

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



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): DuPont TM Talendo[®] fungicide

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: DuPont (New Zealand) Ltd
Central Park Corporate Centre
Level 2, Building 5
666 Great South Road
Greenlane, Auckland 1051

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)

Chemical name: 6-Iodo-2-propoxy-3-propyl-4(3H) quinazolinone (CAS)

Common name: proquinazid

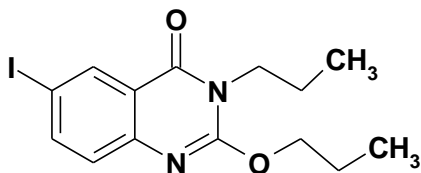
Synonyms: DPX-KQ 926

Trade Names: DuPont Talendo fungicide

CAS No: 189278-12-4

Formula: C₁₄H₁₇IN₂O₂

Structural formula:



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)

Physical and Chemical properties of DuPont Talendo fungicide

Appearance: Brown liquid with pungent, sweet, ester like odour. (DuPont- 12183)

Relative density: 0.9758 (DuPont -12183)

Vapour pressure: 9×10^{-5} Pa(25°C) (Technical) (AMR-3879-96)

pH: 6.18 in a 1% aqueous dilution (CIPAC MT75) (DuPont -12183)

Melting point: 61.5-62°C (technical) (AMR 4297-97)

Partition Coefficient (log Pow) : 5.5 (technical) (AMR 4097-96)

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).

Explosiveness: Non explosive (DuPont -12183)

Flammability: Flash point 74°C closed cup (EEC A9 method) (DuPont -12183)

Oxidising properties: Not an oxidiser (UN Test O.2) (DuPont -12183)

Corrosiveness: Non corrosive

DuPont Talendo fungicide Impact on Hazard classification

1	Explosive	Not triggered
3	Flammable	Triggered 3.1D
5	Oxidising	Not triggered
8.1	Metallic corrosive	Not triggered

Acute toxicity:

Acute Oral Toxicity in Rats

LD₅₀: > 2,000 mg/kg (DuPont- 12086)

LD₅₀: > 5,000 mg/kg (technical) (DuPont -2039)

Acute Dermal Toxicity in Rats

LD₅₀: > 5,000 mg/kg (DuPont -12309)

Acute Inhalation Toxicity in Rats

LC₅₀ : > 5.2mg/L(technical) (DuPont - 10838)

Skin Irritation in Rabbits

Irritating to skin. (DuPont-11972)

Eye Irritation in Rabbits

Irritating to eyes. (DuPont-12324)

Skin Sensitisation in guinea pigs

Not a skin sensitiser (DuPont- 12310)

Impact on Hazard classification- DuPont Talendo fungicide

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

Chronic Toxicology, proquinazid technical

28 day dermal toxicity in rats

NOAEL 500mg/kg/day males, 100mg/kg/day females (DuPont -1131)

Neurotoxicity study in rats- technical

NOAEL 100mg/kg (m) , 50mg/kg/day (f) (HL-1997-00244)

90 day study in rats

NOAEL 100ppm (m: 6.33 mg/kg.bw/day), (f.) 100 ppm (8.01 mg/kg.bw/day) (DuPont-1127, Revision No. 2 Volume 2)

90 day oral toxicity in mice

NOAEL 1,000ppm (m. 185 mg/kg.bw/day), (f. 302 mg/kg.bw/day) (HLR 923-96 Volume 2)

Carcinogenicity study in mice- 18 month study.

There is limited evidence of carcinogenic effects. The NOAEL was 30ppm (m. 3.9 mg/kg/day, f. 5.9 mg/kg/bw/day). (HL-1998-00645 Volume 2, Volume 3, Volume 4, Volume 5.)

