

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TĀIAO



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): SEGURIS

Applicant: Syngenta Crop Protection Ltd

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: Syngenta Crop Protection Ltd
Address: Private Bag 92618 Symonds St, Auckland
Phone: 09-306 1500
Fax: 09-306 1501

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

Address: Tower 2, Level 7, 110 Symonds Street, Auckland

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: George Follas
Position: Development Manager New Zealand
Address: Tower 2, Level 7, 110 Symonds Street, Auckland
Phone: 09-306 1505
Fax: 09-306 1501
Email: george.follas@syngenta.com

Name: Michelle Hickman
Position: Regulatory Product Manager
Address: Level 1, 2-4 Lyon Park Road, North Ryde, NSW Australia 2113
Phone: 61 2 8876 8445
Fax: 61 2 8878 8446
Email: michelle.hickman@syngenta.com

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)

Not applicable

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)

Not applicable

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):	No

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.

Active ingredient:	Isopyrazam
Company Code for ai:	SYN 520453
Substance Name:	SEGURIS
Company code for substance:	A15149W

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

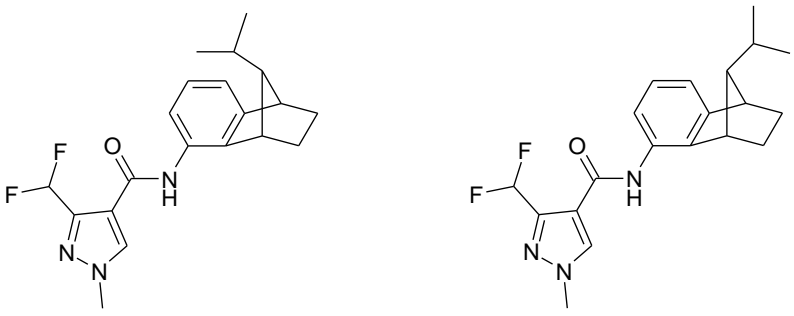
For mixtures, in addition to the above information being provided on the actual mixture, information is also required on the composition of the mixture ie the chemical name, CAS number, function (eg active ingredient, emulsifier, surfactant, filler) and percentages of **ALL** components of the mixture (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)

Information on the identification of Isopyrazam, the principle ingredient, is shown below. Information on the substance composition is confidential and can be found in Section 1 of Appendix 1 of the "Confidential" Volume. Significant impurities of Isopyrazam are confidential and are provided Section 2 of Appendix 1 of the "Confidential" Volume.

Common Name:	Isopyrazam		
Chemical Name:	Isopyrazam (SYN 520453) consists of the syn-isomer (SYN 534969) and the anti-isomer (SYN 534968) in a range of 70:30% to 100:0%. Each of the isomers is a racemate of two enantiomers. The chemical names of the isomers are:		
	<i>IUPAC:</i>	<i>A mixture of:</i>	3-(difluoromethyl)-1-methyl-N-[(1 <i>RS</i> ,4 <i>SR</i> ,9 <i>RS</i>)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (syn-isomer)
		<i>and</i>	3-(difluoromethyl)-1-methyl-N-[(1 <i>RS</i> ,4 <i>SR</i> ,9 <i>SR</i>)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (anti-isomer)
	<i>CA:</i>	<i>A mixture of:</i>	1H-pyrazole-4-carboxamide,3-(difluoromethyl)-1-methyl-N-[(1 <i>R</i> ,4 <i>S</i> ,9 <i>R</i>)-1,2,3,4-tetrahydro-9-(1-methylethyl)-1,4-methanonaphthalen-5-yl]-,rel- (syn-isomer)
		<i>and</i>	1H-pyrazole-4-carboxamide,3-(difluoromethyl)-1-methyl-N-[(1 <i>R</i> ,4 <i>S</i> ,9 <i>S</i>)-1,2,3,4-tetrahydro-9-(1-methylethyl)-1,4-methanonaphthalen-5-yl]-,rel- (anti-isomer)
CAS number:	881685-58-1 (syn-isomer: 683777-13-1 / anti-isomer: 683777-14-2)		
CIPAC No.:	not available		
EINECS No.:	not available		
Company Code Numbers:	SYN520453 Consists of two isomers with the following codes: syn-isomer SYN 534969 anti-isomer SYN 534968		

