FORM HS1

Application for approval to

IMPORT OR MANUFACTURE ANY HAZARDOUS SUBSTANCE FOR RELEASE

under section 28 of the Hazardous Substances and New Organisms Act1996

Name of Substance(s):DuPont ™ Benevia® Insecticide

DuPont™ Exirel ® Insecticide

Applicant: DuPont (New Zealand) Limited

Office use only	
Application Code: ☐☐☐☐☐☐☐☐	Date received:____/____/____
ERMA NZ Contact: _____	Initial Fees Paid: $
Application Version No: _____.	

IMPORTANT

1. Before you fill in this application form, you may find it helpful to consult the *User Guide to Hazardous Substance Applications under the HSNO Act 1996*. This User Guide can either be downloaded from our website or purchased from ERMA New Zealand. The level of information that you need to provide in this application is dependent upon the scale and the significance of the risks and/or whether these risks are well understood and controlled. The User Guide will offer further advice on this.
2. Part B of the User Guide covers applications under Section 28 of the Act and all of the cross references in this application form are to Part B.
3. You can also talk to an applications officer at ERMA New Zealand who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process.
4. This application form may be used to seek approvals for more than one hazardous substance where the substances are related, for example a concentrated compound (active ingredient) and its related formulations or the two parts of an epoxy glue.
5. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included in an Appendix to the application form.
6. Commercially sensitive information must be collated in a separate Appendix.
7. Applicants must sign the form and enclose the correct application fee. The initial application fee can be found in our published *Schedule of Fees and Charges*. Make sure that you have an up to date copy of the Schedule. Please check with ERMA New Zealand staff. We are unable to process applications that do not contain the correct fee.

8. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed. Where an applicant is unable to complete the sections marked optional, this information may be derived by ERMA New Zealand and the costs of doing so will be recovered from the applicant as part of the processing costs.

   You can get more information at any time by contacting us. One of our staff members will be able to help you.

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Section One – Applicant Details

See comments under "Section One of Application Form" in the User Guide for guidance.

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

Name: DuPont (New Zealand) Ltd
Address: PO Box 12173, Penrose, Auckland 1642
Phone: (09) 526 2501
Fax: (09) 526 2505

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

Address: As above

1.3 Name of the contact person for the application:

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions on behalf of the applicant that relate to processing the application, or have the ability to go to the appropriate authority.

Name: Mike Cornwell
Position: Consultant
Address: 24 Belle-Mer Place, Whangaparaoa 0930
Phone: (09) 424 4141
Fax:
Email: cornwemh@actrix.co.nz

Section Two – Application Type and Related Approvals Required

This form is only to be used for an application to import and/or manufacture a hazardous substance for 'release' and if it does not meet the requirements for rapid assessment. Please note that it is the substance(s) which is approved, and thus the approval covers both import and manufacture.

If you are making the application for some other reason, you will need a different form.

2.1 Is the information in this application relevant to import, manufacture or both:
(See comments under "Section 2.1 of Form" in the User Guide)

• Import only?	Yes
• Manufacture only?	No
• Import and manufacture?	No
• If import only, indicate whether or not manufacture is likely in New Zealand	No

2.2 If the information in the application relates to manufacture in New Zealand, provide information on the proposed manufacturing process and any alternatives.
(See comments under "Section 2.2 of Form" in the User Guide)

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

An example of a reason for not giving detailed information is where an approval has been given by another jurisdiction and information that led to that approval can be referenced or the substance will be used in low risk situations or ways.
(See comments under "Section 2.3 of Form" in the User Guide)

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	NA
Medicines Act 1981	NA
Chemical Weapons (Prohibition) Act 1996	NA
Radiation Protection Act 1965	NA
Biosecurity Act 1993	NA
Resource Management Act 1991	NA
Other (please specify):	NA

Section Three – Information on the Substance(s)

Note all information that is commercially sensitive must be attached as an Appendix. The application form should be cross-referenced to the Appendix but should be able to be read as a stand-alone document which will be publicly available.

You will need to provide a brief description of where the information in the application has been sourced from, eg from; inhouse data, research, technical literature, etc. See the introductory comments under "Section Three of the Form" in the User Guide for more details.

If approval is being sought for more than one hazardous substance, this section must be completed separately for each hazardous substance.

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

This section should include all information necessary to unequivocally identify the substance(s) and may include:

- Chemical Name (Chemical Abstracts Preferred Index name or IUPAC name)
- Common Name
- Synonyms
- Trade Names
- CAS Registry Number
- Molecular Formula
- Structural Formula
- Significant impurities

For mixtures, in addition to the above information being provided on the actual mixture, information is also required on the composition of the mixture ie the chemical name, CAS number, function (eg active ingredient, emulsifier, surfactant, filler) and percentages of **ALL** components of the mixture (including non-hazardous components and impurities) should be provided. This information may be best expressed in tabular form. If the composition is variable, please ensure to state the limits.

If there are commercial reasons for not providing full information in the main part of the form, alternative approaches must be discussed with and agreed by ERMA New Zealand. These must include the provision of a unique identifier of some kind.

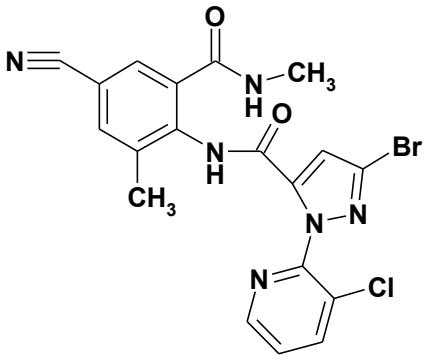
(See comments under "Section 3.1 of Form" in the User Guide)

Common name:	cyantraniliprole
Code No.	DPX-HGW86
CAS:	3-bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-1*H*-pyrazole-5-carboxamide
IUPAC:	3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl)pyrazole-5-carboxanilide
Empirical formula:	$C_{19}H_{14}BrClN_6O_2$
Molecular weight:	473.72 g/mole
CAS Registry number:	736994-63-1
CIPAC number:	Not assigned
EEC number:	Not assigned
Trade names:	DuPont Benevia insecticide (100g/L oil dispersion) DuPont Exirel insecticide (100g/L suspo-emulsion)

]

Structural formula:

Structure of cyantraniliprole (DPX-HGW86)



3.2 Provide information on the chemical and physical properties of the substance(s).

Provide as much information as possible on the chemical and physical properties of the substance(s) [at 20°C and 1 atmosphere unless otherwise stated] eg

- Appearance (colour, odour, physical state or form)
- pH
- Density
- Vapour pressure
- Boiling/melting point
- Solubility in water
- Water/octanol partitioning co-efficient

For mixtures, information is required on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of EACH hazardous component of the mixture

(See comments under "Section 3.2 of Form" in the User Guide)

Main physical and chemical properties of cyantraniliprole

(Ref. DVD, cyantraniliprole, chemistry, DuPont -27746)

Property	Results
Physical state	White fine powder solid
Melting point (pure active ingredient)	~224°C
Relative density (pure active ingredient)	1.4965 ± 0.0074 g/cm^3 at 20°C
Aqueous solubility (at 20°C)	14.24 mg/L
Solubility in various solvents (20°C)	Acetone: 6.54 g/L Ethyl acetate: 1.96 g/L Dichloromethane: 5.05 g/L Toluene: 0.576 g/L n-Octanol: 0.79 g/L Methanol: 4.73 g/L o-Xylene: 0.29 g/L Acetonitrile: 2.45 g/L
Vapour Pressure (20°C)	5.13×10^{-15} Pa at 20°C
Henry's Law Constant (pH7, 20°C)	1.7×10^{-18} atmosphere·m^3/mole
Octanol/water partition coefficient (20°C)	log K_{ow}, 1.94 ± 0.11 (not pH dependent)
Hydrolysis and photolysis	pH 4: Stable pH 7: Stable pH 9: Cyantraniliprole hydrolysed very rapidly with a half-life of <1 day. One major metabolite was observed. Photolysis: 0.233 days at 40° latitude in the summer to 4.12 days at 60° latitude in the winter
Dissociation constant (pK_a at 20°C)	8.80 ± 1.38

Physical and Chemical properties of DuPont Benevia Insecticide (100gL oil dispersion)

(ref. DVD,cyantraniliprole, chemistry, DuPont -27786)

Appearance: Off white colour with a mild oily characteristic odour.
Flashpoint: Non flammable , flash point (closed cup) > 99°C
Explosivity: Non explosive
Corrosivity: Non corrosive
Solubility in Water: Disperses
Relative density: 0.978 @20°C
pH: 5.1 (1% aqueous dispersion)

Physical and Chemical properties of DuPont Exirel Insecticide (100g/L suspo-emulsion)
(ref. DVD,Exirel, chemisty, DuPont-27759)

Appearance: Off white, mild phenyl compound odour.
Flashpoint: Non flammable, flash point (closed cup) >97°C
Explosivity: Non explosive
Corrosivity: Non corrosive
Solubility in Water: Disperses
Relative density: 0.982 @20°C
pH: 5.6 (1% aqueous dispersion)

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

Information should be provided on the hazardous properties of the substance(s) known to the applicant. You must consider each of the six hazardous properties below and provide information on those hazardous properties that trigger any threshold level. If you wish, you may assign the relevant HSNO classification category to each hazardous property that exceeds these threshold levels.