Oral 1 year study in dogs

NOAEL 15mg/kg/day (m) and 60mg/kg/day (f) (HLO- 1998-01341 Volume 3,4

Oral 2 year study in rats

NOAEL 30ppm males and females (1.16mg/kg/day male, 1.39mg/kg/day female) (DuPont HL-1999-00644 Volumes 2,3,4,5,6,7,8,9

Reproductive toxicity study in rats

Multigeneration study

NOAEL (parental toxicity):30 ppm , (reproduction and fertility) 600ppm, (pup growth/development) 150ppm (DuPont -3080 Volumes 2,3,4,5,6

Developmental studies-rats

NOAEL 30mg/kg/day maternal & foetal effects (HL-1997-00707)

Developmental studies-rabbits

NOAEL 2.5mg/kg/day maternal & foetal effects (HL-1998-01281)

Genotoxicity Studies

Bacterial Reverse Mutation test

Under the conditions of this test there was no evidence of mutagenicity. (DuPont -1600)

In vitro chromosome aberration test in human lymphocytes

Test substance did not induce increases in structural chromosome aberrations.

Impact on Hazard classification- for DuPont Talendo fungicide

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

Acceptable daily intake (ADI)

The chronic studies in dogs, rats, and mice were considered the appropriate studies to use as a basis for an ADI. The lowest NOAEL was observed in the 2-year rat study, 30 ppm for males and females, equivalent to 1.16 and 1.39 mg/kg/day, respectively. This NOAEL was based on test substance-related changes in the liver and thyroid at 300 ppm and above. There were no corrections necessary to account for absorption of ingested proquinazid. There was also no need for corrections due to dietary stability.

The prepared diets were stored refrigerated and presented to the to the animals in intervals that ensured proquinazid stability throughout the chronic studies. Therefore, the proposed ADI is 0.012 mg/kg/day, based on the NOAEL of 1.2 mg/kg/day for males and a 100-fold safety factor.

This consists of uncertainty factors of 10 each for extrapolations between species and within a population and is considered sufficiently conservative to protect the consumer. The following is provided as additional support:

- The mechanism of action of proquinazid has been fully determined for thyroid and liver effects.
- The mechanisms of action are unique to rodents and/or occur only at doses exceeding the MTD and thus are not relevant for assessment of human risk.
- A clear threshold for these effects has been determined.

With these considerations, additional uncertainty factor is not warranted to ensure consumer protection.

ACUTE REFERENCE DOSE (ARfD)

An ARfD of 0.2 mg/kg bw is proposed for proquinazid based on applying a 100-fold assessment factor to a dose level of 500 ppm (= 19 mg/kg bw/day for the first week of exposure). At the dose level of 500 ppm, an increased incidence of ocular discharge was seen in one dog at the time of first exposure in a 90-day dietary study with batch KQ926-45

Ecotoxic effects:

Aquatic toxicity

Table 1 Proquinazid aquatic toxicity endpoint values

Species	Test/duration	Measurement endpoint	Endpoint value (mg/L)
<i>Oncorhynchus mykiss</i> AMR 4165-96	Acute (96 hr)	LC ₅₀	0.349
<i>Lepomis macrochirus</i> AMR 4166-96	Acute (96 hr)	LC ₅₀	0.454
<i>Cyprinodon variegatus</i> AMR 4482-97	Acute (96 hr)	LC ₅₀	>0.58
<i>Daphnia magna</i> AMR 4167-96	Acute (48 hr)	EC ₅₀	0.287
<i>Mysidopsis bahia</i> AMR 4481-97	Acute (96 hr)	LC ₅₀	0.11
<i>Crassostrea virginica</i> AMR 4484-97	Acute (96 hr)	EC ₅₀	0.219
<i>Selenastrum capricornutum</i> AMR 4168-96	Acute (72 hr)	EC ₅₀ NOEC	0.615 0.217
<i>Navicula pelliculosa</i> AMR 4478-97	Acute (120 hr)	EC ₅₀ NOEC	0.30 0.25
<i>Anabeana flos-aquae</i> AMR 4480-97	Acute (120 hr)	EC ₅₀ NOEC	>0.884 0.884
<i>Lemna gibba</i> AMR 4580-97	Short term (14 days)	EC ₅₀ NOEC	>0.2 >0.2
<i>Chironomus riparius</i> DuPont-2042	Chronic (28 days)	EC ₅₀ NOEC	>1.0 0.32
<i>Oncorhynchus mykiss</i> HL-1998-00638	Early life stage (90 days)	NOEC	0.003
<i>Cyprinodon variegates</i> AMR 4486-97	Early life stage (32 days)	NOEC	0.00872
<i>Daphnia magna</i> HL-1998-00628	Chronic (21 days)	NOEC	0.0018
<i>Mysidopsis bahia</i> AMR 4485-97	Chronic (28 days)	NOEC	0.0105