Structural formula:	 <p style="text-align: center;"> syn-epimer (SYN 534969) anti-epimer (SYN 534968) </p> <p>Isopyrazam (SYN520453) consists of two isomers, the syn-isomer (SYN534969) and the anti-isomer (SYN534968) in a range of 70:30% to 100:0%. Each of the isomers is a racemate of two enantiomers.</p>
Molecular formula:	$C_{20}H_{23}F_2N_3O$
Molecular weight:	359.4

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)

Chemical and physical properties of substance (A15149W):

	Result
Physical State:	Liquid
Colour:	Brown-orange liquid
pH value <i>1% in deionised water:</i>	3-7
Explosive Properties:	not explosive
Oxidising Properties:	not oxidising

Chemical and physical properties of the active ingredient and other ingredients:

Refer to Sections 1 to 3 in Appendix 2, of the “Commercially Sensitive Information” for the chemical and physical properties of the active ingredient and other ingredients of the substance.

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).

An outline of the hazard assessment is provided below. See Appendix 3 of “Commercially Sensitive Information” for the full assessment.

Explosiveness:	Not triggered
Flammability:	3.1D Triggered
Oxidising Properties:	Not triggered
Corrosiveness:	Not triggered
Toxicity:	
Subclass 6.1 (Acute Toxicity):	6.1D Triggered
Subclass 6.3 (Skin Irritant):	6.3B Triggered
Subclass 6.4 (Eye Irritant):	6.4A Triggered
Subclass 6.5B (Sensitiser):	Not triggered
Subclass 6.6 (Mutagen):	Not triggered
Subclass 6.7 (Carcinogen):	Not triggered
Subclass 6.8 (Reproductive/Developmental):	6.8A Triggered
Subclass 6.9 (Target organ/Systemic):	6.9A Triggered
Ecotoxicity:	
Subclass 9.1 (Aquatic Effects):	9.1A Triggered
Subclass 9.2 (Soil Ecotoxicity):	Not triggered
Subclass 9.3 (Terrestrial Vertebrates Ecotoxicity):	9.3C Triggered
Subclass 9.4 (Terrestrial Invertebrates):	Not triggered

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)

3.1D	F2, F6, F11, F17 I1, I5, I9, I13, I19, I21, I25, I29 P1, P3 D2, D6, D7, D8 EM1, EM4, EM8, EM9, EM10, EM11, EM12, EM13
6.1D	T1, T2, T4, T7, T8 I1, I8, I9, I16, 17, I18, I19, I20, I21, I28, I29, I30 P1, P3, P13* D4, D6, D7, D8 EM1, EM6, EM8, EM11, EM12, EM13
6.3B	T1, T2, T4, T7 I1, I9, I16, I21, I28 P1, P3, P13* D4, D6, D7, D8 EM1, EM6, EM8, EM11, EM12
6.4A	T1, T2, T4, T7 I1, I9, I16, I19, I21, I28 P1, P3, P13* D4, D6, D7, D8 EM1, EM6, EM8, EM11, EM12
6.8A	T1, T2, T3, T4, T7 I1, I9, I16, I17, I18, I19, I21, I28 P1, P3, P13*, PG2 D4, D6, D7, D8 EM8, EM11, EM12
6.9A	T1, T2, T3, T4, T7 I1, I9, I16, I17, I18, I19, I21, I28 P1, P3, P13, PG2 D4, D6, D7, D8 EM8, EM11, EM12

9.1A	E1, E2, E5, E6, E7, E8 I1, I3, I9, I11, I19, I21, I23, I29 P1, P3, P15, PG3 D5, D6, D7, D8 EM1, EM7, EM8, EM11, EM12, EM13 TR1 AH1
9.3C	E1, E2, E4, E6, E8 I1, I9, I11, I19, I21, I29 P1, P3, P15, PG3 D5, D6, D7, D8 EM1, EM7, EM8, EM13

T8 – This may be deleted as it refers to vertebrate poisons. This product is not a vertebrate poison.