- explosiveness
- flammability
- oxidising properties
- corrosiveness
- toxicity
- ecotoxicity

If your substance is a mixture and you cannot provide direct information on its hazardous properties, you can apply mixture rules to the hazardous components of the mixture. If you do this, then you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings.
(See comments under "Section 3.3 of Form" in the User Guide).

DuPont Benevia Insecticide (100g/L OD) and DuPont Exirel Insecticide (100g/L SE)
Impact on Hazard classification

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

Acute toxicity: DuPont Benevia Insecticide (100g/L OD) and DuPont Exirel Insecticide (100g/L SE)

Summary of acute toxicity data for Cyantraniliprole 100 g/L OD
(Ref. DVD,Benevia, toxicology)

Type of study	Species	Results	Reference
Acute oral LD_{50}	Rat	LD_{50} > 5000 mg/kg bw	DuPont-26449, Moore, 2008
Acute dermal LD_{50}	Rat	LD_{50} > 5000 mg/kg bw	DuPont-26450, Moore, 2008
Acute inhalation LC_{50} (4h)	Rat	LC_{50} > 3.3 mg/L	DuPont-27807 Revision No.1, Kegelman, 2009
Skin irritation	Rabbit	Not irritating	DuPont-19079, Finley, 2006
Eye irritation	Rabbit	Not irritating	DuPont-19080, Finley, 2006
Skin sensitisation (LLNA)	Mice	Sensitising	DuPont-19081, Hoban, 2006
Skin sensitisation (Buehler test)	Guinea pig	Sensitising	DuPont-22769, Revision No.1, Lowe, 2009

Summary of acute toxicity data for Cyantraniliprole 100 g/L SE
(Ref. DVD, Exirel, toxicology)

Type of study	Species	Results	Reference
Acute oral LD_{50}	Rat	LD_{50} >5000 mg/kg bw	DuPont-26717, Moore, G.E., 2008a
Acute oral LD_{50}	Mouse	LD_{50} >5000 mg/kg bw	DuPont-26795, Moore, G.E., 2008b
Acute dermal LD_{50}	Rat	LD_{50} >5000 mg/kg bw	DuPont-26718, Moore, G.E., 2008
Acute inhalation LC_{50} (4h)	Rat	LD_{50} >2.4 mg/L	DuPont-26579, Kegelman, T.A., 2009
Skin irritation	Rabbit	Irritating	DuPont-26721, Durando, J., 2008
Eye irritation	Rabbit	Slightly irritating, clearing in 72 hours	DuPont-26720, Durando, J., 2008
Skin sensitisation (Buehler test)	Guinea Pig	Sensitising	DuPont-26791, Durando, J., 2008

Impact on Hazard classification- DuPont Benevia Insecticide (10% OD)

6.1	Acute toxicity	Not triggered
6.3	Skin irritation	Not triggered
6.4	Eye irritation	Not triggered
6.5	Sensitisation	Triggered: skin sensitiser 6.5B
8.2	Skin corrosive	Not triggered
8.3	Eye corrosive	Not triggered

Impact on Hazard classification- DuPont Exirel Insecticide (10% SE)

6.1	Acute toxicity	Not triggered
6.3	Skin irritation	Triggered: skin irritant 6.3B
6.4	Eye irritation	Triggered: eye irritant 6.4A
6.5	Sensitisation	Triggered: skin sensitiser 6.5B
8.2	Skin corrosive	Not triggered
8.3	Eye corrosive	Not triggered

Chronic Toxicology,
Cyantraniliprole technical
(ref. DVD cyantraniliprole, toxicology)

28 day oral toxicity in rats -DuPont-15206

NOAEL < 600 ppm (male), 600ppm (female) mg/kg/d m: >53,f: 62

28 day oral toxicity in mice – DuPont -15205

NOAEL 7,000 ppm (male and female) mg/kg/d m: 1261,f: 1476

28 day oral toxicity in dogs – DuPont-15456

NOEL <1,000 ppm (male and female) mg/kg/day m and f : <35

90 day oral toxicity in rats –DuPont-16993
NOAEL 3,000 ppm (male) 100 (female) mg/kg/d m:168, f: 6.9

90 day oral toxicity in mice – DuPont-16992

NOAEL 7,000ppm (male and female) mg/kg/d m:1091.8, f: 1344.1

90 day oral toxicity in dogs –DuPont-16994

NOAEL 100ppm (male and female) mg/kg/d m:3.1, f:3.5

1year chronic toxicity in dogs –DuPont -19180

NOAEL 200 ppm (male and female) mg/kg/d m:5.7, f:6.0

Dermal 28 day in rats –DuPont-21316

No adverse effects mg/kg/d 1,000 (m and f)

Oral feeding 2 year in rat –DuPont-26842

NOEL 200ppm (male), 2,000ppm (female) mg/kg/d m:8.3, f:106.6

Oral feeding 18 month in mice –DuPont-26843

NOEL 7000 (male and female) mg/kg/d m:768.8, f: 903.8

In vitro bacterial mutagenicity (Ames) - DuPont -27900

Under the conditions of this test there was no evidence of mutagenicity.

In vitro chromosome aberration test -DuPont-27901

Negative.

In vitro mammalian cell mutagenicity –DuPont-31372

Negative.

In vivo micronucleus study in mice –DuPont-31373

Negative

Multigeneration reproduction study in rat (feeding) –DuPont -19187

NOAEL (parental): 200 ppm
Reproductive/fertility:20000ppm
NOAEL (pup):200 ppm

Developmental study in rats –DuPont-19188

NOAEL (maternal): 1,000 ppm
NOAEL (foetus): 1,000 ppm
It is concluded that the test substance has no teratogenic potential in rats..

Developmental study in rabbits –DuPont-19189

NOAEL (maternal): 25 mg/kg/day
NOAEL (foetus): 100 mg/kg/day
It is concluded that the test substance has no teratogenic potential in rabbits.

Acute neurotoxicity screening study in rats –DuPont-16996

NOAEL (m and f.): No adverse effects, mg/kg/day 2,000 ppm (male and female)

Subchronic neurotoxicity, 90 day study in rat –DuPont-19186

NOEL (m and f) No adverse effects. mg/kg/day m: 1195 m, f: 1404

Immunotoxicity, 28 day study in rats (feeding) –DuPont- 21467

NOEL (male and female) 20,000 .mg/kg/day m:1699, f: 1703

Immunotoxicity, 28 day study in mice (feeding) –DuPont-21468

NOEL (male and female) 7000, mg/kg/day m:1065, f:1386

Toxicity studies on metabolites
The only molecule of toxicological relevance is cyantraniliprole.