Table 2 Du Pont Talendo® fungicide aquatic toxicity endpoint values

Species	Test/duration	Measurement endpoint	Endpoint value (mg/L)
<i>Selenastrum capricornutum</i> DuPont -11234	Acute (72 hr)	EC ₅₀ NOEC	3.3 (0.640 mg a.s./L) 0.63 (0.122 mg a.s./L)
<i>Pseudokirchneriella subcapitata</i> DuPont -21739	Acute (72 hr)	EC ₅₀ NOEC	2.5 (0.5 mg a.s./L) 0.8 (0.16 mg a.s./L)
<i>Daphnia magna</i> DuPont -11232	Acute Static (48 hr)	EC ₅₀	1.8 (0.348 mg a.s./L)
<i>Oncorhynchus mykiss</i> DuPont -11233	Acute Static renewal (96 hr)	LC ₅₀	0.349 (0.446 mg a.s./L)

Aquatic

In an early life stage test conducted with the rainbow trout the 90-day NOEC was based on mean measured concentrations of proquinazid and on abnormalities (small size, distended abdomen, lethargy) and length of surviving fingerlings. The 21-d NOEC in a 21-d static-renewal test with *Daphnia magna* was based on mean, measured concentrations and on the total number of live young produced at test end. Proquinazid has a log Pow >3, however the bioconcentration study indicated proquinazid has a low potential to bioconcentrate >100 but <1000 (DuPont -8197). The environmental metabolites (IN-MM671, IN-MM986, IN-MM991, and IN-MT884) all showed less toxicity than proquinazid.

A summary of the aquatic toxicity testing values obtained with active substance, proquinazid and DuPont Talendo® fungicide are summarised in and Table 2 (above).

Terrestrial vertebrates**Table 3 Summary of effects of proquinazid on non-target arthropods**

Species	Test (test substance ^a and test rate)	Measurement endpoint	Endpoint value
<i>Apis mellifera</i> AMR 4592-97	Oral (proquinazid, DPX-KQ926-45)	LD ₅₀	>125 µg proquinazid/bee
<i>Apis mellifera</i> AMR 4592-97	Contact (proquinazid, DPX-KQ926-45)	LD ₅₀	>197 µg proquinazid/bee
<i>Aphidius rhopalosiphii</i> DuPont-10705	Laboratory Tier 1 (Talendo® fungicide (200 g/L EC), DPX-KQ926-100)	LR ₅₀	134.36 g proquinazid/ha
<i>Aphidius rhopalosiphii</i> DuPont -12087	Laboratory Tier 1 (Talendo® fungicide (200 g/L EC), DPX-KQ926-100 and DPX-KQ926-107)	LR ₅₀ (DPX-KQ926-100) LR ₅₀ (DPX-KQ926-107)	135.18 g proquinazid/ha 131.42 g proquinazid/ha
<i>Aphidius rhopalosiphii</i> DuPont-10706	Laboratory Tier 2 (Talendo® fungicide (200 g/L EC), DPX-KQ926-100, 4 x 75 g proquinazid/ha)	Mortality: Reproduction:	max. 3% relative to control 0% relative to control
<i>Aphidius rhopalosiphii</i> AMR 5142-98	Laboratory Tier 2 (Talendo® fungicide (200 g/L EC), DPX-KQ926-71, 3 x 50 g proquinazid/ha)	Mortality: Reproduction:	max. 2% relative to control <50% relative to control
<i>Typhlodromus pyri</i> DuPont -10704	Laboratory Tier 1 (Talendo® fungicide (200 g/L EC), DPX-KQ926-100)	LR ₅₀	97.17 g proquinazid/ha
<i>Typhlodromus pyri</i>	Laboratory Tier 1 (Talendo® fungicide	LR ₅₀ (DPX-KQ926-	62.27 g proquinazid/ha

