than its choline, potassium and sodium salts, and, second, choline, potassium and sodium salts of maleic hydrazide containing more than 1 mg/kg of free hydrazine expressed on the basis of the acid equivalent. The Republic of Korea reported that use is restricted, the amount of hydrazine contamination in technical product must not exceed 15 ppm. Concern about the

effects of the substance on the environment, as well as on human health, is indicated as the reason for the control actions by most countries.

Hazard classification by organization

WHO	Technical product: unlikely to present acute hazard in normal use (based on oral toxicity) (<i>WHO, 1996</i>).
EPA	Toxicity class III (<i>Tomlin, 1994</i>).
EU	Not classified.
IARC	Not classifiable as to its carcinogenicity to humans (group 3) (<i>IARC, 1974</i>).

Protective measures that have been applied concerning the chemical

Measures to reduce exposure

For the health and welfare of workers and the public population, 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* (FAO, 1990) is required.

Packaging and labelling

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

Alternatives

The control action of Austria indicated that there were many alternatives for designated purposes, but without specifications. The European Union did not identify alternatives. The sodium, potassium and choline salts of maleic hydrazide which meet the limits on hydrazine in the formulated product are alternatives.

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* and *The Pesticide Storage and Stock Control Manual* (FAO,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 the 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 specified products) CODEX Na and K Salts (FAO/WHO, 1999 ;IPCS, 1996).	15 mg/kg (onion); 50 mg/kg (potato)
	JMPR ADI (Acceptable Daily Intake) in mg/kg diet (FAO/WHO, 1999). Sum of free and conjugated maleic hydrazide expressed as maleic hydrazide. Based on Na or Ka salt, 99.9% pure and containing not more than 1 mg hydrazine/kg.	0.3 mg/kg/day
Workplace	USA (ACGIH) TLV-TWA (Threshold Limit Value, Time-Weighted Average in mg/m ³).	None.

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. Seek medical attention immediately.

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

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**
- 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	White or colourless crystals
1.2	Formula	C ₄ H ₄ N ₂ O ₂
	Chemical name	1,2-dihydro-3,6-pyridazinedione (CA)
	Chemical class	Pyridazinone
1.3	Solubility	4.507 g/l at pH 4.3 at 25°C
	log P_{ow}	-1.96
1.4	Vapour pressure	10 ⁻⁵ Pa at 25 °C
1.5	Melting point	298-300 °C
1.6	Reactivity	Maleic hydrazide is slightly acidic and forms salts with diethanolamine (DEA), triethanolamine and alkalis, but is stable in acidic and basic solutions. It is stable to hydrolysis but is decomposed by strong oxidizing agents with release of nitrogen (<i>USEPA, 1994</i>).

2 Toxicity

2.1 General

2.1.1	Mode of action	A growth retardant which inhibits mitotic division in plants: weeds are killed indirectly by the inhibition of growth (<i>USEPA, 1994</i>).
2.1.2	Uptake	Maleic hydrazide is readily absorbed through all routes of exposure.
2.1.3	Metabolism	Rabbits administered a single dose of 100 mg/kg of maleic hydrazide excreted 43-62% of the dose within 48 hours (<i>Tomlin, 1994</i>). Rats fed ¹⁴ C-maleic hydrazide excreted 76-87% in the urine with lesser amounts in the faeces. Absorption and elimination were rapid (63% excreted in urine within 4 hours of single dose: 43-55% with repeat dosing). No evidence of bioaccumulation in any tissue or organ.

2.2 Known effects on human health

2.2.1 Acute toxicity

Symptoms of poisoning Symptoms of exposure to this compound may include irritation of the skin, eyes, nose and throat. Other symptoms may include convulsions and coma. Exposure may also result in acute central nervous system effects and chronic liver damage (*NTP, 1986*).

2.2.2 Short- and long-term exposure

Inhalation: in general, low acute and cumulative toxicity in man; only a few cases of acute or chronic occupational poisoning reported. Irritation of skin, eyes and upper respiratory tract observed when protective measures were not taken. Sensitization may occur in cases of skin contact.
Ingestion: unknown in man (*Rose, 1980; Brugnon; 1977; Martin, 1982*).