Impact on Hazard classification- for DuPont Benevia insecticide and DuPont Exirel Insecticide

6.6	Mutagenic	Not triggered
6.7	Carcinogenic	Not triggered
6.8	Reproductive/developmental	Not triggered
6.9	Target organ/systemic	Not triggered

Toxicological end point for assessment of risk following long-term dietary exposure - Acceptable Daily Intake (ADI) or Chronic Reference Dose (CRfD)

The chronic studies in dogs, rats, and mice were considered the appropriate studies to use as a basis for an ADI or CRfD. The most relevant NOAEL in these studies is based on the 1-year study in dogs (5.7 mg/kg bw/day). The proposed ADI or CRfD is 0.057 mg/kg bw/day, based on the NOAEL of 5.7 mg/kg bw/day for male dogs and a 100-fold safety factor (10-fold intra-species variability factor and 10-fold inter-species extrapolation factor).

Ecotoxic effects:
Aquatic organisms (ref. DVD, cyantraniliprole, ecotoxicology)

Summary of the aquatic toxicity testing values obtained with cyantraniliprole

Species	Test/duration	Measurement endpoint	Endpoint value (mg/L)	Reference[a]
Fish				
Rainbow trout	Acute (96 h)	LC_{50}	>12.6	DuPont-19191
Bluegill sunfish	Acute (96 h)	LC_{50}	>13.0	DuPont-19164
Channel catfish	Acute (96 h)	LC_{50}	>10.0	DuPont-19167
Sheepshead minnow	Acute (96 h)	LC_{50}	>12.0	DuPont-19165
Rainbow trout	Early life stage (90 d)	NOEC	>10.7[b]	DuPont-19192
Sheepshead minnow	Early life stage (33 d)	NOEC	2.9	DuPont-19193
Bluegill sunfish	Bioaccumulation	BCF	<1	DuPont-21985
Aquatic crustaceans				
Daphnia magna	Acute (48 h)	EC_{50}	0.0204	DuPont-20148
Gammarus pseudolimnaeus	Acute (48 h)	LC_{50}	0.172	DuPont-18433, Revision No.1
Hyalella azteca	Acute (48 h)	LC_{50}	>1.37	DuPont-18436
Procambarus clarkia	Acute (48 h)	LC_{50}	4.0	DuPont-19194
Americamysis bahia	Acute (96 h)	LC_{50}	1.2	DuPont-17467
Ceriodaphnia dubia[c]	Acute (48-h)	EC_{50}	0.040	DuPont-15590
Ceriodaphnia dubia[c]	Chronic (7 d)	NOEC	0.005	DuPont-15590
Daphnia magna	Chronic (21 d)	NOEC	0.00969[c]	DuPont-17002
Americamysis bahia	Chronic (33 d)	NOEC	0.72	DuPont-17468
Aquatic insects				
Centroptillium triangullifer	Acute (48 h)	LC_{50}	0.0715	DuPont-18434
Lepidostoma ontario	Acute (48 h)	LC_{50}	0.0748	DuPont-20941
Soyedina carolinensis	Acute (48 h)	LC_{50}	14.0	DuPont-18889
Chironomus riparius	Acute (48 h)	LC_{50}	0.719	DuPont-17465
Chironomus riparius	Chronic (28d, sediment spike)	NOEC	0.0241[d]	DuPont-17463, Revision No. 1
Chironomus riparius	Chronic (28d, water spike)	NOEC	0.00179[e]	DuPont-17464
Other aquatic invertebrates				
Crassostrea virginica	Acute (96 h)	LC_{50}	0.45	DuPont-17466
Lumbriculus variegates	Acute (48 h)	LC_{50}	>13.7	DuPont-18435
Aquatic algae				
Pseudokirchneriella subcapitata	Acute (72 h)	E_rC_{50}	>13	DuPont-19190
Anabaena flos-aquae	Acute (96 h)	E_rC_{50}	>15	DuPont-24876
Navicula pelliculosa	Acute (96 h)	E_rC_{50}	>14	DuPont-24877
Skeletonema costatum	Acute (96 h)	E_rC_{50}	>10	DuPont-24878
Aquatic plants				
Lemna gibba G3	7 d	E_rC_{50}	>12.1	DuPont-21477

[a] Summarized in Cyantraniliprole Dossier, Annex IIA, Document M-II, Section 6, DuPont-27751.

[b] Non-GLP toxicity test result. The LC_{50} value was determined at 48 hours.

[c] Most relevant NOEC value.

[d] Based on initial measured concentrations

[e] Mean measured concentration in the water column for the NOEC treatment.

Aquatic toxicity endpoint values for cyantraniliprole 100 g/L OD
(Ref. DVD, Benevia, ecotoxicology)

Species	Test/duration	Measurement endpoint	Endpoint value (mg/L)	Reference[a]
Bluegill sunfish, *Lepomis macrochirus*	Acute/96 h/LC_{50}	37.0	2.4	DuPont-26581
Daphnia magna	Acute/48 h/EC_{50}	0.126	0.00947	DuPont-19853
Daphnia magna	Acute/48 h/EC_{50}	0.215	0.018[b]	DuPont-29051
Pseudokirchneriella subcapitata	Acute/72 h/EC_{50}	63.8	6.62	DuPont-26715

b Test conducted with Cyantraniliprole 100 g/L + Codacide oil. This is the most relevant EC_{50} value for this assessment and will be compared with the EC_{50} from the acute toxicity test with cyantraniliprole technical.

The LC_{50} value for *Daphnia* is <1 mg/L, thus Cyantraniliprole 100 g/L OD is classified as dangerous for the environment and assigned the risk phrase R50

Aquatic toxicity endpoint values for cyantraniliprole 100 g/L SE
(Ref. DVD, Exirel, ecotoxicology)

Species	Test/duration/ measurement endpoint	Endpoint value (nominal mg product/L)	Endpoint value (measured mg cyantraniliprole/L)	Reference[a]
Daphnia magna	Acute/48 h/EC_{50}	0.232	0.0185	DuPont-26737
Pseudokirchneriella subcapitata	Acute/72 h/EC_{50}	32.9	3.39	DuPont-27933

The LC_{50} value for *Daphnia* is <1 mg/L, thus Cyantraniliprole 100 g/L SE is classified as dangerous for the environment and assigned the risk phrase R50

Summary of avian toxicity endpoints for cyantraniliprole
(Ref. DVD, chlorantraniliprole, Benevial, ecotoxicology)

Toxicity study (species)	Test substance	LD_{50} or LC_{50} (mg ai/kg bw/day)	Lowest lethal dose (mg ai/kg bw/day)	NOEL or NOEC (mg ai/kg bw/day)	Reference[a]
Acute oral (northern bobwhite)	Cyantraniliprole	>2250	>2250	2250	DuPont-24248
Acute oral (northern bobwhite)	Cyantraniliprole 100 g/L OD	>2250	>2250	2250	DuPont-24484
Acute oral (zebra finch)	Cyantraniliprole	>2250	>2250	2250	DuPont-27316
Short-term dietary (mallard)	Cyantraniliprole	>2583	>2583	2583	DuPont-21469
Short-term dietary (northern bobwhite)	Cyantraniliprole	>1343	>1343	1343	DuPont-21470
Subchronic and reproductive (mallard)	Cyantraniliprole	Not calculated	>139.6	139.6	DuPont-20917
Subchronic and reproductive (northern bobwhite)	Cyantraniliprole	Not calculated	>93.2	93.2	DuPont-20918

[a] Summarized in Cyantraniliprole Dossier, Annex IIA, Document M-II, Section 6, DuPont-27751.

Avian toxicity endpoints used in risk assessment for cyantraniliprole

Study	Test species	Endpoints used in risk assessment
Acute toxicity	Northern bobwhite	LD_{50} = >2250 mg ai/kg bw/d
Dietary toxicity (short-term)	Northern bobwhite	LDD_{50} = >1343 mg ai/kg bw/d
Reproductive toxicity (long-term)	Northern bobwhite	NOEL = 93.2 mg ai./kg bw/d[a]

[a] According to EFSA guidance, the reproductive toxicity (long-term) evaluation should be based on the $1/10^{th}$ the LD_{50} instead of the chronic NOEL when the NOEL exceeds $1/10^{th}$ of the LD_{50}. For cyantraniliprole, the NOEL for the northern bobwhite quail is the most appropriate endpoint, since it does not exceed $1/10^{th}$ of the LD_{50}.