DuPont -12088	(200 g/L EC), DPX-KQ926-100 and DPX-KQ926-107)	100) LR ₅₀ (DPX-KQ926-107)	47.85 g proquinazid/ha
<i>Typhlodromus pyri</i> , <i>Amblyseius andersoni</i> DuPont -10709	Field test in Germany (Talendo® fungicide (200 g/L EC), DPX-KQ926-100, 4 x 75 g proquinazid/ha	Reduction on population	max. 21% relative to control
<i>Typhlodromus pyri</i> , <i>Amblyseius andersoni</i> , <i>Kampimodromus aberrans</i> , <i>Typhlodromus phialatus</i> DuPont -10712	Field test in Italy (Talendo® fungicide (200 g/L EC), DPX-KQ926-100, 4 x 75 g proquinazid/ha	Reduction on population	max. 28% relative to control
<i>Typhlodromus pyri</i> DuPont -10713	Field test in France (Talendo® fungicide (200 g/L EC), DPX-KQ926-100, 4 x 75 g proquinazid/ha	Reduction on population	max. 21% relative to control
<i>Chrysoperla carnea</i> DuPont -10707	Laboratory Tier 2 (Talendo® fungicide (200 g/L EC), DPX-KQ926-100, 4 x 75 g proquinazid/ha)	Mortality: Reproduction:	max. 0.2% relative to control <50% relative to control
<i>Orius laevigatus</i> DuPont -10708	Laboratory Tier 2 (Talendo® fungicide (200 g/L EC), DPX-KQ926-100, 4 x 75 g proquinazid/ha)	Mortality: Reproduction:	max. 7% relative to control <50% relative to control

Proquinazid was of low acute toxicity to honey bees with acute oral and contact LD₅₀ values of >125 µg a.s./bee and > 197 µg a.s./bee, respectively. The formulated product Proquinazid 200g/L EC was also of low acute toxicity to honey bees with acute oral and contact LD₅₀ values of >99.75 µg a.s./bee and >100 µg a.s./bee, respectively.

Effects on terrestrial vertebrates

A summary of the toxicity endpoints for honey bees and a range of other terrestrial non-target arthropod species resulting from worst-case laboratory testing and higher tier testing at maximum application rate and minimum spray interval are given in Table 3.

Proquinazid displayed low acute toxicity to honey bees. For the 2 sensitive standard non-target arthropod species, *Typhlodromus pyri* and *Aphidius rhopalosiphi* low to moderate acute toxicity was determined under worst-case Tier 1 laboratory conditions. Consequently higher tier testing was conducted with the 2 sensitive standard species plus 2 crop relevant species, *Chrysoperla carnea* and *Orius laevigatus*. Under extended laboratory conditions at maximum application rate and minimum spray interval proquinazid was found to be harmless to *A. rhopalosiphi*, *C. carnea* and *O. laevigatus*. It was proved that proquinazid was harmless to *Typhlodromus pyri* under field conditions at maximum application rate and the maximum number of applications and the minimum spray interval. Overall it is unlikely that the intended use of proquinazid will have unacceptable effects on natural in-field or off-field non-target arthropod populations. Risk mitigation measures will not be necessary to protect off-field non-target arthropods for the potential risk due to spray drift of proquinazid.

