



FORM HS1

Application for approval to

IMPORT OR MANUFACTURE ANY HAZARDOUS SUBSTANCE FOR RELEASE

under section 28 of the
Hazardous Substances and New Organisms Act 1996

Name of Substance(s): **INFINITO ®**

Applicant: **Bayer New Zealand Ltd.**

Office use only

Application Code: Date received: ___/ ___/ ___/

ERMA NZ Contact: _____ Initial Fees Paid: \$

Application Version No: _____

Section One - Applicant Details

1.1 Name and postal address in New Zealand of the organisation making the application:

Name: Bayer New Zealand Ltd.
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1.2 The applicant's location address in New Zealand (if different from above):

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1.3 Name of the contact person for the application:

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Registration consultant:
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Cockle Bay
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Section Two - Application Type and Related Approvals Required

2.1 Is the information in this application relevant to import, manufacture or both:

- Import only? Yes
- If import only, indicate whether or not manufacture is likely in New Zealand No
[Unlikely ever to be economically justified]

2.2 If the information in the application relates to manufacture in New Zealand, provide information on the proposed manufacturing process and any alternatives

Not applicable

2.3 If you have reasons for not providing detailed information in this application, explain what they are and provide some justification.

2.4 If this substance(s) needs an approval under any other legislation, has an application for this approval been made ? (Optional) (See comments under “Section 2.4 of Form” in the User Guide.

Name of Approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	Yes
Food Act 1981	Yes [via ACVMG]
Medicines Act 1981	No N/A
Chemical Weapons (Prohibition) Act 1996	No N/A
Radiation Protection Act 1965	No N/A
Biosecurity Act 1993	No N/A
Resource Management Act 1991	No N/A
Other (please specify)	No N/A

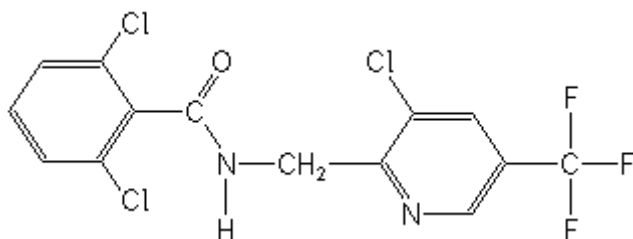
Section Three - Information on the Substance(s)

3.1 State the unequivocal identification of the substance(s).

Infinito is a fungicide containing 62.5 g/L (5.53 % w/w) fluopicolide and 625 g/L (55.3 % w/w) propamocarb (hydrochloride) as a suspension concentrate

1. fluopicolide

- Chemical Name (CA) 2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide
- Chemical Name (IUPAC) 2,6-dichloro-*N*-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide
- Common Name fluopicolide
- Synonyms AEC638206
- Trade Names Infinito
- CAS Registry Number 239110-15-7
- Molecular Formula $C_{14}H_8Cl_3F_3N_2O$
- Molecular weight: 385.59 g/mol
- Minimum purity: 970 g/kg
- Structural Formula



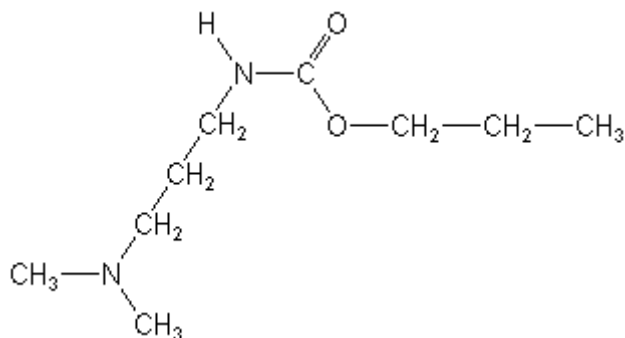
3.1 State the unequivocal identification of the substance(s).

Infinito is a fungicide containing 62.5 g/L (5.53 % w/w) fluopicolide and 625 g/L (55.3 % w/w) propamocarb (hydrochloride) as a suspension concentrate

2. propamocarb

- Chemical Name (CA) propyl [3-(dimethylamino)propyl]carbamate
- Chemical Name (IUPAC) propyl 3-(dimethylamino)propylcarbamate
- Common Name propamocarb
- Synonyms AE B066752
- Trade Names Infinito
- CAS Registry Number 24579-73-5
- Molecular Formula C₉H₂₀N₂O₂
- Molecular weight: 224.7 g/mol
- Minimum purity: 920 g/kg

• Structural Formula



3.2 Provide information on the chemical and physical properties of the substance i.e. the formulated product

INFINITO: PHYSICAL AND CHEMICAL PROPERTIES (FROM MSDS)

pH:	7 at 10 g/l (23 °C)
Freezing temperature:	< -20 °C
Boiling point/ range:	~100 °C
Flash Point:	Not relevant; aqueous suspension
Ignition temperature:	420 °C
Density:	ca. 1.13 g/cm ³ at 20 °C
Water Solubility:	dispersible
Viscosity, dynamic:	520 - 800 mPa.s at 20 °C
Oxidizing properties:	No oxidizing properties
Explosivity;	Not explosive

Impact on Hazard Classification:

1	Explosive	Not triggered
3	Flammable	Not triggered
5	Oxidising	Not triggered
8.1	Metallic corrosive	Not triggered

3.3 Provide information on the hazardous properties of the substance(s).

See table 3.3 below

Bayer assessment of hazards

INFINITO: (product as sold) ACUTE TOXICITY

<u>Study</u>	<u>result/ end point</u>	<u>reference</u> (Disk # 3)
Acute oral toxicity	LD50 rat: > 2,500 mg/kg b.w.	M-220883
Acute dermal toxicity	LD50: rat, m/f: > 4,000 mg/kg b.w.	M-220889
Skin irritation	Rabbit: non-irritating	M-224065
Acute eye irritation	Rabbit: non-irritating	M-224035
Acute inhalation toxicity:	LC50 (4 h. rat, m/f): >3195 mg/m ³	M-231342
Skin sensitisation:	Guinea pig: Non-sensitising	M-224078