Acute oral toxicity to mammals

Substance	Species	Endpoint	Value (mg/kg bodyweight)	Report
Cyantraniliprole	Rat	LD_{50}	>5000	DuPont-18965[a]
Cyantraniliprole 100 g/L OD	Rat	LD_{50}	>5000	DuPont-26449[b]

[a] Summarized in the Cyantraniliprole Dossier, Annex IIA, Document M-II, Section 3, DuPont-27748.

[b] Summarized in the Cyantraniliprole Dossier, Annex IIIA, Document M-II, Section 3, DuPont-27788.

Summary of acute oral and contract toxicity of cyantraniliprole, cyantraniliprole 100 g/L OD and 100g/L SE on honeybees

(Ref. DVD, & CD Benevia, Exirel, ecotoxicology)

Test material	Oral LD_{50} (µg ai/bee)	Contact LD_{50} (µg ai/bee)	Reference[a]
Cyantraniliprole technical	>0.1055[b]	>0.0934	DuPont-17000
Cyantraniliprole 100 g/L OD	0.39[e]	0.65	DuPont-19229
Cyantraniliprole 100 g/L SE	0.92[b]	2.78[b]	DuPont-25995

[a] Reports are summarized in Cyantraniliprole Dossier, Annex IIA, Document M-II, Section 6, DuPont-27751.

[b] Tested up to maximum water solubility limit.

[c] Tested in water plus 1% acetone.

[d] Tested at maximum solubility in water plus 1% acetone.

[e] 72-hour assessment.

Honeybee hazard quotients for cyantraniliprole and Cyantraniliprole 100 g/L OD

Test substance	Route	Hazard quotient 12.5 g cyantraniliprole/ha	Hazard quotient 90 g cyantraniliprole/ha	Annex VI limit
Cyantraniliprole	Contact	<134	<964	50
Cyantraniliprole	Oral	<118	<853	50
Cyantraniliprole 100 g/L OD	Contact	19	138	50
Cyantraniliprole 100 g/L OD	Oral	32	231	50

Effects on non-target terrestrial arthropods

(Ref. DVD, &CD Benevia, Exirel, ecotoxicology)

Summary of effects of Cyantraniliprole 100 g/L OD on non-target arthropods tested with artificial (glass) substrates (Tier 1)

Species and test material	Application rates (g cyantraniliprole/ha)	Endpoint value	Reference[a]
Aphidius rhopalosiphi	0.0039, 0.0156, 0.0625, 0.25, 1.0	48-hour LR_{50} = 0.1019	DuPont-21472
Typhlodromus pyri	14.38, 28.75, 57.50, 115.0, 230.0	7-day LR_{50} >230.0	DuPont-21471

[a] Summarized in Cyantraniliprole Dossier, Annex IIA, Document M-II, Section 6, DuPont-27751.

Summary of effects of Cyantraniliprole 100 g/L SE on non-target arthropods tested with artificial (glass) substrates (Tier I)

Species and test material	Test type, substrate, and duration	Application rates (g ai/ha)	Endpoint value (g ai/ha)	Reference[a]
Aphidius rhopalosiphi	Laboratory glass plate, Tier I	0.0123, 0.037, 0.111, 0.333, 1.00	48 h LR_{50} = 0.095 ER_{50} >0.111	DuPont-25994
Typhlodromus pyri	Laboratory glass plate, Tier I	18.75, 37.5, 75.0, 150.0, 300.0	7-day LR_{50} >300 14-day ER_{50} >300	DuPont-25993

[a] Reports are summarized in the Cyantraniliprole Dossier, Annex IIA, Document M-II, Section 6, DuPont-27751

Summary of effects of Cyantraniliprole 100 g/L OD on the non-target arthropod species, *Chrysoperla carnea* and *Coccinella semptempunctata*, tested under extended laboratory Tier 2 conditions

Species	Formulation	Test	Parameter	Effect level (relative to controls)	Reference[a]
Chrysoperla carnea (green lacewing)	Cyantraniliprole 100 g/L OD	Worst-case lab dose response (Tier II, bean leaves)	Mortality:	LR_{50} = 264.0 g ai/ha	DuPont-25525
			Reproduction reduction:	ER_{50} >131.2 g ai/ha	
Chrysoperla carnea	Cyantraniliprole 100 g/L OD plus Codacide oil	Worst-case lab (Tier II, exposure to field-aged residues on bean leaves treated at 2 × 100 g ai/ha including 2 × 2.5 L Codacide oil/ha. 7 day spray interval)	Correct. Mortality: Reproduction:	Fresh-dried spray deposits: 0% not different to control[b]	DuPont-28013
			Correct. Mortality: Reproduction:	14-day aged spray deposits: -2.8% not different to control	
Coccinella septempunctata (lady bird beetle)	Cyantraniliprole 100 g/L OD	Worst-case lab dose response (Tier II, bean leaves)	Mortality:	LR_{50} = 62.2 g ai/ha	DuPont-25526
			Reproduction reduction:	ER_{50} >60.7 g ai/ha	
Coccinella septempunctata	Cyantraniliprole 100 g/L OD plus Codacide oil	Worst-case lab (Tier II, exposure to field-aged residues on bean leaves treated at 2 × 100 g ai/ha including 2 × 2.5 L Codacide oil/ha. 7 day spray interval)	Correct. Mortality: Repro. reduction:	Fresh-dried spray deposits: 66.7% nd	DuPont-28014, Revision No. 1
			Correct. Mortality: Repro. reduction:	14-day aged spray deposits: 2.6% not different to control	
			Correct. Mortality: Repro. reduction.	28-day aged spray deposits: -2.8% not different to control	

[a] Reports are summarized in Cyantraniliprole Dossier, Annex IIA, Document M-II, Section 6, DuPont-27751.

[b] Bioassay not valid.

Not significantly different to control: Effect on eggs per female and egg hatching rate <50%.

Summary of effects of cyantraniliprole 100 g/L SE extended laboratory studies with *Chrysoperla carnea* and *Coccinella septempunctata*

Species	Formulation	Test	Parameter	Effect level (relative to controls)	Reference[a]
Chrysoperla carnea	SE	Worst-case lab dose response (Tier II, bean leaves)	Mortality: Reproduction reduction:	LR_{50} = 218.6 g ai/ha ER_{50} >231.3 g ai/ha	DuPont-26927
Chrysoperla carnea	SE plus Codacide oil	Worst-case lab (Tier II, exposure to field-aged residues on apple leaves treated at 2 × 150 g ai/ha including 2 × 2.5 L Codacide oil/ha; 7 day spray interval)	Correct. mortality: Reproduction red.: Correct. mortality: Reproduction red.: Correct. mortality: Reproduction red.:	<u>Fresh-dried spray deposits:</u> 14.3% Not different to control <u>14-day aged spray deposits:</u> 10.3% Not different to control <u>28-day aged spray deposits:</u> 8.1% Not different to control	DuPont-27851
Coccinella septempunctata	SE	Worst-case lab dose response (Tier II, bean leaves)	Mortality: Reproduction reduction:	LR_{50} = 44.5 g ai/ha ER_{50} >25.7 g ai/ha	DuPont-26928
Coccinella septempunctata	SE plus Codacide oil	Worst-case lab (Tier II, exposure to field-aged residues on apple leaves treated at 2 × 150 g ai/ha including 2 × 2.5 L Codacide oil/ha; 7 day spray interval)	Correct. mortality: Reproduction red.: Correct. mortality: Reproduction red.: Correct. mortality: Reproduction red.:	<u>Fresh-dried spray deposits:</u> -35.3%[b] Not different to control <u>14-day aged spray deposits:</u> 11.5% Not different to control <u>28-day aged spray deposits:</u> -3.5% Not different to control	DuPont-27852

[a] Reports are summarized in Cyantraniliprole Dossier, Annex IIA, Document M-II, Section 6, DuPont-27751.