- 2.2.3 **Epidemiological studies** Maleic hydrazide:
There are no adequate epidemiological studies on effects on human health related to maleic hydrazide.
- Hydrazine:
Limited epidemiological studies have not indicated that occupational exposure to hydrazine is a risk for cancer (IARC, 1974).
- 2.3 Toxicity studies with laboratory animals and *in vitro* systems**
- 2.3.1 **Acute toxicity**
- Oral** The oral LD₅₀ for rats ranged from 3800-6800 mg/kg (*Richardson, 1994*).
- Dermal** Maleic hydrazide caused mild dermal irritation. The LD₅₀ for rabbits was calculated to be > 4000 mg/kg (*Richardson, 1994*).
- Inhalation** The inhalation LC₅₀ (1hour) for rats was calculated to be 20 mg/l (*Richardson, 1994*).
- Irritation** Dermal application on rabbit (duration not specified) of 0.5 ml caused mild irritation and 100 mg applied to eyes caused no irritation (*Richardson, 1994*).
- Skin sensitization** Negative results of skin sensitization were observed in guinea pigs (*USEPA, 1994*).
- 2.3.2 **Short-term exposure** The oral LD₅₀ (15 day) for rats was calculated to be in the range of 6300-6680 mg/kg (male and female).
In a 21-day dermal study, potassium salt of maleic hydrazide (KMH) showed no treatment related effects at any dosage level. The NOEL for dermal toxicity is ≥ 1 000 mg/kg/day (*USEPA, 1994*).
- 2.3.3 **Long-term exposure** In a chronic feeding study with rats, potassium salt of maleic hydrazide (KMH) showed decreased body weights as the only effect, with a NOEL or systemic toxicity of 25 mg/kg/day and a LOEL of 500 mg/kg/day. In a chronic study with beagles, reduced body-weight and heart-weight were observed at lower levels of treatment. At the maximum dose (950 mg/kg), additional treatment-related effects included increased thyroid-weight in females and thyroid focal follicular hyperthermy, increased hepatic lobulation and inflammation in both sexes. The NOEL is 29 mg/kg/day of maleic hydrazide (*USEPA, 1994*).
- 2.3.4 **Effects on reproduction** Maleic hydrazide:
Four-generation reproduction study in rats of feeding 5000, 10000, 20000, 50000 ppm of sodium salt of maleic hydrazide showed no effects on fertility, lactation or other reproductive parameters (*Richardson, 1994*).
- In a gavage rats study (6-15th day of gestation), 0, 400, 800, 1200, 1600 mg/kg, with rats killed on day 22 of gestation, no adverse maternal foetotoxicity or teratogenic effects were observed (*Richardson, 1994*).
- In a gavage rabbits study (7-27th day of gestation), 0, 100, 300, 1000 mg/kg/day, no maternal toxicity was observed. 300 or 1000 mg/kg caused malformed scapulae in fetuses indicating a NOEL of 100 mg/kg/day (*Richardson, 1994*).

Hydrazine:

Pregnant Fischer 344 rats were treated with 0 to 10.0 mg/kg intraperitoneally on gestation days 6-15. Dose-related embryo lethality (principle toxic effect) and maternal toxicity were observed at 2 higher doses (*Keller et al., 1982*).

2.3.5 **Mutagenicity**Maleic hydrazide:

Several mutagenicity tests have been conducted using maleic hydrazide, potassium salt of maleic hydrazide (KMH) and diethanolamine salt of maleic hydrazide (DAE). When all are considered, together with the results of all the other toxicological studies, it was concluded that the potential genotoxic hazard is negligible and does not warrant concern (*USEPA, 1994*). It was reported that in one study there are indications that diethanolamine salt of maleic hydrazide (DAE), but not sodium salt of maleic hydrazide (NA), may have reached gonadal tissue to reduce fertility indices (*USEPA, 1982*).

Hydrazine:

Using mouse liver microsomal mutagenicity assay, hydrazine was mutagenic to 5 strains of *Salmonella typhimurium* (*Erbold B. et al., 1976*).

Of the 10 chemicals tested for their abilities to produce novobiocin-resistant mutants in *Hemophilus influenzae*, hydrazine was unique because it induced a high incidence of mutation without killing significant numbers of cells at concentrations tested. Hydrazine may be acting as both mutagen and antimutagen in this system (*Kimball R.F. et al., 1975*).