Impact on Hazard classification

6.1	Acute toxicity	Triggered: see above	6.1E
6.3	Skin irritation	Not triggered: see above	
6.4	Eye irritation	Not triggered: see above	
6.5	Sensitisation	Not triggered: see above	
8.2	Skin corrosive	Not triggered: see above	
8.3	Eye corrosive	Not triggered: see above	

Chronic Toxicity of the active ingredients (fluopicolide, propamocarb)**Propamocarb HCl chronic toxicity studies (summary of conclusions)**
(for full reports and other studies, see Disk # 1)**M-157582 Micronucleus test**

From the results obtained, it was concluded that CP 604 (SN 66752, Previcur N) failed to show any evidence of mutagenic potential, when administered orally, in this test procedure.

M-157583 Dominant lethal study / mutagenicity

There were no consistent responses suggesting that Previcur N is mutagenic to the mouse at or below MTD levels by this test method. Statistical analysis of the data failed to show significant differences that could be attributed to an effect of Previcur N at $p < 0.01$.

M-157595 Dog: 90 day feeding study

The continuous feeding of ZK 17.296 for 90 days to dogs at dietary levels up to 1000/2000 ppm, did not evoke any effects that could be related to treatment.

M-157597 Rabbit: embryotoxicity/ teratogenicity

Previcur N (CP 604) exerted toxic effects in the dams (depression of body weight gain) and embryo-lethal effects at 0.4 ml/kg and above. 0.2 ml/kg have been revealed as no effect level. Neither the non-embryo-lethal nor the embryo-lethal dosages had teratogenic effects.

M-157599 Rat: 2 year chronic toxicity / carcinogenicity

This study has shown that a level of 1000 ppm SN 66 752 given to rats in the diet for two years produces no changes which can be attributed to the test compound. This level is equivalent to a mean intake of 36.5 mg/kg bodyweight/day in males and 45.4 mg/kg bodyweight/day in females.

M-157604 Mouse: 2 year chronic toxicity / carcinogenicity

Clinical findings: There were no signs of reaction to treatment. (inc. mortality, feed intake, bodyweight changes, feed utilisation, macroscopic/ microscopic pathology).

M-157607 Rat: reproductive toxicity

Early development of offspring was not adversely affected at any dietary concentration.

M-157610 Mutagenicity: Ames' test

The mutagenic activity of Previcur N was tested in 5 histidine requiring strains of *Salmonella typhimurium* strains (TA 98, TA 100, TA 1535, TA 1537, TA 1538) and *E. coli* WP 2 *uvrA*, with and without activation by rat liver microsomes. Without and with metabolic activation Previcur N was not mutagenic at doses of 5 - 5,000 µg per plate toward all tested strains.

M-157641 Metaphase chromosome analysis of human lymphocytes cultured in vitro

It is concluded that when tested using sterile distilled water as the solvent and at dose levels extending into the toxic range, technical propamocarb hydrochloride, showed no evidence of clastogenic activity.

M-183560 Rat: 2 generation reproductive study

Dietary administration of 8000 ppm of Propamocarb Hydrochloride liquid concentrate to rats for two successive generations induced parental toxicity (as evidenced by reductions in body weight gain and/or body weight and slightly lower food intake) in both the F0 and F1 generation females and F, generation males.

Neonatal toxicity was also evident as reduced F1 and F2 pup body weights. No reproductive toxicity was seen at any dose level.

The No-Observed-Adverse-Effect Level (NOAEL) was 1250 ppm, equivalent to an overall mean achieved daily intake of about 81 mg test article/kg body weight in F0 and F1 males combined and to about 127 mg/kg/day in F0 and F, females combined.

M-197256 Mouse: In vitro mammalian cell mutation test

Slight, but not statistically significant, increases in mutant frequency were seen in both tests when cells were exposed to the test substance for 24 hours in the absence of S9 mix. No significant increases in mutant frequency were observed in any other test, either in the absence or the presence of S9 mix.

The slight increases do not satisfy the criteria for a positive response. Therefore it is concluded that Propamocarb Hydrochloride Liquid Concentrate, 780 g/l did not demonstrate mutagenic potential in this *in vitro* mouse lymphoma mutation test, under the experimental conditions described.

Impact on Hazard classification

6.6	Mutagenic	Not triggered: see above	
6.7	Carcinogenic	Not triggered: see above	
6.8	Reproductive/developmental	Triggered: see above	6.8B
6.9	Target organ/systemic	Not triggered: see above	

Fluopicolide chronic toxicity studies (summary of conclusions)

(for full reports and other studies, see Disk # 3)

M-216694 Dog: 52 week toxicity test

The test item, AE C638206, was administered by the oral route (gavage) to beagle dogs for 52 weeks at the dose levels of 70, 300 or 1000 mg/kg/day.

Reduced body weight gain of males and increased cholesterol levels in females given 1000 mg/kg/day were the main treatment-related effects.

Consequently, under our experimental conditions, the No Observed Adverse Effect Level (NOAEL) was established at 300 mg/kg/day.

M-205579 Mouse: 90 day oral toxicity test

The No Observed Effect Level of AE C638206 in both sexes is considered to be 50 ppm.