[b] Bioassay not valid

Toxicity endpoint values for earthworms

(Ref. DVD & CD Benevia, ecotoxicology)

Test item	Test/duration	Endpoint	Endpoint value (mg/kg dry wt soil)[a]	Reference
Acute studies				
Technical	Acute, 14 d	LC_{50}	>1000	DuPont-24880[b]
100 g/L OD	Acute, 14 d	LC_{50}	>1000	DuPont-24879[c]
Chronic studies				
Technical	Sub-lethal, 56 d	NOEC	1000	DuPont-26883[b]
100 g/L OD	Sub-lethal, 56 d	NOEC	1000 (plus 1578 for Codacide oil)	DuPont-29052[c]

Effects on soil microflora-

(ref. DVD &CD cyantraniliprole, Benevia, ecotoxicolgy)

Laboratory testing was conducted to evaluate the effects of cyantraniliprole and its major metabolites on non-target soil micro-organisms. (DuPont-27751). Soil was treated with exaggerated rates of cyantraniliprole and major metabolites. Effects on carbon mineralisation and nitrogen transformation were evaluated. The results of the studies demonstrated that nitrogen transformation and carbon mineralisation rates in treated soil at both rates for cyantraniliprole and its major metabolites were comparable to those obtained in control soil; the deviations in measured activity at the end of the study period (28 days) being less than 25% for all parameters examined. It may be concluded that cyantraniliprole and its major metabolites would be expected to pose low risk to soil microflora function.

Organic matter breakdown

(ref. DVD &CD cyantraniliprole, Benevia, ecotoxicolgy)

There was no significant impact on straw decomposition due to cyantraniliprole or any of its metabolites up to 6 months after litter bag burial in the treated soils. (DuPont-27790) When applied according to Good Agricultural Practice, it is expected that Cyantraniliprole 100 g/L OD will pose little risk to soil organisms responsible for organic matter breakdown.

Fate and behaviour in air

(Ref. DVD cyantraniliprole, chemistry DuPont -18861

The low vapour pressure and Henry's law constant of cyantraniliprole indicate a low potential for volatilisation of the active ingredient from soil under practical conditions of use. Therefore, a field volatility study was not conducted.

Fate and behaviour in water

(Ref. DVD cyantraniliprole, fate in the environment, DuPont -17058, 17060)

Hydrolytic degradation of cyantraniliprole in water is pH dependant and degradation is much faster at pH 9 (DT_{50}=1.77 days) as compared to the degradation rate at pH 4 (DT_{50}=260.5 days. Hydrolysis in neutral water showed a DT_{50} of 60.7 days. Aquatic contamination will be minimal since the products will be confined to application by ground hydraulic sprayers to vegetable crops. (DuPont-29552)

Fate and behaviour in soil

Ref. DVD, chlorantraniliprole, environmental fate)

Metabolism of cyantraniliprole was investigated in both laboratory and field trials. It was demonstrated that the degradation of the parent compound occurs via microbial as well as chemical transformation in the absence of light.Ten field studies were conducted during 2006 through 2008 seasons in the United States, Canada and Europe. (DuPont-27750) The field studies were conducted with two different formulations (Cyantraniliprole 100 g/L OD and Cyantraniliprole 200 g/L SC). Various dissipation modules were addressed in all these field studies. The dissipation modules include; bare soil plots with sampling in multiple depth segments to a total depth of 90 cm, cropped plots in parallel with bare soil plots to determine the extent of crop uptake or the impact of crop presence on the dissipation rates, contribution from photolysis of the parent compound towards the dissipation in field, and contribution from run-off from the bare soil plots due to normal irrigation events.

The normalized geomean DT_{50} value for cyantraniliprole after application to all field sites was 32.4 days. The dissipation rate in the field with formulated product was not substantially different from the degradation rates in laboratory soils.

Effects on terrestrial vertebrates

Cyantraniliprole has negligible acute, dietary and reproductive effects in birds. The oral acute and oral dietary LD/LC_{50} values were greater than the highest doses tested. The no observed test levels (NOEL) for the reproduction tests were the highest doses tested. Cyantraniliprole has negligible acute and reproductive effects in mammals. The oral acute toxicity was > 5,000mg/kg body weight for rats. The NOEL from the rat two-generation test was 1,353 mg/kg body weight, the highest test dose.

Effects on aquatic species

Cyantraniliprole has negligible acute and chronic toxicity to fish and negligible bioconcentration in fish. The most sensitive acute LD_{50} value is greater than 10.0mg/L (channel catfish), the highest mean measured concentration tested and also the apparent limit of solubility in that test system. The most sensitive chronic no observed effects concentration (NOEC) is 1.01 mg/L (rainbow trout)

Cyantraniliprole has negligible effects on algae and aquatic plants. The most sensitive EC_{50} values for algae *(Skeletonema costatum)*and aquatic plants *(Lemna gibba*) were greater than the highest concentration tested, the apparent limit of solubility in that system.

Cyantraniliprole can be highly toxic to aquatic invertebrates. The most sensitive acute LD_{50} and chronic NOEC values are 0.0204mg/L *(Daphnia magna)* and 0.00179mg/L (*Chironomus riparius),* respectively. Daphnia magna were less sensitive to metabolites of cyantraniliprole in acute toxicity tests.

Bioaccumulation

Cyantraniliprole has a log P_{ow} value of 2.0 (worst-case, at 20°C and pH 7). This value is below the trigger of 3.0, indicating bioaccumulation and food chain behaviour evaluations are not required. The fish bioconcentration value for cyantraniliprole was 1.0, indicating almost no accumulation of cyantraniliprole or metabolites. (DuPont -27751)

Effects on bees and other arthropod species

Laboratory acute oral and acute contact LD_{50} values were >0.1055 and > 0.0934µg/bee respectively.
Acute testing on honeybees demonstrated similar toxicities of the two formulations, cyantraniliprole 100 g/L OD and cyantraniliprole 100 g/L SE. Foliar residue studies with cyantraniliprole 100g/L OD at 150 ga.i/ha aged for 3 hours resulted in no treatment related mortality during the 24 hour exposure period and no treatment related behavioural abnormalities at the 1 or 24hour assessments.

Field tests with two applications of 150ga.i/ha cyantraniliprole during flowering and after flowering had no affects on mortality, behavior , brood development or colony strength. Overall, it is DuPont's position that the intended uses of cyantraniliprole 100 g/L SE or 100g/L OD pose no unacceptable acute and chronic risks for honeybees, colony development and survival and behaviour when used according to Good Agricultural Practices and in accordance with the product label. (Dossier, Annex IIA, Document M-II, Section 6, DuPont-27751)

Based on the Tier 1 risk assessment for the sensitive indicator species, *T. pyri,* Cyantraniliprole 100 g/L OD will pose low risk in-field. *A. rhopalosiphi* was susceptible under worst-case Tier 1 laboratory conditions to Cyantraniliprole 100 g/L OD. The Tier 1 in-field and off-field risk assessment for the sensitive indicator species, *A. rhopalosiphi,* results HQ value of 1502 and 109, respectively, indicating potential risk (HQ value >2).

Because the in-field and off-field HQ triggers were not met, non-target arthropod testing with additional species was performed. Additional studies were conducted with green lacewing (*Chrysoperla ca*rnea) and lady bird beetle (*Cocinella septempuntata.)* Exposure to the fresh dried and 14,28 day aged cyantraniliprole spray deposits resulted in no significant effect on either species or reproduction compared to the controls.

Effects on earthworms

Cyantraniliprole has negligible acute and sub-lethal effects on earthworms. The LC_{50} and NOEL were greater than 1,000mg/kg

Effects on other non target plants

Cyantraniliprole has negligible effects in non target terrestrial plants when tested with applications of cyantraniliprole 100g/L OD applied either pre-ermegence (soil exposure) or post emergence (foliar exposure).EC50 values for all test species were greater than the rate of 150g a.i/ha.