2.3.6 **Carcinogenicity**Maleic hydrazide:

Maleic hydrazide was administered in daily doses of 1000 mg/kg bw by stomach tube to 36 mice of each sex for 3 weeks, beginning when animals were 7 days old. Then 3000 ppm were mixed directly with diet which was fed *ad libitum* for approximately 18 months. No significant increase in incidence of tumors was observed in comparison with untreated controls (*IARC, 1974*).

No significant increase in number of tumors was observed in 30 rats fed 1% maleic hydrazide in diet for 100 weeks in comparison with that found in 20 control animals (*IARC, 1974*).

Subcutaneous application to mice and rats (100 weeks) of 500 mg/kg weekly showed no difference in tumour incidence as compared to controls (*Richardson, 1994*).

Hydrazine:

Since small amounts of hydrazine were detected in maleic hydrazide formulations (*Bakker, 1983*), and for its agricultural uses maleic hydrazide is sold in the form of its potassium salt or its diethanolamine salt, the carcinogenic properties of hydrazine should be taken into account. Hydrazine is an animal carcinogen and a suspected human carcinogen (*IARC, 1974*).

Adequate oral studies in different strains of mice have demonstrated that hydrazine given mainly as the hydrazine sulphate produces a high incidence of multiple pulmonary adenomas and adenocarcinomas (*IARC, 1974*).

In groups of 19 to 26 male and female BALB/c/Cb/Se mice, the lowest dose used (21 mg) produced an incidence of pulmonary tumours of 54% in males and 32% in females surviving up to 78 weeks, while the incidence was 24% in males and 4% in females of the control groups, mostly between 90 and 100 weeks (*IARC, 1974*).

Hepatomas and hepatocarcinomas have been observed in 3 strains of mice (BALB/c/Cb/Se, CBA/Cb/Se and C3Hb/Cb/Se) treated orally with hydrazine sulphate (*IARC, 1974*).

In a drinking water lifetime study in 40 female C3H mice, with 0.012% of hydrazine sulphate in drinking water, a significant increased incidence of lung tumours and a significant reduction of mammary tumours were observed (*IARC, 1974*).

Hydrazine sulphate does not show initiating activity when administered orally to BALB/c/Cb/Se mice, followed by skin application of croton oil (*IARC, 1974*).

An incidence of 96% with an average of 3 tumours per mouse was observed in 25 newborn mice treated with hydrazine sulphate with doses in the range of 25-600 µg/day by stomach tube (*IARC, 1974*).

Adenomas and adenocarcinomas of the lungs were observed in 21% of males and 28% of females rats exposed to daily doses of respectively 18 mg or 12 mg of hydrazine sulphate by stomach tube for 109 weeks. Hepatic cell sarcomas and spindle cell sarcomas were also observed in males rats. No liver or lung tumours were found in untreated controls (*IARC, 1974*).

No significant increase of tumours in Syrian golden hamsters was observed after oral administration of hydrazine sulphate (*IARC, 1974*).

In a intraperitoneal administration study 30 male and 30 female white mice where injected with hydrazine in physiological saline. Four mice developed reticulum cell sarcomas of the mediastinum and 9 mice developed myeloid leukaemias (*IARC, 1974*).

An increased incidence of lung tumours was also observed in other strains of mice (*IARC, 1974*).

3 Exposure

- | | | |
|-----|-----------------------------|--|
| 3.1 | Food | The amount of maleic hydrazide in potatoes and onions harvested from 1969 to 1973 was reportedly within the established tolerance limits (50 and 15 ppm, respectively), when the herbicide (applied as 58% diethanolamine salt in an inert vehicle) was applied as specified in the label directions (<i>Howard, 1990</i>). |
| 3.2 | Occupational | For two groups of workers exposed to maleic hydrazide (applicators and harvesters) the average was 0.74 µg/hour and 10 µg/hour for high- and low-clearance operators, respectively. NIOSH (Survey 1981-1983) has statistically estimated that 1442 workers are exposed to maleic hydrazide in the USA (<i>Howard, 1990</i>). |
| 3.3 | Environment | Maleic hydrazide may enter the environment from production sites, due to its use on agricultural crops such as tobacco, stored onions, stored potatoes and citrus crops and its use in turf and roadside maintenance (<i>Howard, 1990</i>). |
| 3.4 | Accidental poisoning | Cases of accidental poisoning have not been reported. |

4 Effects on the Environment

4.1 Fate

4.1.1 Persistence If released to soil, maleic hydrazide should be removed by microbial degradation (half-life, days to weeks) and by leaching. Soil half-lives of up to 100 days have been reported. Maleic hydrazide may generally be expected to be mobile in soils with low clay content and relatively immobile in soils with high clay content.