TR1 - The general tracking requirement may be deleted as it is based on the environmental hazard and will not add to the management of the risks associated with the substance.

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, Transport and Storage

The substance, SEGURIS will be manufactured overseas and it will be imported into New Zealand fully formulated and packaged in the sale packs. The proposed sale packs are 1 to 20 litre HDPE bottles.

There is a possibility that the substance may also be imported into NZ in larger bulk containers for re-packing in New Zealand. This would take place at facilities approved for this function under the ACVM Act 1997. There may also be a need for other repacking, but this will only be undertaken in the situation of where there are damaged packs. This activity would only be undertaken in facilities that are suitable and equipped to carry out this function. The product will be labelled in accordance to the requirements of the ACVM Act 1997 and the HSNO Act 1996 controls.

The label and safety data sheet includes information on the storage of the product. The product will be transported by road to the agents/dealers/distributors premises. The 1 to 20 litre pack size will remain stored as single units or in the shippers at the dealers warehouses/stores and when on display for sale.

The product has a minimum shelf life of at least 2 years when kept in its original container stored at ambient temperature. The product should not be stored in direct sunlight for prolonged periods. Storage will be in Auckland and Christchurch at warehouses contracted for this service by Syngenta Crop Protection Ltd. These stores have procedures in place for managing a wide range of chemical products. The staff have been trained in, and are familiar with the protocols for the segregation of products according to their properties, for safe handling and storage, and in the measures to adopt in case of any emergency. The substance will be stored in its sale packaging.

Product Use

SEGURIS is a fungicide specifically for the control of a range of foliar diseases in cereals. The full directions for use are included on the product label. The application of the product is limited to the growing period, after crop emergence. A maximum of two applications are permitted in wheat and barley for resistance management, resulting in a maximum of 2000 mL of the substance being applied per hectare of wheat and 1200mL/ha on barley per year.

The product is applied diluted in water and applied to the crop using vehicle mounted sprayers. The precise rates and methods of application are detailed on the product label. The product should not be applied when weather conditions favour drift from the target area.

The product will be used by cereal growers, who are familiar with the safe practices regarding the storage and handling of pesticides.

Precautions, First Aid advice and advice for spills are also included on the product label. A Safety Data Sheet and Haznote (TM) is available for handlers and users of the product to provide further information on safety, disposal and clean up of spills.

A copy of the label and Safety Data Sheet can be found in Appendix 5 of the “Commercially Sensitive Information Volume”.

Disposal

The label clearly specifies how much product to mix for each use, therefore if the label directions are followed there should be no left over diluted spray mix. There should be no need to dispose of any product in the sale packs as unused product can be safely stored in its original container until required for a later application. If there is a need to dispose of product it should be diluted and sprayed out on to barren ground.

Empty containers should be triple rinsed and the rinsate added to the spray tank. Empty containers, should be recycled through Agrecovery. Alternatively containers may be crushed and buried in a suitable landfill. The containers should not be used for any other purpose.

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

It is believed that the proposed controls combined with the controls set by the Agricultural Compounds and Veterinary Medicines Group will result in adequate management of any risk to the user, the public and the environment from SEGURIS if the substance is transported, stored and used as per the label directions. The risk of possible adverse effects for other reasons is considered below.