M-197622 Rat: 90 day oral toxicity test

The no observed effect level (NOEL) for both sexes was 100 ppm, equivalent to a daily intake for the combined sexes of 7.9 mg/kg/day.

M-197259 Bacterial reverse mutation (Ames) test

AE C638206 was mutagenic in this bacterial mutation test at precipitating dose levels.

M-197260 Chinese hamster lung v79 cells chromosome aberration assay

AE C638206 was clastogenic in this in vitro chromosome aberration assay with V79 Chinese hamster lung cells in both the presence and absence of metabolic activation.

M-201582 In vitro mammalian chromosome aberration test in human lymphocytes

It is concluded that AE C638206 has shown no evidence of clastogenic activity in this *in vitro* cytogenetic test system, under the experimental conditions described.

M-202155 Rat oral developmental toxicity (teratogenicity) study

With regard to the present study the No Observed Effect Level (NOEL) is 60 mg/kg/day for maternal toxicity and for developmental toxicity.

M-223119 Micronucleus-test on the male mouse

After two intraperitoneal treatments of males with doses up to and including 600 mg/kg no indications of a clastogenic effect of AE C638206 were found.

M-225595 Mouse: dietary carcinogenicity test

Consequently, under our experimental conditions, the No Observed Adverse Effect level (NOAEL) was 50 ppm (corresponding to 7.9 mg/kg/day for the males and 11.5 mg/kg/day for the females) for toxicity and 400 ppm (corresponding to 64.5 mg/kg/day for the males and 91.9 mg/kg/day for the females) for carcinogenicity.

M-232532 Rat: 2 generation reproductive study

In conclusion, a dietary concentration of AE C638206 at 500 ppm should be considered as the No-Observed-Adverse-Effect-Level (NOAEL), based on the likelihood of the increased liver weights in F1 females being an adaptive change and not an adverse toxicological effect. The minimum mean achieved

dosages for the FO animals at this NOAEL (500 ppm) are 25.5 mg/kg/day for the males and 32.9 mg/kg/day for the females.

The No-Observed-Effect-Level (NOEL) for developing offspring is considered to be 500 ppm, equivalent to a minimum mean achieved dosage of 35.8 mg/kg/day for FO females during gestation and lactation.

The No-Observed-Effect-Level (NOEL) for reproductive parameters is considered to be 2000 ppm, equivalent to a mean achieved dosage of at least 103.4 mg/kg/day for FO males and at least 127.3 mg/kg/day for FO females before pairing.

Impact on Hazard classification

6.6	Mutagenic	Triggered: see above	6.6B
6.7	Carcinogenic	Triggered: see above	6.7B
6.8	Reproductive/developmental	Triggered: see above	6.8B
6.9	Target organ/systemic	Not triggered: see above	

INFINITO (product as sold): ACUTE ECOTOXICITY

Report: C 039863: Alga, growth inhibition test with *Pseudokirchneriella subcapitata*

The NOEC (growth rate) was determined to be 4.3 mg/L. The ErC50 could not be calculated, since the highest test concentration caused an inhibition of the growth rate, which was less than 50%. Thus, the ErC50 was defined to be >100 mg AE B066752 04 SC61 A1/L.

Report No. C 039853: AE B066752 04 SC61 A1: Acute toxicity test with common carp (*Cyprinus carpio*) under static conditions

During the 96 hour observation period, no mortality was observed in the test solutions with 6.25 and 12.5 mg AE B066752 04 SC61 A1/L. At concentrations of 25 mg AE B066752 04 SC61 A1/L and higher, all fish died within the 96 hour exposure period. The 96 hour LC50 was defined to be 18 mg test item/L.

Report No. C 038493: AE B066752 04 SC61 A1: Acute toxicity test with rainbow trout (*Oncorhynchus mykiss*) under static conditions

The 96 hours LC50 was calculated to be 6.6 mg AE B066752 04 SC61 A1/L.

Report No. C 030856: AE B066752 04 SC61 A1: Acute immobilisation test with daphnids (*Daphnia magna*) under static conditions

Effect concentrations and NOECs were based on nominal concentrations of the test item and are presented in mg test item/L.

During the 48 hour exposure period no sublethal effects or immobilised daphnids were observed, neither in the control nor in one of the treatment levels except the lowest treatment level where 4 out of 20 daphnids were lethargic. These effects were not dose response related and hence were not considered for the definition of the NOEC.

Hence, the NOEC was ≥ 100 mg test item/L and the EC₅₀ was >100 mg test item/L.

Study .Number 4863-06AVO: Avian Oral Acute Toxicity Study for INFINITO SC

The no observed effect level (NOEL) and lowest observed effect level (LOEL) were laid down as higher 2000 mg/kg bw (nominal concentration). Under the test conditions and based, on nominal dose, LD50 was considered greater than 2000 mg/kg bw.

Report: C 027693: Oral toxicity (LD50) to honey bees (*Apis mellifera* L) Propamocarb hydrochloride + AE C638206

The oral LD 50's were calculated as:

LD 50: for 24, 48, 72 hours: > 203.52 µg product per bee.

Report No. C 027325: Contact toxicity (LD50) to honey bees (*Apis mellifera* L.)

The contact LD 50's were calculated as:

LD 50: for 24, 48, 72 hours: > 143.1 µg product per bee.

Report No. C 035162: (Code: AE B066752 04 SC 61 A1): Acute Toxicity to Earthworms (*Eisenia fetida*)

Observations: No morphological and behavioural effects were observed.

Related to weight alterations and symptoms, the no-observed-effect-concentration (NOEC) was 316 mg test item/kg dry weight soil, the lowest-observed-effect concentration (LOEC) 1000 mg test item/kg dry weight soil.

