

EVALUATION SHEET

CANDIDATES FOR REASSESSMENT PRIORITY LISTING

Name of Substance: Benomyl & Carbendazim

CAS No. 17804-35-2 / 10605-21-7

Listing Proposed by: ERMA New Zealand

Brief Description of Substance and Background Context:

Benomyl and carbendazim are closely related systemic fungicides of the methyl benzimidazole carbamate family. Benomyl degrades to carbendazim. Benomyl is used to control smut diseases in onions, maize and wheat seeds in New Zealand. Carbendazim is used to control specific diseases in a range of fruits, vegetables, cereals, ornamentals and the causal organism of facial eczema in New Zealand. There are also a number of substances containing carbendazim used as timber antisapstains that have been approved under HSNO.

A reassessment of benomyl and carbendazim could cover the following HSNO approvals:

- Benomyl (HSR002816)
- Wettable powder containing 500 g/kg benomyl (HSR000347)
- Carbendazim (HSR003016)
- Emulsifiable concentrate containing 36 g/litre carbendazim, 20-21 g/litre iodocarb and 460 g/litre sodium orthophenylphenate (HSR000874)
- Emulsifiable concentrate containing 36 g/litre carbendazim, 460 g/litre sodium orthophenylphenate (HSR000915)
- Emulsifiable concentrate containing 40 g/litre carbendazim and 50 g/litre chlorothalonil (HSR000899)
- Emulsifiable concentrate containing 75 g/litre carbendazim, 75 g/litre oxine-copper and 30 g/litre permethrin (HSR000855)
- Hylite Clear II (HSR002477)
- Soluble concentrate containing 100 g/litre carbendazim, 22.6 g/litre cupric oxide and 82.4 g/litre 8-hydroquinoline (HSR000880)
- Soluble concentrate containing 80 g/litre carbendazim and 100 g/litre dodine (HSR000865)
- Suspension concentrate containing 130 g/litre carbendazim and 100 g/litre prochloraz (HSR000891)
- Suspension concentrate containing 100 - 250 g/litre carbendazim and 250 - 450 g/litre chlorothalonil (Substance B) (HSR000146)
- Suspension concentrate containing 100 - 250 g/litre carbendazim and 250 - 450 g/litre chlorothalonil (Substance A) (HSR000870)
- Suspension concentrate containing 113 g/litre carbendazim, 53.2 g/litre 2-(diiodomethylsulfonyl)-toluene and 39.8 g/litre didecyl dimethyl ammonium bromide (HSR000902)
- Suspension concentrate containing 125 g/litre carbendazim and 375 g/litre fenpropimorph (HSR000897)
- Suspension concentrate containing 200 - 250 g/litre carbendazim and 125 - 300 g/litre triadimenol (HSR000456)
- Suspension concentrate containing 29.9 g/ carbendazim and 53.6 g/litre 4,5-dichloro-2-octyl-3(2H)-isothiazolone (HSR000887)
- Suspension concentrate containing 500 g/litre carbendazim (Substance A) (HSR000453)
- Suspension concentrate containing 500 g/litre carbendazim (Substance B) (HSR000464)
- Suspension concentrate containing 75 g/litre carbendazim and 75 g/litre oxine-copper (Substance A) (HSR000868)

- Suspension concentrate containing 75 g/litre carbendazim and 75 g/litre oxine-copper (Substance B) (HSR000873)
- Taratek GC (HSR000046)
- TNL2190 (HSR007633)
- Water dispersible granule containing 500 - 800 g/kg carbendazim (HSR000455)
- Wettable powder containing 500 g/kg carbendazim (HSR000585)
- Wettable powder containing 56.25 g/kg carbendazim, 93.75 g/kg chlorpyrifos and 400 g/kg mancozeb (HSR000173)
- Other substances for which approval is sought prior to the start of reassessment