Effects on Birds

Proquinazid is of low acute toxicity to birds, producing no mortality at the maximum dose levels used in the single oral and short-term dietary tests. Effects on reproductive parameters manifested as reduction in hatching success and offspring survival in quail and hatchling body-weight in mallard ducks.

A summary of avian toxicity endpoints are presented in Table 4 and Table 5 (below)

Table 4 Summary of avian toxicity endpoints proquinazid

Test	Measurement endpoint	Bobwhite quail	Mallard duck
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Single oral dose AMR 4184-96	LD ₅₀	>2250 mg/kg b.wt.	-
Short-term dietary (8 day) AMR 4182-96	LC ₅₀	>5620 ppm	>5620 ppm
Reproduction (21 week) AMR 4407-97	NOEC	85 ppm	255 ppm

Table 5 Summary of avian toxicity endpoints DuPontTalendo® fungicide

Test	Measurement endpoint	Bobwhite quail
Single oral dose DuPont -10702	LD ₅₀	>2250 mg Talendo® fungicide (200 g/L EC)/kg bw

Effects on earthworms-

Ecotoxicological endpoints as obtained in tests with earthworms.

Neither the technical nor product are toxic to earthworms.

Table 6

Test Organism, time scale	Proquinazid technical	DuPont Talendo fungicide
Earthworm (<i>Eisenia foetida</i>) 14 dayLC ₅₀ ,NOEC	>1,000 mg/kg dry wt. Soil AMR 4588-97	>1,000 mg/kg dry weight soil DuPont-10710

Soil microflora- (ref. DuPont -12083)

There were no statistically significant differences in short-term respiration and the nitrogen turnover in soil treated with 1-times and 10-times the maximum field application rate of 0.375 L DuPont Talendo® fungicide (200 g/L EC)/ha (0.5 and 5.0 µL Talendo® fungicide (200 g/L EC)/kg soil dry weight) and control soil at Day 28. Du Pont Talendo® fungicide (200 g/L EC) therefore can be categorized as having low risk to soil microflora.)

Effects of DuPont Talendo fungicide on non-target plants (ref.DuPont -12084)

Six terrestrial plants were sprayed with DuPont Talendo fungicide at a rate of 375mL/ha (maximum single use application rate The plants were- perennial ryegrass (*Lolium perenne*) , oat (*Avena sativa*), onion (*Allium cepa*), rape (*Brassica napus*), soybean (*Glycine max*), sugar beet (*Beta vulgaris*)

For the six terrestrial plant species tested only minor to moderate foliar symptoms were observed. No effect of 50% or greater occurred following foliar exposure to the maximum application rate of 75 g proquinazid/ha (equivalent to 375 mL Du Pont Talendo® fungicide (200 g/L EC)). Therefore, proquinazid is not considered to be phytotoxic.

Fate and behaviour in air

The low vapour pressure of proquinazid ie 9×10^{-5} Pa (25°C) (AMR-3879-96) demonstrates the low volatilization potential for the substance in the environment. Therefore, further assessment on the degradation in air is not required.

Fate and behaviour in soil

Proquinazid is degraded in soil by two mechanisms: 1) de-iodination to give IN-MM671; and 2) replacement of the propoxy group by a hydroxyl group to give a hydroxyl quinazolinone that readily tautomerizes to a quinazolinone (IN-MM986). (AMR 3716-95) (DuPont – 13715)

The rate of degradation of proquinazid was determined under both laboratory and field conditions. In laboratory studies, DT₅₀ values ranged from 39.5 to 345 days, with an average DT₅₀ value of 162 days, a geometric mean of 112 days and a median of 131 days. There was no clear correlation between pH and the rate of degradation in non-sterile soils. (AMR 3859-96)

The rate of degradation of proquinazid in field soils was determined at 8 sites in Europe.