Effects on the Environment

Due to the cost of the material and the threat of prosecution it is unlikely that any person would deliberately release the substance into the environment in violation of the label directions. However, it is possible that poor disposal habits, such as spreading residual amounts of the substance or rinsings from containers onto the ground or into waterways could cause harm to the environment. The predominant risk from release of the concentrate by non-conformance is to non target organisms, birds, mammals, earthworms, terrestrial and aquatic arthropods and plants.

Effects on the economic, social, cultural and physical well-being of communities.

Economic effects

Use of the substance will have no adverse economic effects to communities but will be of benefit when used correctly by potentially increasing grain yields for wheat and barley due to the significant reductions in disease damage from the use of SEGURIS. There could be a risk to earnings if residues of the substance were detected in the produce above the allowable levels set, resulting in rejection of the produce. This will be managed by the adherence to recommended application rates and methods, including observance of the set withholding period.

Health effects – direct exposure

Accidental misuse of the substance has very limited potential to cause harm to humans. Given the low acute toxicity of the substance it is very unlikely that a person could ingest a lethal dose, either accidentally or deliberately. In all cases of ingestion the victim must be given immediate medical attention. Advice for first aid can be found on the product label, product SDS and HAZNOTE. These documents are freely available. A veterinarian should also treat poisoning of animals promptly.

An operator exposure model (POEM) has been utilised to determine the potential risk to the user of using the substance with various levels of protective equipment. This is included as Appendix 7 of the “Commercially Sensitive Information”. The results indicate that there is a very low risk to the operator or bystanders under normal conditions of use.

Health effects – residues

Residue studies have been conducted in New Zealand and overseas on wheat and barley crops. A withholding period will be set and printed on the product label for each crop to ensure that SEGURIS when used as directed will lead to the lowest levels of residue, which in most cases, will be below the limit of detection in food for human consumption.

Environmental effects

The protection of indigenous flora and fauna and natural resources and the purity of air, water, land and natural habitats has been considered. SEGURIS will be used only in areas under agricultural production, where fungicides and other pesticides that have comparable or greater hazards to the environment and people, have been used for decades with adequate control practices. Therefore there are no additional risks to flora, fauna, natural resources, air, water and land from the proposed uses of SEGURIS.

Social and Cultural effects – including issues relating to Treaty of Waitangi and Maori cultural, spiritual and ethical issues.

It is believed that under normal conditions of use the substance will have no detrimental effects on cultural, spiritual and ethical issues. Nor would accidental misuse lead to adverse effects culturally, spiritually and ethically if dealt with appropriately. The only potential area for adverse effects would be sabotage, but this is a remote risk.

Effect on Forseeable Needs of Future Generations

Loss of value of ecosystems

The substance should not accumulate to harmful levels in the environment any adverse effects on the environment would be reversible and would not lead to long term loss of value of ecosystems.

Development of resistance

It is quite possible that target disease pathogens may develop resistance to the substance over time. To minimise this, the substance must be used in a resistance management program and the number of applications on any crop within a growing season will be restricted.

Development of persistent residues in soil and water

The substance is dissipated in soil after application and will degrade in water over time. It is unlikely that persistent residues will accumulate in soil and water.

COSTS

The major cost associated with the substance is the financial cost to the user. This includes the initial purchase price, the cost of spray equipment and safety equipment and the cost of labour to apply the spray. A market analysis has been carried out and it has been determined that the financial benefits of the substance outweigh the financial costs. Quite simply the farmers would not use the substance if they did not receive a financial benefit from its use.

It is believed that the proposed HSNO controls, ACVM requirements and label restrictions will eliminate any potential costs to the economy, society or the environment from the use of the substance. An analysis of the benefits is included in the next section.