Report No. C 035530: Effects of AE B066752 04 SC 61 A1 on Reproduction and Growth of Earthworms *Eisenia fetida*

Conclusion: AE B066752 04 SC 61 A1 did not show effects on mortality, growth, reproduction and feeding activity of the earthworm *Eisenia fetida* if applied up to the rate of 30.0 L product/ha.

The no-observed-effect-level (NOEL) found in this study was the rate of 30.0 L product/ha, i.e. the highest rate tested.

Report No. C 035158: AE C638206 & Propamocarb SC 62.5 + 625 (AE B066752 04 SC61 A1): Determination of effects on carbon transformation in soil

Observations. During the 30-day experiments, the maximum field rate of AE C638206 & Propamocarb SC 62.5 + 625 and the 10-fold overdose of the compound had no influence on carbon transformation after addition of glucose to a silty sand soil.

Conclusion. When used as recommended, AE C638206 & Propamocarb SC 62.5 + 625 should not have an impact on carbon transformation in soils.

Report No. C 035160: AE C638206 & Propamocarb SC 62.5 + 625 (AE B066752 04 SC61 A1): Determination of effects on nitrogen transformation in soil

Observations. During the 28-day experiment, the maximum field rate of AE C638206 & Propamocarb SC 62.5 + 625 and the 10-fold overdose of the compound had no influence on nitrogen transformation in a silty sand soil amended with lucerne-grass-green meal.

Conclusion: When used as recommended, AE C638206 & Propamocarb SC 62.5 + 625 should not have an impact on nitrogen transformation in soils.

Impact on Hazard classification

9.1	Aquatic	Triggered	9.1 B
9.2	Soil	Not triggered	
9.3	Terrestrial vertebrate	Not triggered	
9.4	Terrestrial invertebrate	Not triggered	

Ecotoxicity of the active ingredients (fluopicolide, propamocarb)

Propamocarb HCl ecotoxicity studies (summary of conclusions)

(for full reports and other studies, see Disk # 1)

M-157838 Earthworms: acute toxicity

The median lethal concentration (LC50) of Previcur N to *Eisenia foetida* was shown to be in excess of 1000 mg/kg artificial soil. Application of Previcur N at the recommended use rate would result in a concentration of approximately 7.98 mg/kg in the upper 2.5 cm of the soil. It is unlikely that earthworm populations will be adversely affected under normal agricultural use conditions.

M-157853 Bluegill sunfish, *Lepomis macrochirus*: acute toxicity

There were no mortalities or signs of abnormal behavior or appearance in treated or control tanks during the test period. All fish, treated and controls, appeared normal.

The 96 hour LC50 of propamocarb-HCl to bluegill sunfish is greater than 92 mg/L.

Propamocarb is, therefore, non-toxic to bluegill sunfish.

M-157858 Rainbow trout, *Oncorhynchus mykiss*: Static acute toxicity

There were no mortalities or signs of abnormal behaviour or appearance in treated or control tanks during the test period. All fish, treated and controls, appeared normal.

The 96 hour LC50 of propamocarb-HCl technical to rainbow trout is greater than 99 mg/l.

Propamocarb is, therefore, non-toxic to rainbow trout.

M-157891 *Daphnia magna*: acute toxicity, static

There were no mortalities in the treated or control chambers. There was one daphnid swimming on the surface in one of the treated and in one of the control replicates. All remaining daphnids, treated and controls, appeared normal.

The 48 hour EC50 of propamocarb-HCl to *Daphnia magna* is greater than 106 mg/l.

Conclusions: Propamocarb is non-toxic to *Daphnia magna*.

M-157904 Bobwhite quail: acute oral toxicity

The acute oral LD50 of Previcur N SL to the Bobwhite quail was found to be in excess of 2770 mg/kg, the maximum dose level tested. The highest no-observed effect level was 693 mg/kg.

M-157906 Mallard duck: acute oral toxicity

There were no mortalities. A number of birds showed an emetic response shortly after dosing at 277 and 2770 mg/kg. On the day of dosing two birds at 2770 mg/kg were very unsteady following dosing but recovered during Day 1. All birds remained in good health after Day 1. No treatment-related effects were observed on bodyweights or food consumption.

At macroscopic *post-mortem* examination, no abnormalities were observed.

Conclusion: Because of the emetic effects of Previcur N SL to the Mallard duck, it was not possible to determine an LD50 value in this study. The highest no-observed effect level was 28 mg/kg.

M-167971 Bobwhite Quail Dietary Reproduction Study

The no observed effect concentration for bobwhite quail treated with Propamocarb HCl Liquid Concentrate in the diet during this reproduction study was 8450 ppm (equivalent to an achieved daily intake of 853 mg Propamocarb HCl Liquid Concentrate/Kg body weight/day), which is higher than the US EPA Estimated Environmental Concentration (residue level) of 216 ppm a.i. immediately after a single field application.

M-185341 *Coccinella septempunctata* larvae: acute toxicity

Conclusions: It was concluded that fresh residues of Previcur N were not harmful to the foliar active predatory beetle, *Coccinella septempunctata*, when applied to glass plates at the equivalent of either 2 L or 4 L product/ha.

M-192422 *Aphidius rhopalosiphi*: acute toxicity

Conclusions: The results of this laboratory test indicated that AE B066752 00 SL67 A2 was harmful to adult *Aphidius rhopalosiphi* at deposition rates of 7.5 µg/cm² or greater, which in this test was equivalent to 0.75 L/ha or greater when applied to a 2 dimensional surface. The EC30 was 4.6 µg product/cm², and the EC50 was 8.7 µg. product/cm². The lowest treatment rate evaluated (2.5 µg product/cm²) was not harmful to the wasps.