Applications were made in the late spring to early summer. The DT₅₀ in field soils ranged from 6 to 70 days, with an average DT₅₀ value of 30 days, geometric mean of 22 days and a median of 29 days. DT₉₀ values in field soils ranged from 18 to 231. Since the DT₉₀ values were less than 1 year, soil accumulation testing was not conducted. (DuPont -10357)

Data from the batch equilibrium adsorption study shows that proquinazid was strongly sorbed to soil (average K_{oc} = 10296 mL/g). This lack of mobility was confirmed by FOCUS groundwater modelling where the PEC groundwater for proquinazid did not exceed 0.1 µg/L in any scenario. (DuPont -13554)

Fate and behaviour in water

Proquinazid is hydrolytically stable at pH 4, 7 and 9 having a half life greater than 1 year. However, proquinazid is rapidly photolysed with a DT₅₀ of 0.03 days. (ref. DuPont -9785) (DuPont -9998)

Ecotoxicity [hazard classification]DuPont Talendo fungicide

9.1	Aquatic	triggered 9.1A	based on aquatic toxicity.
9.2	Soil	Not triggered	
9.3	Terrestrial vertebrate	Not triggered	
9.4	Terrestrial invertebrate	Not triggered	

Proposed overall classification 3.1D, 6.3B, 6.4A, 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
Proquinazid (active ingredient)		
Du Pont Talendo fungicide. Emulsifiable concentrate containing 200g/L proquinazid)	3.1D, 6.3B, 6.4A, 9.1A	Flammable F2, F6, F11 Toxic T1, T2, T4, T5, T7, Ecotoxic E1, E2, E3, E5, E6, E7, E8, Identification I1, I3, I5, I9, I11, I13, I16, I17, I18, I21, I23, I25, I28, I29, I30 Packaging and Packaging Group P1, P3, P5, P13, P15, PG3, PS4 Disposal D2, D4, D5, D6, D7, D8, Emergency Management EM1, EM4, EM6, EM7, EM8, EM9, EM10, EM11, EM12, EM13 Approved handler 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 Talendo fungicide is manufactured in the USA and Europe and will be imported into New Zealand as the formulated product, packed for retail sale.

Manufacture, Formulation in New Zealand:

The substance is not expected to be manufactured in New Zealand on the grounds of economics.

Packaging:

DuPont Talendo fungicide will be packed in 1 and 5L HDPE containers. Packaging will comply with UN specifications.

Transport:

The product will have the following Dangerous Goods classification for Land, Sea, Air Transport:

UN No: 3082

Description: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S. (Proquinazid)

Class: 9

Packing Group: III

The manufactured product 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 warehouse of Chemfreight, 10C Stonedon Drive, 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 substance will be stored primarily in the dedicated chemical warehouse of Chemfreight situated at 10 C Stonedon Drive, East Tamaki, Auckland. The store 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 quantity stored in distributors 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 Talendo fungicide are restricted by label claims to horticulturalists 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:**Grapes:**

DuPont Talendo fungicide is recommended for application to grapes, to control powdery mildew applied in a spray programme with other fungicides..It will be used only during the flowering period from about 30% flower with up to three applications at 10-14 day intervals. The application rate is 25mL/100L of water or approximately 250mL/ha. Maximum water volumes are expected to be 1,000L/ha

Apples:

DuPont Talendo fungicide can be applied for control of powdery mildew in apples as mid season cover sprays. The dilute spraying use rate is 25mL/100L and trees should be sprayed to achieve good coverage. Maximum water volumes are expected to be 2,500L/ha. A minimum of 14 days between applications and a maximum of three applications per crop per season to manage fungicide resistance.

Cucurbits (Pumpkins, squash, zucchini):

DuPont Talendo fungicide is recommended for powdery mildew control in a range of cucurbit crops when applied in a programme at the first sign of mildew. The fungicide is applied at 250mL/ha in sufficient water to achieve good coverage of the crop. A maximum of three sprays per season is stipulated to manage fungicide resistance.