BENEFITS

Financial benefits to farmers

The total area of grain and seed crops grown in New Zealand was estimated at 165,422 ha in 2006/07 season made up of 40,537 wheat, 51,481 barley with the remainder being maize, dry peas, oats, other grains and certified small seeds (.Situation and Outlook for New Zealand Agriculture and Forestry (August 2008)). Milling wheat is grown in Canterbury to supply the South Island while North Island mills are supplied with wheat that is mostly imported. Cereal production is a major income source for cropping farmers. There are a number of cereal diseases of wheat and barley that cause potential losses in yield and reductions in grain quality. These diseases such as Leaf Rust, Speckled Leaf Blotch, Stripe Rust in wheat and Leaf Rust, Net Blotch (spot and net form), Ramularia Leaf Spot, Scald, in barley can cause yield losses of up to 40+% as well as significant reductions in milling quality in wheat and malting quality of barley. Given an average price in 2008 of \$510/t for milling and \$460/t feed wheat and \$435/t for barley (Federated Farmers October 14, 2008

<http://www.fedfarm.org.nz/n1019,44.html>) and yields of 8t /ha for wheat and 6t/ha for barley, low to moderate yields, this could mean a loss of \$1600/ha in wheat and \$1000 /ha in barley. Based on an average crop ha per farm of 50 ha this is a potential loss per farm of \$50,000- \$80,000 / farm. These are clearly potentially significant losses.

To prevent these losses farmers implement disease control management programs that include the use of timed fungicide applications.

The use of fungicides in cereals has and continues to undergo substantial change as seen with the introduction of strobilurin chemistry. The introduction of SEGURIS brings a new mode of action and chemical class to the cereal industry with unique attributes that will enhance disease control and yields of treated crops. The inclusion of SEGURIS in the fungicide program for cereal disease control has shown average yield increases of 9% in barley and 21% in wheat compared with the untreated.

The only cost of SEGURIS to growers will be cost of the product. SEGURIS will be similar in cost to existing products available for cereal disease control. There are no additional costs to the grower for labour and plant for the actual spraying, as SEGURIS will replace existing spray applications of other products. Therefore it is quite clear that the cost of the product will result in increased financial return to the farmer from the prevention of loss of grain yield due to cereal disease damage and optimise grain and yield and quality by maintaining a healthy green leaf.

Financial benefits to the economy

There are flow-on effects in the local community and the New Zealand economy from the financial benefits to the individual farmers. Virtually all of the cereal grain produced in New Zealand is used domestically, as either flour for bread or as livestock feed. There is a need to ensure that New Zealand continues to be able to produce sufficient high quality grain to meet this domestic requirement. The introduction of SEGURIS will assist farmers to meet the quality and yield requirements of their customers and to match fungicide use to the new wheat and barley varieties. This is of overall benefit to the New Zealand economy.

Environmental benefits

The substance has a suitable ecotoxic profile for its use as a fungicide in wheat and barley crops. SEGURIS is selective to beneficial insects that can provide natural control of pests in crops and therefore preserving and encouraging them is of importance to the farmer. SEGURIS is not toxic to honey bees and does not trigger ecotoxic classifications for the soil environment or terrestrial invertebrates. The substance is applied at low rates, 75-125 gai/ha compared with the fenpropidin rate of up to 750 gai/ha, azoxystrobin 187.5 gai/ha or prothioconazole 200gai/ha. This results in a potentially low chemical load in the environment. Due to the longer period of disease control that SEGURIS can deliver this has the potential for less fungicide applications over the season, therefore the total potential environmental loading in the season will also be lower. The use pattern of SEGURIS can also result in reductions in emissions and demands on the environment resulting from spray applications such a tractor exhausts, burning of diesel, water consumption etc.

The substance has a low mobility in soil and therefore there is minimal risk of leaching into ground water. The substance is not expected to accumulate in waterways due to extensive degradation. Therefore use of the substance will maintain and can, in some situations contribute to an enhancement of the current ecosystems.

Human safety benefits

SEGURIS is of low acute toxicity. The label will carry a requirement to wear goggles and standard protectant clothing as a safety precaution for skin and eye irritation. SEGURIS does not possess intrinsic carcinogenic potential at doses that are not excessively toxic to laboratory animals.