M-228223 *Typhlodromus pyri* : acute toxicity

Conclusion: Up to the 8100 mL product/ha application rate no statistically significantly effects on mortality were observed. The corrected number of escapees was below 10 % in all test item treatments (escape rate in control was 16.7 %).

Reproduction was statistically significantly reduced compared to the control in the 6319 mL product/ ha treatment group only.

Based on these results a calculation of the LC50 was not possible.

M-240390 Freshwater Green Alga, *Pseudokirchneriella subcapitata*; acute toxicity

Cell density: The 96-hour EC50 was extrapolated to be 84 mg a.i./L, with 95% confidence limits of 34 to 290 mg a.i./L. Based on Williams' test, the 96-hour No-Observed-Effect Concentration (NOEC) was determined to be 20 mg a.i./L.

Biomass: The 72-hour EbC50 was extrapolated to be 120 mg a.i./L, with 95% confidence limits of 40 to 520 mg a.i./L. Based on Williams' Test, the 72-hour NOEC was determined to be 35 mg a.i./L. Since 22% inhibition occurred at this treatment level, the NOEC was empirically estimated to be 13 mg a.i./L, the highest concentration tested with <10% inhibition of biomass.

Growth rate: Since no concentration tested resulted in >50% reduction in growth rate, therefore, the 72-hour ErC50 was empirically estimated to be >85 mg a.i./L, the highest mean measured concentration tested. Based on Williams' Test, the 72-hour NOEC was determined to be 35 mg a.i./L.

Impact on Hazard classification

9.1	Aquatic	Not triggered
9.2	Soil	Not triggered
9.3	Terrestrial vertebrate	Not triggered
9.4	Terrestrial invertebrate	Not triggered

Fluopicolide Ecotoxicity Studies (summary of conclusions)

(for full reports and other studies, see Disk # 1)

M-219743: Common Carp (*Cyprinus carpio*); 96-hour static acute toxicity

96-Hour LC50 : 1.3 mg/L. (95% Confidence Interval: 0.98 - 2.0 mg/L.)

NOEC: 0.25 mg/L

M-240805 Bluegill Sunfish, *Lepomis macrochirus*: Acute Toxicity

48 / 96 hour LC50: 0.75 (95% Confidence Interval: 0.56 - 1.0 mg/L.)

M-240807 Water Flea, *Daphnia magna* : Acute Toxicity

The 48-hour EC50 of AE C638206 technical to *Daphnia magna* could not be determined under the conditions of this study and is greater than 1.8 mg/L. The no observed effect concentration (NOEC) was 1.8 mg/L.

M-241192 *Anabaena flos-aquae* (Blue-green Alga): Growth Inhibition Test

The 72 and 96 hour EhCso (biomass) and ErC50 (growth rate) values of AE C638206 technical to *Anabaena flos-aquae* were greater than 2.2 mg/L. The no observed effect concentration (NOEC) was 2.2 mg/L. The lowest observed effect concentration (LOEC) could not be determined under the conditions of this study.

M-219737 Freshwater alga (*Selenastrum capricornutum*) : Acute Toxicity

72 hour ErC50: > 4.3 mg/L
 72 hour NOAEC: 2.4 mg/L
 96 hour ErC50: > 4.3 mg/L
 96 hour NOAEC: 1.2 mg/L

M-240576 Mallard :acute oral toxicity study

The acute oral LD50 value for mallards exposed to AE C638206 Technical as a single oral dose was determined to be greater than 2250 mg a.i./kg. The no mortality dosage and the no-observed-effect dosage was 2250 mg a.i./kg the highest dosage tested.

M-240577 Northern bobwhite quail: acute oral toxicity study

The acute oral LD50 value for northern bobwhite exposed to AE C638206 Technical as a single oral dose was determined to be greater than 2250 mg a.i./kg, the highest dosage tested. The no mortality dosage and the no-observed-effect dosage were both 2250 mg a.i./kg.

M-240713 Mallard : dietary LC50 study

The dietary LC50 value for mallards exposed to AE C638206 Technical was determined to be greater than 5620 ppm a.i., the highest concentration tested. The no mortality concentration was 5620 ppm a.i.. Based upon a slight, but statistically significant ($p < 0.05$), reduction in body weight gain at the 5620 ppm a.i. test concentration, the no-observed-effect concentration was 3160 ppm a.i.

M-240713 Northern Bobwhite Quail: dietary LC50 study

The dietary LC50 value for northern bobwhite exposed to AE C638206 Technical was determined to be greater than 5620 ppm a.i., the highest concentration tested. The no mortality concentration was 5620 ppm a.i.. Based upon a slight, but statistically significant ($p < 0.05$), reduction in body weight gain at the 3160 ppm a.i. test concentration, the no-observed-effect concentration was 1780 ppm a.i..

Report No. C 035110**Acute dose-response toxicity (LRso) of AE C638206 00 SC40 A2 to the cereal aphid parasitoid *Aphidius rhopalosiphi***

There was no significant difference in mortality compared to the control group.

Because of no or negligible mortality in all test item treatment groups, a calculation of the LR50 was not possible.

The LR50 has to be regarded above the highest tested application rate of the test item (861 ml product/ha).

No statistically significant difference in reproduction (mean number of mummies/ female) was observed in all test item groups, when compared to the control group.

Report No. C 035109**Acute toxicity (LR50) of AE C638206 00 SC40 A2 to predatory mite *Typhlodromus pyri***

There were statistically significant differences in mortality (caused by a repellent effect a high number mites escaped) in the 383, 574 and 861 ml product/ha test item treatment groups compared to control group.