Disposal of excess product and packaging: The preferred option will be to use as the product as per the label directions. Because of the value of the product and good 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)

4.1 Identification of risks, costs, benefits.

Review of potential environmental effects

Air, water, soil effects

Proquinazid is hydrolytically stable at pH 4, 7 and 9 having a half life greater than 1 year. However, proquinazid is rapidly photolysed with a DT₅₀ of 0.03 days.

The low vapour pressure and Henry's law constant of proquinazid indicate a low potential for volatilisation of the active substance from soil under practical conditions of use.

Proquinazid is degraded in soil by two mechanisms: 1) de-iodination to give IN-MM671; and 2) replacement of the propoxy group by a hydroxyl group to give a hydroxyl quinazolinone that readily tautomerizes to a quinazolinedione (IN-MM986).

The rate of degradation of proquinazid was determined under both laboratory and field conditions. In laboratory studies, DT₅₀ values ranged from 39.5 to 345 days, with an average DT₅₀ value of 162 days, a geometric mean of 112 days and a median of 131 days. There was no clear correlation between pH and the rate of degradation in non-sterile soils.

The rate of degradation of proquinazid in field soils was determined at 8 sites in Europe. Applications were made in the late spring to early summer. The DT₅₀ in field soils ranged from 6 to 70 days, with an average DT₅₀ value of 30 days, geometric mean of 22 days and a median of 29 days. DT₉₀ values in field soils ranged from 18 to 231. Since the DT₉₀ values were less than 1 year, soil accumulation testing was not conducted.

Data from the batch equilibrium adsorption study shows that proquinazid was strongly sorbed to soil (average K_{foc} = 10296 mL/g). This lack of mobility was confirmed by FOCUS groundwater modelling where the PEC groundwater for proquinazid

Ecological Effects

Proquinazid also has a low potential to bioconcentrate (>100 but <1000). The environmental metabolites (IN-MM671, IN-MM986, IN-MM991, and IN-MT884) all show less toxicity than the parent.

Proquinazid displays low acute toxicity to honey bees, and low to moderate toxicity to *Typhlodromus pyri* and *Aphidius rhopalosiphi*. Under extended laboratory conditions at maximum application rate and minimum spray interval proquinazid was found to be harmless to *A. rhopalosiphi*, *C. carnea* and *O. laevigatus*. Overall it is unlikely that the intended use of proquinazid will have unacceptable effects on natural in field or off-field non-target arthropod populations. Risk mitigation measures will not be necessary to protect off-field non-target arthropods for the potential risk due to spray drift of proquinazid.

DuPont Talendo® fungicide was tested in vegetative vigour under greenhouse conditions, and can be considered to be low risk to non-target terrestrial plants.

DuPont Talendo® fungicide has little to no effect on soil micro-organisms associated with nitrogen transformation and carbon mineralisation.

Based on the environmental hazard assessment for aquatic species, bees and other arthropods, earth worms and other soil-micro-organisms, the proposed use of DuPont Talendo® fungicide in grapes, cucurbits or apples will not pose an unacceptable risk.

Effects on native flora

None expected-no herbicidal activity.

Effects on Human Health-workers, operators, bystanders

DuPont™ Talendo® fungicide is a 200 g/L EC formulation which has no significant acute toxicity via the oral (> 2000 mg/kg female rats), dermal (> 5000 mg/kg) or inhalation routes of exposure. The product is however, a skin and eye irritant, but does not cause skin sensitisation.