Ecotoxicity [hazard classification]DuPont Benevia insecticide and DuPont Exirel insecticide

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

Proposed overall hazard classifications

DuPont Benevia insecticide : 6.5B, 9.1A

DuPont Exirel insecticide : 6.3B, 6.4A, 6.5B, 9.1A

3.4 Identification of the default Controls on the substance(s).

A range of default controls are triggered by the hazardous property classification(s) attached to the substance. If you wish, you can list what these default controls are. If you don't provide this information, ERMA New Zealand will do it for you. Regardless, you need to be aware of what the default controls are so that you can take them into account when assessing risks – see Section 4. **(Optional)** (See comments under "Section 3.4 of Form" in the User Guide)

Substance	HSNO Classification	HSNO Default Controls
DuPont Benevia Insecticide	6.5B 9.1A	Toxic T1, T2, T4,T5, T7 Ecotoxic El, E2, E5, E6, E7, E8, Identification I1, I3, I9, I11, I16, I17, I18, I19, I21, I23, I28, I29 Packaging and Packaging Group P1, P3, P13, P15, PG3, PS4 Disposal D4, D5, D6, D7, D8, Emergency Management EM1, EM6, EM7, EM8, EM11, EM12, EM13 TR1, AH1
DuPont Exirel Insecticide	6.3B, 6.4A, 6.5B 9.1A	Toxic T1, T2, T4,T5, T7 Ecotoxic El, E2, E5, E6, E7, E8, Identification I1, I3, I9, I11, I16, I17, I18, I19, I21, I23, I28, I29 Packaging and Packaging Group P1, P3, P15, PG3, PS4 Disposal D5, D6, D7, D8, Emergency Management EM1, EM7, EM8, EM11, EM12, EM13 AH1

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.

This information is used in the development of exposure scenarios and the assessment of risks, costs and benefits and should therefore be as expansive as possible.
(See comments under "Section 3.5 of Form" in the User Guide)

Manufacture, Formulation:

DuPont Benevia and DuPont Exirel Insecticides are manufactured overseas and will be imported into New Zealand as the formulated product, packed for retail sale.

Manufacture, Formulation in New Zealand:

Neither substance is expected to be manufactured in New Zealand: neither is justified on the grounds of economics.

Packaging:

DuPont Benevia Insecticide will be packed in 1 and 5L HDPE (High density polyethylene) , PET (Polyethylene terephthalate or PE/EVOH (Polyethylene/ethylene-vinyl alcohol) containers. DuPont Exirel insecticide will be packed in 1,5 and 10L HDPE (High density polyethylene) , PET (Polyethylene terephthalate or PE/EVOH (Polyethylene/ethylene-vinyl alcohol) containers. Packaging will comply with UN specifications.

Transport:

The products will have the following Dangerous Goods classification for Land, Sea, Air Transport:
DuPont Benevia Insecticide
UN No: 3082
Description: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S. (Cyantraniliprole)
Class: 9
Packing Group: III

DuPont Exirel Insecticide
UN No: 3082
Description: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S. (Cyantraniliprole)

The manufactured products will be imported by sea or air freight into Auckland, New Zealand in containers, complying with UNRTG requirements. The containers will be shrink wrapped on pallets and labelled with the approved NZ label. Transportation is by approved carriers to the Chemfreight warehouse in East Tamaki,, Auckland.. From this store, product is despatched to the various stores of resellers throughout NZ again by approved carriers equipped with the MSDS and HAZNOTE (EPG).

Storage:
The substances will be stored primarily in the dedicated chemical warehouse of Chemfreight situated at 10C Stonedon Drive, East Tamaki, Auckland.. This store has , location certificate and two approved handlers on site. It is bunded, well equipped with fire extinguishers and carries the approved signage. The staff are trained in and are familiar with the procedures for separation of products according to their hazardous properties and in safe handling, storage and preparation of products for transportation.
Distributors too have dedicated pesticide storage facilities and staff trained in the safe handling and storage of pesticide products and dealing with any emergencies that might arise. The maximum quantities of either substance stored in distributor's stores is not expected to exceed 500 litres.
MSDS's for products are readily available to all store workers and the customers.
Use:
The uses of DuPont Benevia and DuPont Exirel Insecticide are restricted by label claims to horticulturalists and farmers who are familiar with safe practices regarding the storage and handling of pesticides: The insecticides will not present them with any hazards with which they are not already familiar. We would not expect on-farm storage to exceed 50 litres.

Use Patterns:

DuPont Benevia Insecticide
Vegetables
DuPont Benevia is recommended for application to potatoes, field tomatoes and onions .
Its use in potatoes and tomatoes will be for control of tomato/potato psyllid, potato tuber moth, tomato fruit worm and green peach aphid and in onions to control thrips. DuPont Benevia is recommended at an application rate of 500mL/ha at 7-10 day intervals as part of a programme. To manage insect resistance, a maximum of three applications are advised per crop per season.
DuPont Exirel Insecticide
Fodder brassicas
DuPont Benevia is recommended for application to various fodder brassicas (turnips, kale, forage rape, swedes) It will be used for control of cabbage white butterfly, diamondback moth, soybean looper caterpillar, European leaf miner and grey cabbage aphid. It is recommended at an application rate of 150mL/ha at 2-3 week intervals as part of a programme. To manage insect resistance, a maximum of three applications are advised per crop per season.

Disposal: The preferred option will be to use as the products as per the label directions. Because of the value of the products and stability, any unused product can be carried over into the next season.
If disposal of product still poses a problem the user should contact the local regional council for advice. Empty containers will be triple rinsed, with rinsate added to spray tank.
If recycling is not possible the empty container will be punctured and disposed of at an approved landfill.

Section Four: Risks, Costs and Benefits

These are the positive and adverse effects referred to in the HSNO Act. It is easier to regard risks and costs as being adverse (or negative) and benefits as being positive. In considering risks, cost and benefits, it is important to look at both the likelihood of occurrence (probability) and the potential magnitude of the consequences, and to look at distribution effects (who bears the costs, benefits and risks).

You will need to consider the effects on the environment and human health and welfare, including any social effects.

In each section set out below, it might be easier for you, and most useful for ERMA New Zealand, if the information is set out under the following three sub sections:

- Costs and benefits which can be stated in monetary (dollar) terms
- Non-monetary risks and costs
- Non-monetary benefits.

Complete this section as far as you can. If the analysis provided is incomplete, then it will be completed by ERMA New Zealand. However, the costs of doing this will be chargeable.

You will need to provide a brief description of where the information in the application has been sourced from, eg from; inhouse research, independent research, technical literature, community or other consultation.

(See comments under "Section 4 of Form" in the User Guide)

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

Identification is the first step in assessing risks, costs and benefits. The introductory part of "Section 4 of Form" in the user Guide provides detailed guidance on what kinds of costs,

risks and benefits should be thought about. It is important to think about the source of the risk, ie the way in which the risk is created (the exposure pathway), and then the consequences and likelihood of exposure.

You should try to think as widely as possible about every potential risk, cost and benefit and give a brief description. The range of matters that you will need to think about is discussed in the User Guide. You must also decide how significant that risk, cost or benefit is likely to be. If the risk, cost, or benefit is obviously not significant (and you can give reasons), then there is no need to further assess that risk, cost, or benefit.
(See comments under "Section 4.1 of Form" in the User Guide)

Risks.

Review of potential environmental effects

Air, water, soil contamination.

The low vapour pressure and Henry's law constant of cyantraniliprole indicate a low potential for volatilisation and air contamination under practical conditions of use.

Hydrolysis in neutral water showed a DT_{50} of 60 days . Aquatic contamination will be minimal since the products will be confined to application by ground hydraulic sprayers to vegetable and fodder crops.

Ten field studies to evaluate fate in soil were conducted during 2006 through 2008 seasons in the United States, Canada and Europe. The field studies were conducted with the two different formulations (Cyantraniliprole 100 g/L OD and Cyantraniliprole 200 g/L SC). Various dissipation modules were addressed in all these field studies. The dissipation modules include; bare soil plots with sampling in multiple depth segments to a total depth of 90 cm, cropped plots in parallel with bare soil plots to determine the extent of crop uptake or the impact of crop presence on the dissipation rates, contribution from photolysis of the parent compound towards the dissipation in field, and contribution from run-off from the bare soil plots due to normal irrigation events. The normalized geomean DT_{50} value for cyantraniliprole after application to all field sites was 32.4 days.

Effects on terrestrial vertebrates

Cyantraniliprole has negligible acute, dietary and reproductive effects in birds. The oral acute and oral dietary LD/LC_{50} values were greater than the highest doses tested. The no observed test levels (NOEL) for the reproduction tests were the highest doses tested.