No statistically significant differences in reproduction were found in the test item treatment groups, which were tested, compared to the control group.

The LR50 (median lethal rate) of AE C638206 00 SC40 A2 to *Typhlodromus pyri* was 642 ml product/ha with 95 % confidence limits ranging from 591 to 698 ml.

Impact on Hazard classification

9.1	Aquatic	Triggered	9.1 B **
9.2	Soil	Not triggered	
9.3	Terrestrial vertebrate	Not triggered	
9.4	Terrestrial invertebrate	Not triggered	

** Taking the view that the data in Report: C 039863 (for the product) is of higher value than that in Report M-219737 (above) for fluopicolide technical.

The sum of our proposed hazard classifications is as follows:

6.1E, 6.6B, 6.7B, 6.8B, 9.1B

3.4	Identification of the default Controls on the substance(s).
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Substance	HSNO Classification	HSNO Default Controls
propamocarb plus fluopicolide		
suspension concentrate containing 62.5g/litre fluopicolide and 625g/litre propamocarb This includes the following trade name product: INFINITO	6.1 E 6.6 B 6.7 B 6.8 B 9.1 B	Toxic T1, T2, T4, T5, T7, T8 Ecotoxic E1, E2, E6, E8, Identification I1, I3, I8, I9, I11, I16, I17, I18, I19, I21, I23, I28, I29, I30 Packaging and Packaging Group P1, P3, PS4, P13, P15, PG3 Disposal D4, D5, D6, D7, D8, Emergency Management EM1, EM6, EM7, EM8, EM11, EM12, EM13

3.5 Provide information on what will happen to the substance throughout its whole life from its introduction into New Zealand, its uses, through to disposal.

Manufacture, Formulation:

Infinito is manufactured in Germany and will be imported into New Zealand as the formulated product, packed for retail sale.

Manufacture, Formulation in New Zealand:

It is not expected to be either manufactured [active ingredient] nor formulated in New Zealand: neither is justified on the grounds of economics.

Packaging:

Infinito will be packed in 5, 10 and 20 litre HDPE bottles, to UN specifications. The quantity imported per year is not expected to exceed 10 tonnes, and it may be assumed this will be imported into Auckland and Christchurch in September or October each year.

Transport:

UN-No	3082
Labels	9
Packaging group	III
Description of the goods	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (FLUOPICOLIDE, SOLUTION)

Storage:

Bulk Storage: Infinito will be stored primarily in the dedicated chemical warehouse of Bayer New Zealand Ltd., situated at Cryers Road, East Tamaki, Auckland, and 91 Treffers Road, Wigram, Christchurch. These stores have procedures in place for managing a wide range of chemical products. The staff are trained in and familiar with the protocols for the separation of products according to their characteristics, for safe handling and storage, and the measures to adopt in case of any emergency.

Infinito will be stored in original packaging, palletised, in 500 litre lots.

Distributors: During the course of sale and distribution the product will be transported to the premises of agricultural distributors each of whom has dedicated pesticide storage facilities, and whose staff have been trained in the procedures for managing and storing such products, and in dealing with emergencies that might arise. The maximum quantity of Infinito stored in such a distributor's store is not expected to exceed 500 litres.

End users: [potato growers] are all expected to be familiar with safe practices regarding the storage and handling of pesticides: Infinito will not present them with any hazards with which they are not already familiar. We would not expect on-farm storage to exceed 200 litres.

Use:

Infinito is recommended for use on potatoes for the control of late blight, for no more than three applications per season, at a rate of 1.2 – 1.6 litres in 200-300 litres of water for both ground and aerial application.

Disposal:

The preferred option for disposal, and considered the primary route, is for its use as per the label instructions. Because of the value of the product, and its chemical stability, any unused material can be held over to the following season without incurring any special problems.

If disposal as above is not possible, due to product contamination, or for other reasons, Infinito may be disposed of in an approved landfill, or in a pit dug especially for such a purpose on the farm, at least 50 cm deep and well away from any body of water.

4.1 Identify all of the potential risks, costs and benefits of the substance(s)

4.1 Identification of risks, costs, benefits.

Environmental Constants:

	propamocarb	fluopicolide
Vapour Pressure	3.8×10^{-5} Pa at 20 °C	3.03×10^{-7} Pa. at 20 °C.
Henry Constant	$K = 8.50 \times 10^{-9}$ Pa m ³ mol ⁻¹	4.15×10^{-5} Pa m ³ mol ⁻¹
water solubility	> 1000 g/l	2.8 mg/l, pH 7, 20 °C.
Soil DT 50	>365 days, pH 5 to 9	sandy loam (1) 274-291 days sandy loam (2) 752-581 days
Partition coefficient	Log P _{OW} -1.21, pH 7, 22 °C.	Log P _{OW} 2.9 (pH 4 – 9)

Review of potential environmental effects

Air contamination:

The active ingredients in Infinito, propamocarb and fluopicolide, are not volatile, and have very low Henry Constants. Air contamination is unlikely. The product is expected to have no adverse effect on air quality.

Water contamination/ degradation:

Propamocarb. While propamocarb is very soluble in water its toxicity to aquatic organisms is low (See reports for propamocarb tech., and the study conducted with Infinito against *Pseudokirchneriella subcapitata*).

Fluopicolide: Conversely fluopicolide is toxic to aquatic organisms but has low water solubility and moderate soil adsorption. The partition coefficient of both active ingredients is low.