If released to water, maleic hydrazide may undergo rapid photochemical decomposition. Aqueous solutions of maleic hydrazide (in the presence of oxygen) were destroyed completely after approximately 48 hours irradiation with UV light at wavelengths of >290 nm. The products of this photolysis reaction were nitric acid, formic acid, succinic acid, maleic acid, fumaric acid and more than 12 other non-volatile products.

If it is released to the atmosphere, maleic hydrazide should be expected to be almost entirely adsorbed in the particulate phase, based upon its estimated very low vapour pressure. It will be subjected to reaction with photochemically produced hydroxyl radicals and oxone with an overall atmospheric half-life of 2.2 hours for these processes (*Howard, 1990*).

4.1.2 Bioconcentration The potential for maleic hydrazide to bioaccumulate in fish is very low (*USEPA, 1994*).

4.2 Ecotoxicity

4.2.1 Fish The 96-hour LC₅₀ for rainbow trout is above 1435 mg/l; and for bluegill sunfish it is 1608 mg/l (*Tomlin, 1994*).

4.2.2 Aquatic invertebrates The 48-hour EC₅₀ is above 1000 mg/l for *daphnia* (potassium salt). The 96-hour EC₅₀ is above 100 mg/l for algae; the 5 days is above 9.84 mg/l (potassium salt) (*Tomlin, 1994*).

4.2.3 Birds The acute oral LD₅₀ for mallard ducks is above 4640 mg/kg. The eight-day dietary LC₅₀ for mallard ducks is above 10000 mg/kg (*Tomlin, 1994*).

4.2.4 Bees Maleic hydrazide is not toxic to bees with an LD₅₀ >100 µg/bee (potassium salt) (*Tomlin, 1994*).

4.2.5 Other The LC₅₀ for earthworms is above 1000 ppm (potassium salt) (*Tomlin, 1994*).

Annex 2 - Details on reported control actions

AUSTRIA

Effective:	1992
Control action:	Banned since 01.01.88 in all applications where food contact is possible. All uses banned as of 20.02.92.
Reasons:	High mobility in soils and potential for contamination of water. The herbicide is suspected to have a carcinogenic potential. Its residue in food is highly toxic, causing negative effects on central nervous system and liver damage.
Alternatives:	Many alternatives for designated purposes.

DENMARK

Effective:	1997
Control Action:	The authorization for the product containing maleic hydrazide as an active substance has been withdrawn from the market 31 December 1996 and a further use has been banned from 01 July 1997. No uses are allowed.
Uses still allowed:	For other categories than agriculture a written authorization has to be obtained. Currently no authorizations are given for other purposes.
Reasons:	Maleic hydrazide is assessed as a risk to cause groundwater pollution.

EUROPEAN UNION

Effective:	1991
Control action:	The placing on the market and the use of the following plant protection products are prohibited: products containing (a) maleic hydrazide and its salts, other than its choline, potassium and sodium salts, and (b) choline, potassium and sodium salts of maleic hydrazide containing more than 1 mg/kg of free hydrazine expressed on the basis of the acid equivalent.
Reasons:	The uses of compounds mentioned in the control action in section (a) and those of section (b) not meeting certain purity criteria are likely to give rise to harmful effects on human and animal health as well as a highly unfavourable influence on the environment. The compounds mentioned may release hydrazine (CAS No. 302-01-2) in considerable amounts during shelf-life. Hydrazine has been classified by the EC as a category 2 carcinogen (probably carcinogenic 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.)

REPUBLIC OF KOREA

Effective:	1981
Control action:	The amount of hydrazine contamination in technical product must not exceed 15 ppm.
Uses still allowed:	Use is still allowed in tobacco plant.
Reasons:	Health risk and environmental impact.

Annex 3 - List of designated national authorities

AUSTRIA

CP

Department II/3
 Ministry of the Environment
 Stubenbastei 5
 Vienna, A - 1010
 Fax +431 51522 7744
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DENMARK

CP

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EUROPEAN UNION

CP

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CP **DNA** Industrial chemicals and pesticides
P **DNA** Pesticides
C **DNA** Industrial chemicals

Annex 4 - References

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