Studies on the active ingredient proquinazid, has demonstrated no significant acute toxicity via the oral, dermal or inhalation routes of exposure. It is not an eye or skin irritant and does not cause skin sensitisation. Proquinazid is not genotoxic, is not a reproductive toxin, and is not teratogenic or uniquely toxic to the conceptus of rats or rabbits. It is not neurotoxic following subchronic exposure, and decreases in motor activity following acute exposure to high doses may represent secondary systemic effects rather than primary neurotoxicity. Based on the results of a 28-day dermal study in rats (as well as the dermal LD50 study), proquinazid is poorly absorbed through the skin. The lowest effect levels following exposure to proquinazid are based primarily on minimal thyroid effects in rats, liver toxicity in mice, and body weight decrements in dogs. Following chronic dietary administration in rats, proquinazid produced benign thyroid tumours (follicular cell adenomas) in male rats and liver tumours (hepatocellular adenomas and cholangiocarcinomas, intestinal type) in female rats.

Equivocal increases in thyroid adenomas and hepatocellular adenomas were observed in female mice only at the highest dose tested. Clear thresholds were established for all tumour types, consistent with their nongenotoxic mechanisms of action.

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.

To minimize or delay the onset of resistance the label will carry a warning statement and a limit to the number of applications per season.

Transport / Storage

DuPont Talendo fungicide introduces no special risks. At all times the product 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

Label statements warn: "Keep out of reach of children" "Ecotoxic" "Very toxic to aquatic organisms. Avoid contamination of any water supply with chemical or empty container."

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 Talendo fungicide

Source of potentially significant risk	Adverse effect/ impact	Likelihood	Distribution of effects [geographic]	Distribution of effects [demographi c]	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 and Benefits

Grapes, pomme fruit, cucurbits

The area planted in grapes is approximately 20,000 ha, apples and pears approximately 10,000 ha and cucurbits(squash, pumpkins, zucchini etc) approximately 9,000 ha. Powdery mildew in these crops reduces the photosynthetic area of the leaves and in severe cases causes defoliation,. Crop yields are reduced and quality affected resulting in diminished returns to growers and reduced export earnings for New Zealand. DuPont Talendo fungicide will form an important role in a spray schedule for mildew control in these crops by providing high efficacy at low rates of application,, alternative mode of action to assist with fungicide resistance management, low impact on the environment and safety to beneficials.

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 Talendo fungicide 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)

DuPont Talendo fungicide is already registered in a range of EU and non EU countries and an application has been submitted to APVMA in Australia and ACVM in NZ. Residues in food products and wine will be accommodated by the setting of MRL's established in those countries and/or by Codex and in alignment with New Zealand.. This process, supported by labelling to ensure the appropriate use pattern (GAP) is observed and MRL's in local or export crops/wine are not violated.

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

The product will be transported, stored and handled by persons familiar with these types of products. The fungicide 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 toxicity/aquatic toxicity hazards posed by the product.

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 posed by the toxicity and ecotoxicity is far outweighed by the benefits to the New Zealand orchardist and commercial grower. The new product is extremely efficacious at low rates of use, virtually non toxic to operators, safe to birds, bees, earthworms and soil microflora and has 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)

DuPont Talendo fungicide is already registered in a range of EU and non EU countries and an application has been submitted to APVMA in Australia and ACVM in NZ.

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 Talendo® fungicide

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)

To import DuPont Talendo fungicide, containing proquinazid, for the control of powdery mildew in grapes, apples, squash, pumpkins and zucchini.

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 Talendo fungicide into New Zealand for control of powdery mildew in grapes, apples and various cucurbit crops. The product will be formulated and packed overseas and contains 200g/L proquinazid as an emulsifiable concentrate.

We believe the hazard classification to be 3.1D, 6.3B, 6.4A, 9.1A

DuPont Talendo fungicide will provide an important tool in spray schedules for powdery mildew control for apple orchardists, vineyard managers and commercial growers of cucurbit species.

The fungicide offers a low application rate, an alternative mode of action to assist with fungicide resistance management, low impact on the environment and safety to beneficials.

The product poses a negligible risk to humans or the environment if handled and used according to label directions.

Following importation, DuPont Talendo fungicide 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 excess product 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.

CHECKLIST

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

Signed

Date 8 November 2010