Formulations containing benomyl have been registered for use in New Zealand since 1991 and formulations containing carbendazim from 1973. Benomyl 50 Seed Dressing Fungicide is the only product that contains benomyl that is currently registered for agricultural use in New Zealand. There are 19 products containing carbendazim that are currently registered for agricultural use in New Zealand. These are Addstem, Agpro Carbendazim, Assure, Bavistin Fl, Bayer Carbendazim, Carben 50SC, Chief Fungicide, Goldazim 500SC, Islandcarben, MBC 50 WP, MBC 500 Flo, MBC 800WDG, Mycotak, No Insects Or Disease Spectrum, Prolific, Protek, Twin-Carb, X-Spore and Zelum Carbendazim.

Application of Criteria:

<i>Specific Criteria</i>	<i>Assessment</i>
<p>(1) The inherent risks of the substance given current and projected patterns of use. This should include consideration of:</p> <ul style="list-style-type: none"> • Hazardous properties; • Exposure pathways; • Quantity and patterns of use; • And, thus risks to people, communities and the environment. 	<p><i>Hazardous Properties</i></p> <p>The Agency has classified benomyl as:</p> <ul style="list-style-type: none"> 6.3B skin irritant 6.4A eye irritant 6.5B contact sensitiser 6.6A mutagen 6.8A reproductive or developmental toxicant 6.9B suspected target organ systemic toxicant 9.1A very ecotoxic in the aquatic environment 9.2B ecotoxic in the soil environment <p>The Agency has classified carbendazim as:</p> <ul style="list-style-type: none"> 6.1E acute oral toxicant 6.6A mutagen 6.8A reproductive or developmental toxicant 6.9B suspected target organ systemic toxicant 9.1A very ecotoxic in the aquatic environment 9.2B ecotoxic in the soil environment. <p>The Agency has insufficient data to classify benomyl with respect to respiratory sensitisation and carcinogenicity. The Agency has insufficient data to classify carbendazim with respect to respiratory sensitisation and carcinogenicity.</p> <p>The exact hazards of the formulations used in commercial applications differ, as they are also affected by excipients, but retain at least the following hazards as triggered by the benomyl or carbendazim component: 6.6A, 6.8A, 6.9B, 9.1A, 9.2C.</p> <p>The controls applicable to individual formulations can be located on the ERMA New Zealand register.</p> <p>Benomyl and carbendazim are broad spectrum benzimidazole carbamate fungicides with systemic activity. They inhibit fungal mitotic microtubule formation, thus affecting fungal cell division and eventually preventing fungal growth and spore germination.</p>

Acute exposure to carbendazim may cause headaches, nausea, diarrhoea and vomiting. For benomyl, skin and eye irritation and skin sensitisation are the likely symptoms. Chronic effects associated with both benomyl and carbendazim include liver toxicity, developmental toxicity (such as foetal eye and brain malformations and increased mortality), and reproductive (testicular) effects. Both benomyl and carbendazim are mutagenic and cause aneuploidy (an increase or decrease in the number of chromosomes). They are also considered possible human carcinogens. Carbendazim is a suspected endocrine disruptor. It has been included by the European Commission on a priority list of chemicals that are believed to affect hormone function.

The World Health Organisation (WHO) has set an Acceptable Daily Intake (ADI) value for benomyl and carbendazim of 0.1 and 0.03 mg/kg bodyweight respectively.

Benomyl is very ecotoxic to the aquatic environment and toxic to soil organisms. Benomyl and carbendazim are both very ecotoxic to fish with LC₅₀'s of 0.006 and 0.014 mg/l respectively. The substance is not readily degradable. It binds strongly to soil and does not dissolve in water to any great extent. When applied to turf or soil, it is rapidly converted to its major metabolite, carbendazim, which is more persistent giving an overall half-life of up to 12 months. This reduces its bioavailability to terrestrial and aquatic organisms, as well as its ability to leach into ground water. Benomyl and carbendazim both have low potential for bioaccumulation with bioconcentration factors of 27 and 159 respectively. These substances also have low octanol water partition coefficients (logKow = 1.36 and 1.52 respectively).