Cyantraniliprole has negligible acute and reproductive effects in mammals. The oral acute toxicity was > 5,000mg/kg body weight for rats. The NOEL from the rat two-genetation test was 1,353 mg/kg body weight, the highest test dose.

Effects on aquatic species

Cyantraniliprole has negligible acute and chronic toxicity to fish and negligible bioconcentration in fish (Bioconcentration value 1.0). The most sensitive acute LD_{50} value is greater than 10.0mg/L (channel catfish), the highest mean measured concentration tested and also the apparent limit of solubility in that test system. The most sensitive chronic no observed effects concentration (NOEC) is 1.01 mg/L (rainbow trout)

Cyantraniliprole has negligible effects on algae and aquatic plants. The most sensitive EC_{50} values for algae *(Skeletonema costatum)*and aquatic plants *(Lemna gibba*) were greater than the highest concentration tested, the apparent limit of solubility in that system.

Cyantraniliprole can be highly toxic to aquatic invertebrates. The most sensitive acute LD_{50} and chronic NOEC values are 0.0204mg/L *(Daphnia magna)* and 0.00179mg/L (*Chironomus riparius),* respectively. Daphnia magna were less sensitive to metabolites of cyantraniliprole in acute toxicity tests.

Effects on bees and other arthropod species

Laboratory acute oral and acute contact LD50 values were >0.1055 and > 0.0934µg/bee respectively.
Acute testing on honeybees demonstrated similar toxicities of the two formulations, cyantraniliprole 100 g/L OD and cyantraniliprole 100 g/L SE. Field tests with two applications of 150ga.i/ha cyantraniliprole during flowering and after flowering had no affects on mortality, behavior , brood development or colony strength. Overall, it is DuPont's position that the intended uses of cyantraniliprole 100 g/L SE or 100g/L OD pose no unacceptable acute and chronic risks for honeybees, colony development and survival and behaviour when used according to Good Agricultural Practices and in accordance with the product label.

Based on the Tier 1 risk assessment for the sensitive indicator species, *T. pyri,* Cyantraniliprole 100 g/L OD will pose low risk in-field. *A. rhopalosiphi* was susceptible under worst-case Tier 1 laboratory conditions to Cyantraniliprole 100 g/L OD. The Tier 1 in-field and off-field risk assessment for the sensitive indicator species, *A. rhopalosiphi,* results HQ value of 1502 and 109, respectively, indicating potential risk (HQ value >2). Additional studies were conducted with green lacewing (*Chrysoperla ca*rnea) and lady bird beetle (*Cocinella septempuntata.)* Exposure to the fresh dried and 14,28 day aged cyantraniliprole spray deposits resulted in no significant effect on either species or reproduction compared to the controls.

Effects on earthworms

Cyantraniliprole has negligible acute and sub-lethal effects on earthworms. The LC_{50} and NOEL were greater than 1,000mg/kg

Effects on native flora

None expected-no herbicidal activity.

Effects on Human Health-workers, operators, bystanders

DuPont Benevia and Exirel Insecticides have no significant acute toxicity via oral, dermal and inhalation routes of exposure. Both substances can cause skin sensitisation and DuPont Exirel, in addition, triggers hazard classifications for skin and eye irritation. Neither substance is genotoxic, carcinogenic, neurotoxic or immunotoxic. Neither are they reproductive or developmental toxins. The proposed ADI or CRfD is 0.057 mg/kg bw/day, based on the NOAEL of 5.7 mg/kg bw/day for male dogs and a 100-fold safety factor (10-fold intra-species variability factor and 10-fold inter-species extrapolation factor).

Effects on Economic Social and Cultural Well being of Communities

No adverse effects are anticipated.

Effects on Foreseeable Needs of Future Generations

No adverse effects are anticipated.

Development of Insect Resistance

Although the products represent an entirely new family of chemistry with a totally different action to all those currently employed, poor management strategies could lead to insect resistance.To minimize or delay the onset of resistance the label will carry a warning statement and recommend strategies of use.

Transport / Storage

DuPont Benevia and DuPont Exirel Insecticides introduce no special risks. At all times the products 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.

Warehouse staff ,resellers and users are required to observe Codes of Practice [ISO 9002 or Growsafe] for storage and growers are also Growsafe accredited. [As per NZS 8409:2004]
Stores are provided with MSDS's and transporters with HAZNOTES (EPG's)

Dispensing and use
As well as providing directions for use, labels carry hazard warnings and precautions during mixing and spraying for protection of operators, bystanders and the environment in accordance with EPA classifications and controls.

Disposal of excess product, empty containers
Advice regarding disposal is included on the label. The value of the product is such as to discourage careless disposal.

Table 4.1 Summary of risk identification of DuPont Benevia and DuPont Exirel insecticides

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	Not expected	N/A	N/A	Nil	Insignificant
	Aquatic environment	Very unlikely	Localised		Short term	Reversible	Involuntary	Minor	Insignificant
	Terrestrial Environment	Very unlikely	Localised		Not expected	N/A	N/A	Nil	Insignificant
Damage to packaging during storage	Human health	Very unlikely	Localised	Not expected	Not expected	N/A	N/A	Nil	Insignificant
	Aquatic environment	Very unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Insignificant
	Terrestrial Environment	Very unlikely	Localised		Not expected	N/A	N/A	Nil	Insignificant
Spillage of substance during dispensing and use	Human health	Unlikely	Localised	Not expected	Not expected	N/A	N/A	N/A	Insignificant
	Aquatic environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Insignificant
	Terrestrial Environment	Unlikely	Localised		Not expected	N/A	N/A	N/A	Insignificant
Incorrect disposal of surplus substance	Human health	Unlikely	Localised	Not expected	Not expected	N/A	N/A	N/A	Insignificant
	Aquatic environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minor	Insignificant
	Terrestrial Environment	Unlikely	Localised		Not expected	N/A	N/A	N/A	Insignificant

4.2 Provide an assessment of those risks, costs, and benefits identified in Section 4.1 which might be significant.

This section excludes risks, costs, and benefits which relate specifically to Māori taonga or to international agreements. See Sections 4.3 and 4.4 below for those aspects.

Assessments only need to be done for those risks, costs and benefits which Section 4.1 shows might be significant. Section 4.2 in the User Guide provides a detailed explanation of how to do an assessment. Remember that assessments can be qualitative ie based on judgements, if there is no analytical information available. But it is essential that a firm conclusion is drawn about the size and likelihood of the risks, costs or benefits, and also about the certainty of the assessment.

In assessing risks especially, it is important to take account of the extent to which risks will be reduced by the default or other controls (see Section 3.4 above and 4.5 below).
(See comments under "Section 4.2 of Form" in the User Guide)

Costs

The proposed HSNO controls , ACVM requirements and label restrictions will eliminate any potential costs to the NZ economy, our society and the environment in the use of these insecticides.
The cost associated with their use will be to the user who obviously would not outlay the cost of the products, spray equipment and safety equipment without seeing a satisfactory financial benefit.

Benefits

Potato/tomato/onion growers

The tomato/potato psyllid and the Liberibacter pathogen spread by the psyllid, has cost the potato industry over $100 million in the past three seasons based on an estimate of $47-56 million in 2008-9 and $28 million in the last two seasons. (Potatoes NZ September 2011 bulletin) Liberibacter interferes with the potato plant's transportation of sugars into tubers resulting in mottling,browning and discolouration (zebra chip) of cooked chips or crisps. With the intensive use of insecticides over the past seasons to control the psyllid , risk of insect resistance is a constant concern..
Green peach aphids can attain very high densities on young plant tissue, causing water stress, wilting, and reduced growth rate of the plant. Prolonged aphid infestation can cause appreciable reduction in yield of root crops and foliage crops. In addition, they transmit a number of viruses, the management of which is fundamental to potato and tomato production in New Zealand.
Tomato fruit worm is a key pest of processing tomatoes in the major growing regions of Hawkes Bay and Gisborne where it damages up to 30% of the fruit in unsprayed, late season crops.
Onion thrips are the main insect pest of onions in New Zealand and uncontrolled infestations cause loss of green tissue and yield. In addition, onion thrips feeding on onion bulbs lower the quality and consequently export value to the Industry. Control of onion thrips is largely dependant on application of a programme of effective insecticides based on monitoring insect populations throughout the growing season. Insect resistance however has already been confirmed to synthetic pyrethroid and organo-phosphate insecticides and presents an ongoing threat to other chemistry.