Benefits to Forseeable Needs of Future Generations

It is a goal of Syngenta and indeed New Zealand agriculture as a whole to develop and support sustainable agriculture, to ensure a consistent and adequate food supply for the future. To this end Syngenta invests millions of dollars annually striving to develop new agricultural pesticides which ideally meet the following criteria:

- Efficacious for their stated purpose so that yields are increased, less land is required to grow the necessary food crops and the quality of the harvest is superior.
- Less impact to the environment than currently available agricultural chemicals. This includes lower application rates (ai/ha) resulting in lower chemical load in soil and water, acceptable degradation rates, lack of bioaccumulation and reduced toxicity to living organisms including non-target pests.
- Reducing the risks to human health by lowering application rates (ai/ha), better application methods and lower toxicity.
- Novel biological activity on target pests resulting in an additional tool for resistance management. SEGURIS offers growers an alternative fungicide from a new chemical group with no cross resistance to existing chemistry, which should help to prolong the life of existing chemistry when used in a cereal disease management program. SEGURIS offers greater protectant activity against major foliar diseases of cereals in particular rusts compared to other current fungicides.

SEGURIS is a fungicide that meets the above criteria and its use as an alternative to current fungicides will be a valuable tool in sustainable agriculture.

None of these benefits will be available to New Zealand growers if SEGURIS is not introduced.

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)

Identification and Assessment of significant risks

Lifecycle Activity and Associated Source of Risk	Likelihood	Description of Potential Hazard	Magnitude	Level of Risk
IMPORTATION, TRANSPORT OR STORAGE Spillage of concentrate through transport accident or during importation	Unlikely	Effect on environment – Toxic effects to aquatic species if it enters aquatic environments. Effects are not expected to be long term. Flammability Effect on human health - Acute Toxicity, Skin & Eye Irritant, Sensitiser, Target organ.	Minor	Low
USE Spillage or mishandling of concentrate during dilution for use	Unlikely	Effect on environment – Toxic effects to aquatic species if it enters aquatic environments. Effects are not expected to be long term. Flammability Effect on human health - Acute Toxicity , Skin & Eye Irritant, Sensitiser , Target organ	Minimal	Negligible
Spillage or mishandling of diluted substance during use	Very unlikely	Effect on environment – Toxic effects to aquatic species if it enters aquatic environments. Effects are not expected to be long term.	Minimal	Negligible
Spray drift during use	Unlikely	Effect on environment – Toxic effects to aquatic species if it enters aquatic environments. Effects are not expected to be long term. Effect on human health - Bystanders Skin & Eye Irritant, Sensitiser, Target organ.	Minimal	Negligible
DISPOSAL Incorrect disposal of concentrate (including packaging)	Very Unlikely	Effect on environment – Toxic effects to aquatic species if it enters aquatic environments. Effects are not expected to be long term. Flammability Effect on human health - Acute Toxicity , Skin & Eye Irritant, Sensitiser , Target organ	Minor	Negligible

Lifecycle Activity and Associated Source of Risk	Likelihood	Description of Potential Hazard	Magnitude	Level of Risk
Incorrect disposal of diluted substance	Very Unlikely	Effect on environment – Incorrect disposal of a large volume of the diluted substance could result in toxic effects to aquatic organisms. High residues in soil at disposal area will degrade over time. Substance does not bioaccumulate. Effect on human health - Acute Toxicity , Skin & Eye Irritant, Sensitiser, Target organ	Minimal	Negligible

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 use of SEGURIS on commercial arable farms will have no adverse effects on native flora or native fauna based on the environmental data available; however there could be a potential risk to aquatic organisms. The nature of this risk has been examined in section 4.1 above. However, this potential risk is lower than the effects currently encountered through the use of existing fungicides and other pesticides. It is believed that under normal conditions the substance will have no detrimental effects on cultural, spiritual and ethical issues. Nor would accidental misuse lead to adverse effects culturally, spiritually and ethically if dealt with appropriately.