Soil contamination / degradation:

According to field studies the soil half life (DT 50) is expected to be as follows:

<u>Soil type</u>	<u>pH 5 - 9</u>	<u>sandy loam (1)</u>	<u>sandy loam (1)</u>
propamocarb	>365 days		
fluopicolide		274-291 days	752-581 days

Photodegradation

Propamocarb: Photodegradation of Propamocarb Hydrochloride can be described by first-order kinetics with a half-life of 35.4 days.

Fluopicolide :HPLC analysis demonstrated that [14C]-AE C638206 degraded over the irradiation period, accounting for 72% at 15 days.

Effects on ecosystems:

No detrimental effects are expected. The terrestrial biocidal activity of the substance is limited to a narrow range of fungal diseases.

Effects on aquatic organisms:

See comments on Water contamination/ degradation, above.

Effects on vertebrates:

No adverse effects are anticipated.

Effects on native flora:

Infinito is a fungicide: it is not expected to be phytotoxic to any plant species and its limited range of activity means that it is unlikely to have any effect on the natural range of free living or parasitic fungi in the environment.

Effects on native fauna:

The toxicity of propamocarb to fauna is low (see reports on page 12). Fluopicolide is toxic to aquatic organisms but has low toxicity to terrestrial fauna (see reports page 14).

Effects on Economic Social and Cultural Wellbeing of Communities

Adverse effects on public health:
No adverse effects are anticipated.

Protection of workers, operators bystanders.

For protection of the user

The acute toxicity of Infinito is low. Users should avoid unnecessary contact with the product. Label statements will advise that Infinito be stored under lock and key, in a cool but frost-free place, away from food for human or animal consumption, out of the reach of children, and only in the sealed original container.

“ Wear protective clothing, including a face mask and protective gloves when working with the product. After working with the product wash your hands and any skin areas that have come in contact with the product thoroughly with soap and water.”

First aid-measures

In the event of poisoning decontaminate and give first aid. Consult a doctor.

For the doctor

Initial treatment should be symptomatic and supportive.

Contraindication: atropine.

Poisoning symptoms: not ascertained

No poisoning symptoms expected.

Consumers:

Summary of Proposed End Points	fluopicolide mg/kg bw/day	propamocarb HCl mg/kg bw/day
ADI	0.08	0.29
TMDI (% ADI) according to WHO European diet	0.00077 (<1%)	
AOEL	0.05	0.29
ARfD	0.18	1.0

Effects on Foreseeable Needs of Future Generations

Loss of value in Ecosystems

No adverse effects are anticipated. Infinito will be applied to relatively small areas of a single crop, potatoes: even drift or misapplication is unlikely to result in any adverse effect.

Development of Resistance

Resistance to fungicides is known. In the case of Infinito the label will advise a limit of three applications per season, integrated with fungicides from different chemical groups.

Development of persistent residues in soils and waterways.

This is unlikely. Infinito is applied only to potato crops. These are limited in area and the crop is typically not grown in the same field in consecutive seasons, for disease control reasons.

Identification of risks

Infinito introduces no special risks, peculiar to itself. At all times it will be handled, stored transported and used by persons who are trained and experienced in the handling of pesticides, and for whom the product will present no challenges.

Transport/ use

Transport:

UN-No	3082
Labels	9
Packaging group	III
Description of the goods	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (FLUOPICOLIDE, SOLUTION)

- a) Damage to packaging during storage
 Infinito conforms to the requirements of Schedule 4 of the Hazardous Substances. (Packaging)Regulations 2001. We are advised by Bayer AG that the packaging for Infinito is required to meet a “drop-test” of 1.8 metres. Warehouse staff of proprietors and resellers are required to observe Codes of Practice [ISO 9002 or Growsafe] while storing Infinito, growers are also Growsafe accredited. [As per NZS 8049:1999]
- b) Spillage of substance during dispensing and use
 Label statements warn: Toxic to aquatic organisms. Do not mix or load near any body of water: avoid spray drift over, or spillage into open water. Avoid contamination of any water supply with chemical or empty container.
- c) Incorrect disposal of surplus substance
 Advice regarding disposal is included on the label. The value of the product is such as to discourage careless disposal. In the event of deliberate or accidental contamination of soil the effect will be minimal, in the case of water there is a risk of toxicity to aquatic organisms, but this is expected to be of short duration.

Table 4.1 Summary of risk identification of Infinito

Source of potentially significant risk	Adverse effect/ impact	Likelihood	Distribution of effects [geographic]	Distribution of effects [demographic]	Distribution of effects [temporal]	Reversible/ irreversible	Voluntary/ involuntary	Magnitude	Level of residual risk
Transport accident over land	Human health	Very unlikely	Localised	Not expected	Short term	Reversible	Involuntary	Minimal	Insignificant
	Aquatic environment	Very unlikely	Localised		Short term	Reversible	Involuntary	Minor	Insignificant
	Terrestrial Environment	Very unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Insignificant
Damage to packaging during storage	Human health	Very unlikely	Localised	Not expected	Short term	Reversible	Involuntary	Minimal	Insignificant
	Aquatic environment	Very unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Insignificant
	Terrestrial Environment	Very unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Insignificant
Spillage of substance during dispensing and use	Human health	Unlikely	Localised	Not expected	Short term	Reversible	Involuntary	Minimal	Insignificant
	Aquatic environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minor	Insignificant
	Terrestrial Environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Insignificant
Incorrect disposal of surplus substance	Human health	Unlikely	Localised	Not expected	Short term	Reversible	Involuntary	Minimal	Insignificant
	Aquatic environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minor	Insignificant
	Terrestrial Environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Insignificant

Identification of Benefits

Infito is a new mid to late season blight fungicide based on active ingredient fluopicolide. Infito acts on foliar, stem and tuber blight and, uniquely, at all stages of the blight life cycle.