Use & Exposure

Benomyl and carbendazim are systemic fungicides. In New Zealand, benomyl is used to control smut diseases in onions, maize and wheat seeds while carbendazim is used to control specific diseases in a range of fruits, ornamentals, crops and the causal organism of facial eczema. Carbendazim is also used in timber antisapstain formulations.

Application rate and methods vary according to the product and crop. Individual product labels should be referred to for exact rates and methods. These can be obtained through the Agricultural Compounds and Veterinary Medicines (ACVM) [ACVM Register](#).

No specific data on the quantities of benomyl/carbendazim used in New Zealand have been identified. A report produced by HortResearch for the Ministry for the Environment, *Trends in Pesticide Use in New Zealand: 2004*, estimated that 4.4 tonnes of Benzimidazole fungicides were sold in 2003 in New Zealand. However, the proportion of this figure attributable to benomyl and carbendazim is not known.

Workers may be exposed to benomyl or carbendazim through application. Other people may be exposed by re-entry into areas where fungicides containing benomyl or carbendazim have recently been applied. Members of the public may be exposed to benomyl or carbendazim through spray drift or residues in food previously treated with fungicides containing benomyl or carbendazim.

At this stage the Agency has collected no information on concentrations of benomyl or carbendazim in the environment or to which people are exposed as a result of use of products containing these active ingredients. Maximum residue limits in food are set by New Zealand Food Safety Authority (NZFSA) under the Food Act and monitoring of actual residue levels are conducted against these.

(2) The extent to which the existing management regime (including controls) is achieving effective management of risks.

Incident Reports

The Agency has not collected incident data relating to benomyl or carbendazim in New Zealand at this stage in the process of screening substances for reassessment.

Incident data highlighted by the Pesticide Action Network is informative:

- Carbendazim is one of the twelve most commonly detected pesticides in EU food residue monitoring programmes. In 2000, it was found in baby food made by Heinz and Milupa and sold in Tesco and Waitrose. Additionally, in 2000, one third of all pears, 16% of apples tested, and over a quarter (27%) of apple juice samples contained

	<p>carbendazim residues. Although carbendazim was found in low levels in all the samples, an issue was perceived because babies are especially vulnerable, and apples and pears are amongst those foodstuffs most commonly eaten by toddlers.</p> <ul style="list-style-type: none"> • In 1993, a series of articles was published in the UK alleging a possible link between exposure of pregnant mothers to benomyl and their children being born without eyes (anophthalmia) or with related syndromes including reduced eyes and blindness due to severe damage of the optic stem. • In 1992, benomyl exposure caused adverse occupational health effects (headaches, diarrhoea and sexual dysfunction) in agricultural workers in Florida. <p>Further details of incidents are available in the Pesticide Action Network benomyl and carbendazim Fact Sheets.</p>
<p>(3) The extent to which new and relevant information is both required and is available, or will shortly become available particularly if under review overseas, for the reassessment process.</p>	<p><i>New Information</i></p> <p>Many overseas regulatory jurisdictions are currently in the process of reviewing benomyl and carbendazim. The EU and US Environment Protection Agency (EPA) have reviewed benomyl, and the Australian Pesticides and Veterinary Medicines Authority (APVMA) is reviewing this substance. The Canadian Pest Management Regulatory Agency (PMRA) has reviewed carbendazim and the EU is in the process of reviewing this substance. Subsequently, much relevant new information has, and will continue to, become available that will assist with any reassessment of both benomyl and carbendazim in New Zealand.</p> <p>The EU released Decision 2002/928/EC for benomyl in November 2002, which was supported by information released in a Final Review Report in May 2002.</p> <p>The US EPA released a Reregistration Eligibility Decision (RED) document for benomyl in July 2002. A Fact Sheet for benomyl has also been released, which summarises this information.</p> <p>The Canadian PMRA announced the discontinuation of all products containing benomyl in July 2003. It also released a Re-evaluation Document for carbendazim in April 2006.</p>
<p>(4) Regulatory action taken overseas</p>	<p><i>Overseas Regulatory Action</i></p> <p>European Union</p> <p>The EU banned plant protection products containing benomyl in 2002.</p> <p>The Maximum Residue Limit (MRL) for carbendazim for both apples and pears was amended on 15 September 2006 from 2 mg/kg to 0.2 mg/kg. Subsequently, pesticide regulators across the EU have or will be revoking use in apples and pears, as use of such would lead residues to exceed these new MRLs.</p> <p>Carbendazim has been listed by the European Commission on a priority list of chemicals that are believed to affect hormone function. European Commission Endocrine Disruptors website</p> <p>United States</p> <p>All benomyl registrations were voluntarily cancelled by registrants, effective in January 2002. Carbendazim is not approved in the US.</p> <p>Canada</p> <p>The Canadian PMRA has reassessed carbendazim and has come to the decision that the risks associated with products containing carbendazim in Canada are acceptable with an additional label statement requiring applicators to wear long pants, a long-sleeved shirt and chemical-resistant gloves when handling carbendazim.</p> <p>It is noted that in Canada, carbendazim is registered for use as a fungicide to control Dutch</p>