Farmers growing fodder brassicas

Some 300,000 ha of fodder brassicas are now grown in New Zealand for livestock as a supplementary feed option to pasture. Insect pests are a major constraint to sustainable production. The key pests are Cabbage white butterfly*(Pieris rapae)* , Diamond back moth *(Plutella xylostella)* and European leaf miner.(*Scaptomyza flava)*
Diamond back moth has become resistant to many standard insecticides used previously to control caterpillars and alternative chemistry is required. Also, important is the development of effective natural enemies (parasitoids) of some of the key pests which can also assist in an overall IPM system if suitable "selective" insecticides are available.

Benefits (cont.)

DuPont Benevia® and DuPont Exirel insecticides will provide useful additional tools for the control of insect pests that cause loss of yields and quality of produce to these crops. The new insecticides represent a new class of chemistry with a new mode of action to the insecticides currently in use . They have a low toxicity, are relatively safe to beneficial insects and insect parasitoids, safe to bees and earthworms. DuPont Benevia will provide growers with a useful additional tool in the control of insect pests in potatoes tomatoes and onions. DuPont Exirel insecticide will assist livestock farmers to maximise yields of fodder brassicas.

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

We have asked for a separate response in this area because these requirements are different to other risks, costs and benefits. These are explained in more detail in Section 4.3 of the User Guide. Please note that if there are potentially significant risks in this area, it will almost certainly be necessary to consult with Māori in preparing an assessment.
(See comments under "Section 4.3 of Form" in the User Guide)

The importation and use of DuPont Benevia and DuPont Exirel insecticides will not adversely affect the natural resources of the flora, fauna, waterways, land, culture or other taonga of the indigenous Maori, or impact on the Treaty of Waitangi.

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

This is a specialist area which ERMA New Zealand will handle. However, any information you are able to provide on relevant international agreements would help us and save time and cost.
(Optional) (See comments under "Section 4.4 of Form" in the User Guide)

Registration is pending in Australia, USA, Canada and EU countries.

4.5 Provide information on the proposed management of the substance.
This section should provide information on managing the effects identified and assessed in Sections 4.1 - 4.4 above. The starting point for this is the range of default controls triggered by the hazardous property classification(s) attached to the substance (see Section 3.4). You should describe how these controls would be implemented and indicate other mean of managing risks.. The information provided must be specific to the substance(s) and cover all areas of intended use. Reference should be made to Codes of Practice or standard operating procedures that will be followed. If changes to the default controls triggered by the substance classification are proposed, the reasons for these changes should be provided.

Please note that you will find it easiest to complete this section in conjunction with section 4.2. That is because the management of risks will influence their residual level.
(See comments under "Section 4.5 of Form" in the User Guide)

The overall management of the substances 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 8409:2004] Documentation to facilitate this will include the ready availability of the product container label, Product HAZNOTE (Safety Card) and Material Safety Data sheet.

The two insecticide products will be transported, stored and handled by persons familiar with these types of products. Both insecticides present a low risk to humans and the environment. The warnings and precautions set out on labelling, SDS and HAZNOTE will eliminate or mitigate the slight human and aquatic toxicity hazard posed by the products.

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.

Doing this overall evaluation is the main task of the Authority. However, you may wish to express a view on the relative importance of the different risks, costs and benefits and how they should be brought together in making a decision.
(Optional) (See comments under "Section 4.6 of Form" in the User Guide)

In summary-the slight hazard s posed by the toxicity/ecotoxicity is far outweighed by the benefits to the New Zealand commercial grower and livestock farmer. The new products represent a new chemical group, they are extremely efficacious at low rates of use, virtually non toxic to operators, safe to birds, bees, earthworms and soil microflora and have a favourable breakdown pattern in the environment.

Section Five – International Considerations

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. If you are aware of this, please provide details of the results of such consideration. (Optional) (See comments under "Section 5.1 of Form" in the User Guide)

A globally harmonised OECD registration dossier is being reviewed at present. Registration is expected to be approved in USA, EU, Canada, Australia and New Zealand (ACVM) during late 2012

Section Six – Miscellaneous

6.1 Provide a glossary of scientific and technical terms used in the application.
(See comments under "Section 6.1 of Form" in the User Guide)

6.2 Provide here any other information you consider relevant to this application not already included.
(See comments under "Section 6.2 of Form" in the User Guide)

Section Seven – Summary of Public Information

The information provided in this section may be used in the Authority's public register of substances required under Section 20 of the HSNO Act.

This summary information will be used to provide information for those people and agencies (eg Ministry for the Environment, Department of Conservation, Regional Councils, etc), who will be notified of the application, and for potential submitters who request information. This information will also be used to prepare the public notice of the application.

For these reasons, applicants should ensure that this summary information does not contain any commercially sensitive material.

7.1 Name of the substance(s) for the public register:

Please use a maximum of 80 characters.
(See comments under "Section 7.1 of Form" in the User Guide)

DuPont™ Benevia ®Insecticide
DuPont™ Exirel® Insecticide

7.2 Purpose of the application for the public register:

This should include (in a maximum of 255 characters) an abstract giving information on the intended use of the substance and why an application is needed based on its hazardous properties.
(See comments under "Section 7.2 of Form" in the User Guide)

The purpose of the application is to seek approval to import and release DuPont Benevia Insecticide for control of certain insect pests in onions, potatoes and field tomatoes.
Approval is sought to import and release Du Pont Exirel Insecticide for the control of a range of insect pests in fodder brassica crops.
The application is required since the two products trigger hazards for toxicity and ecotoxicity.

7.3 Use Categories of the substance(s):

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance(s).

- Main category: There are four main categories - see User Guide for details.
- Industry category: There are 16 industry categories - see User Guide for details.
- Function/Use category: There are 55 function/use categories - see User Guide for details.

(Optional) (See comments under "Section 7.3 of Form" in the User Guide)

Main Category	3
Industry Category	1
Function/ Use	38

7.4 Executive Summary:

In this section, the applicant should provide a summary of information contained in this application, including:

- the identification of the substance, its hazardous properties and intended uses
- an assessment of the risks, costs and benefits
- the methods implemented to manage the risks, particularly in relation to emergency management and disposal.

(See comments under "Section 7.4 of Form" in the User Guide)

This is an application to import DuPont Benevia® Insecticide and DuPont Exirel® Insecticide into New Zealand for control of certain insect pests. The products , which will be formulated and packed overseas, contain the same active ingredient (cyantraniliprole) but have different formulations.
DuPont Benevia insecticide is a 10% oil dispersion (OD)formulation and will be used by potato and , field tomato growers to control tomato/potato psyllids, potato tuber moth, tomato fruit worm and green peach aphid .It will also be used by onion growers to control thrips..
DuPont Exirel Insecticide is formulated as a 10% suspo-emulsion (SE) and will be used by livestock farmers to control certain caterpillars, leaf miners and grey cabbage aphid in various fodder brassica crops.

We believe DuPont Benevia insecticide has the hazard classifications 6.5B and 9.1A
and that DuPont Exirel insecticide has the hazard classifications 6.3B, 6.4A, 6.5B, 9.1A

The two products pose a low risk to humans or the environment if handled and used according to label directions.
Following importation , the products 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 8409:2004] Documentation to facilitate this will include the ready availability of the container label, HAZNOTE (Product Safety Card) and Material Safety Data sheet.

The benefits of the two new insecticides are:

- Efficacy at low rates of application on a range of important insect pests in commercial vegetablecrops and in fodder brasicas.
- New chemistry, new mode of action to assist with insect resistance management.
- Low toxicity to operators.
- A high margin of safety to bees, beneficials, earthworms and soil microflora.
- Not expected to accumulate in the environment.

CHECKLIST

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

Signed Mike Cornwell

(Consultant to DuPont NZ Ltd) Date 19 December 2011

Appendix 1. Commercially Sensitive Information