Key advantages

- Consistent high level activity on leaves, stems and tubers
- Systemic, protectant and translaminar activity
- Active at all stages in life cycle of the Late blight pathogen
- Strong anti-sporulant activity
- Flexible rates of use depending on disease pressure
- Long-lasting activity
- Controls phenylamide sensitive and resistant strains
- Rainfast in 1 hour providing spray has dried on the leaf
- Excellent crop safety: use on early, maincrop potatoes, seed and processing crops

4.3 Provide an assessment of any particular risks, costs and benefits which arise from the relationship of Maori and their culture and traditions with their taonga, or which are, for other reasons, of particular relevance to Maori.

In our judgement the importation and use of Infito will not adversely affect the natural resources of the flora, fauna, waterways, land and culture of the indigenous Maori.

4.4 Provide an assessment of any risks, costs or benefits to New Zealand's international obligations.

Infito is already registered in the E.U., the U.S.A. and in Japan. Residues in products exported to other countries will be accommodated by MRL's established in those countries and/or by the Codex Alimentarius. In any case the use rate and use timing of Infito will ensure there are no residues in treated produce above the default MRL. Our international obligations are satisfied.

4.5 Provide information on the proposed management of the substance.

Infinito is an agricultural fungicide which will be handled, stored, transported and used by persons familiar with similar materials. Handled with care and according to the label we consider it represents a low risk, both to humans and to the environment. It is our opinion that the warnings and precautions set out on the label, are adequate to eliminate or mitigate the slight hazard posed by the product.

The overall management of the substance in respect of transport, storage, application use and container disposal will be in compliance with the Code of Practice for the Management of Agrichemicals. [NZS 8409:1999] Documentation to facilitate this will include the ready availability of the container label, Product Safety Card and Material Safety Data sheet.

4.6 Provide an overall evaluation of the combined impact of all of the risks, costs and benefits set out in sections 4.2, 4.3 and 4.4.

4.6 Quantification Analysis of risks

	Risk	At risk	Probability of occurrence	Degree of effect	Risk score = probability x degree §	Level of risk without controls	Level of risk with controls
1	Oral exposure	End user	1	1	1	negligible	negligible
		Storeman	1	1	1	negligible	negligible
2	Dermal / eye exposure	End user	1	1	1	negligible	negligible
		Storeman	1	1	1	negligible	negligible
3	Inhalation exposure	End user	1	1	1	negligible	negligible
		Storeman	1	1	1	negligible	negligible
4	Food residues	Consumer	1	1	1	negligible	negligible
	Water contamination	Fish	1	2	2	low	negligible
		invertebrates	1	2	2	low	negligible
		Aquatic plants	1	2	2	low	negligible
5	Soil contamination	Soil micro flora, fauna	1	1	1	negligible	negligible
6	Non-target species	Plants, animals	1	1	1	negligible	negligible

§ Scale: 1 = Negligible risk.

10 = Monitoring/ intervention required.

5.1 ERMA New Zealand is interested in whether this substance (or any of its components) has been considered by any other regulatory authority in New Zealand or by any other country.

Infinito is registered in the E.U., U.S.A., Japan.

It is also being submitted to the ACVMG for registration under the ACVM Act.

Section 6.1 Glossary

Section 7.1 Name of the substance for the public register

Infinito ®

Section 7.2 Purpose of the Application, for the public register

To import or manufacture Infinito for use as a fungicide for the control of late blight in potatoes (Category C).

7.3 Use Category

Main Category	4
Industry Category	1
Function/ Use	38

Section 7.4 Executive Summary

This is an application to import Infinito into NZ for use as an agricultural fungicide. The product will be formulated and packed overseas and contains 62.5g/litre fluopicolide and 625g/litre propamocarb in the form of a suspension concentrate.

The product is intended for the control of late blight in potatoes.

The recommended dose rates for the product are 1.2 – 1.6 litres in 200-300 litres of water hectare, the time interval (10 – 14 days) and dose rate depending on growth rate/ disease conditions. The restriction on the number of applications is for the purpose of managing disease resistance.

Fluopicolide is a new anti-oomycetes fungicide with a new mode of action inducing perturbation of a spectrin-like protein. Infinito combines this active ingredient with the protective properties of propamocarb.

Our estimation of the hazard classification of Infinito is as follows:

6.1E, 6.6B, 6.7B, 6.8B, 9.1B

There are risks to aquatic organisms. With normal care during handling and application, and the observance of label directions we believe the risks to users, consumers, bystanders and the environment are negligible.

In our judgement the importation and use of Infinito will not adversely affect the natural resources of the flora, fauna, waterways, land and culture of the indigenous Maori.

Following importation Infinito will be handled, stored and transported by trained personnel, experienced in the safe management of hazardous substances. The overall management of the substance in respect of transport, storage, application and container disposal will be in compliance with the Code of Practice for the Management of Agrichemicals. [NZS 8409:1999] Documentation to facilitate this will include the ready availability of the container label, Product Safety Card and Safety Data sheet.

In summary, the benefits of Infinito are:

- Consistent high level activity on leaves, stems and tubers
- Systemic, protectant and translaminar activity
- Active at all stages in life cycle of the Late Blight pathogen
- Strong anti-sporulant activity
- Flexible rates of use depending on disease pressure
- Long-lasting activity
- Controls phenylamide sensitive and resistant strains
- Rainfast in 1 hour providing spray has dried on the leaf
- Excellent crop safety: use on early, maincrop potatoes, seed and processing crops

CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	Yes / NA
Fees enclosed	Yes
Application signed and dated	Yes

Signed

Date