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)

Isopyrazam is being developed for use in other countries and is currently being assessed in Europe.

There is a potential risk to trade if the use of the substance results in residues of the active ingredient, Isopyrazam, being detected above the Maximum Residue Level in produce. Controls are in place to ensure that the risk of unacceptable residues in cereal grain does not occur, including detailed label directions and Good Agricultural Practice.

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 means 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 proposed default controls for SEGURIS are summarised in the following table:

Flammable:	F2, F6, F11, F17
Toxic:	T1, T2, T3, T4, T7
Ecotoxic:	E1, E2, E6, E8
Identification:	I1, I8, I9, I16, I17, I18, I19, I20, I21, I28, I29, I30
Packaging and Packing group:	P1, P3, P13, PG2
Disposal:	D2, D4, D6, D7, D8
Emergency management:	EM1, EM4, EM6, EM8, EM9, EM10, EM11, EM12, EM13
Approval Handler:	AH1

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)

From the analysis provided in Sections 4.1 and 4.2 it is believed that overall the benefits of the substance outweigh the insignificant risks.

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)

An application has been submitted to the ACVM Group. This product was submitted for registration in Europe for registration for use on Cereals. This application was submitted in December, 2008. An application will be submitted to Korea for use on capsicums. This application is planned for submission later this year.

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)

Not required

- 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)

No other relevant information

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.

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)

SEGURIS

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 this application is to gain approval under the HSNO Act for the import and release of the substance SEGURIS, a fungicide for the control of foliar diseases in wheat and barley.

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:	4
Industry category:	1
Function/Use category:	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 application is to gain ERMA approval for the import and release of the substance SEGURIS, a fungicide for the control of foliar diseases in wheat and barley.

The substance will be imported into New Zealand as the finished good. There may be downsizing of the product into sale packs in New Zealand. As a finished good there will be no contact with the raw materials. If repacked this will be carried out in a suitable facility. Standard safety procedures will be followed. The substance can be stored in the original packaging until completely used for its intended use, so there should normally be no need to dispose of excess substance.

SEGURIS contains 125 g/L Isopyrazam, the fungicidal ingredient. A large amount of research has been conducted on Isopyrazam, covering toxicology, ecotoxicology, environmental chemistry and fate, residues, plant safety and efficacy. The other components in the substance are commonly used in crop protection agents such as wetting agents, dispersing agents and antifoams.

SEGURIS is in the form of a liquid that is added to water. The mixture is then agitated until dispersed and applied as a spray to crops. The application rates, timing and method of application will be clearly stated on the product label. As the application rates are low, the amount of the substance being released into the environment annually is low.

A full hazard assessment has been conducted on the substance based on its chemical/physical properties and other available data. A number of studies have been carried out on the substance itself, including acute oral, dermal and inhalation toxicity, eye irritancy, skin irritancy and skin sensitisation and some ecotoxicology studies. Chronic toxicity studies are not available for the substance as a whole but the full range of standard studies have been conducted on the active ingredient, Isopyrazam, and a database search has been conducted on the other ingredients. A large number of environmental chemistry and ecotoxicology studies have also been conducted on Isopyrazam and SEGURIS.

The full hazard assessment has revealed that the substance is hazardous as it triggers thresholds; being: 3.1D, 6.1D, 6.3B, 6.4A, 6.8A, 6.9A, 9.1A and 9.3C. A full risk/cost/benefit analysis has been conducted on the substance, and the applicant concludes that the benefits of the substance far outweigh the risks. Based on the threshold triggers the default controls have been identified, and it is believed that these controls combined with controls already in place for the agricultural chemical industry will ensure that the potential risks are manageable.

Therefore it is concluded that hazards of SEGURIS have been fully identified and the risks to the user, the public, the Maori people and the environment are acceptable and manageable.

CHECKLIST

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

Signed

Date