	<p>elm disease in elm species, and is applied by root flare injection. It is not registered for use on food crops.</p> <p>All products containing benomyl were discontinued in Canada in 2003.</p> <p>Australia</p> <p>The approvals for benomyl were suspended from 20 October 2003 until 31 December 2004, as the APVMA had concerns over the occupational and dietary risks associated with products containing benomyl in Australia. There are currently no products containing benomyl registered for use in Australia.</p>
(5) The level of public interest or concern, measured amongst other things by the results of periodic consultation on the reassessment programme.	<p>Public Concern</p> <p>There is general public concern about the use of pesticides.</p> <p>Both benomyl and carbendazim were listed as Priority 1 Pesticides for Reassessment in Petition 1999/227 of Kees Bon, presented to the Local Government and Environment Select Committee, September 2006. This petition was signed by 147 people.</p>
(6) Other information	<p>Other Information</p> <p>Carbendazim is the major metabolite of benomyl. There are currently available pesticides containing each of these actives in New Zealand. Thus, the reassessments of benomyl and carbendazim should be considered together.</p>

OVERALL EVALUATION

Benomyl and carbendazim are systemic fungicides of the methyl benzimidazole carbamate family. In New Zealand, benomyl is used to control smut diseases in onions, maize and wheat seeds. Carbendazim is used to control specific diseases in a range of fruits, ornamentals, crops and the causal organism of facial eczema. It is also used in timber antisapstain formulations. There is currently one product containing benomyl and 19 containing carbendazim that are registered for agricultural use in New Zealand. Both products are toxic to humans with the main concerns being over reproductive and developmental effects. Carbendazim is a suspected endocrine disruptor that has been included by the European Commission on a priority list of chemicals that are believed to affect hormone function. Both products are also very ecotoxic in the aquatic and soil environment, and carbendazim is also persistent. The EU banned benomyl in 2002, and imposed more stringent MRLs for carbendazim on apples and pears. Benomyl was voluntarily cancelled by registrants in the US. Carbendazim is not approved in USA and uses in other countries, such as Canada, are restricted. In Australia, approvals for benomyl were suspended from 20 October 2003 until 31 December 2004. There are currently no products containing benomyl registered for use in Australia.

RECOMMENDATION

It is considered appropriate that ERMA New Zealand should review the grounds for reassessment of the approvals containing benomyl as well as those containing carbendazim, given the potential for adverse effects in humans and concerns of overseas regulators. The grounds for reassessment of benomyl should be considered jointly with carbendazim.

Proposed by Reassessments Manager: Robin Toy

Agreed by Chief Executive: Rob Forlong