ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

FORM HS2/2

Application for approval to

IMPORT OR MANUFACTURE ANY HAZARDOUS SUBSTANCE FOR RELEASE by Rapid Assessment

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

Under the Criterion that is Similar to a Substance with an Existing HSNO Approval

Name of Substance(s): **TERMIDOR®**

Applicant: **BASF New Zealand Limited**

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

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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.

2. Part D of the User Guide covers applications under Section 28A of the Act using the criterion that it is 'similar' to a substance with an existing HSNO approval and all of the cross references to this guide that are in this application form relate to Part D.

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. 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.

5. Commercially sensitive information must be collated in a separate Appendix.

6. 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.

7. 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: BASF New Zealand Limited
Address: PO Box 407, Auckland 1140
Phone: +9-255-4300
Fax: +9-255-4307

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

Address: 3 Airpark Drive, Airport Oaks, Manukau

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: John Gray
Position: Technical Manager Regulatory Affairs
Address: PO Box 407, Auckland 1140
Phone: +9-255-4300
Fax: +9-255-4307
Email: john.gray@basf.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' that meets the criterion that is "similar" to a substance with an existing HSNO approval. 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 The Authority may make a "rapid assessment" of applications to import or manufacture a hazardous substance for release if certain criteria apply. You need to confirm that the following criterion applies and provide reasons in support of this.

(See comments under "Section 2.1 of Form" in the User Guide)

The application is for a substance(s) that has a similar composition and similar hazardous properties to an approved, existing substance — Yes/~~No~~

The justification for claiming that criterion has been met is as follows (cross reference to Section 3.1, 3.2, and 3.3 of this form as appropriate): ERMA NZ has determined that the proposed substance is eligible for a rapid assessment under the criterion that is similar to the reference substance with an existing HSNO approval.

2.2 Identify the substance with an existing approval for which you wish to use as the reference substance(s). Note you will need to supply an approval number. Applicants will probably find it convenient to cross-reference their response to the details in later sections of the application.

(See comments under "Section 2.2 of Form" in the User Guide)

HSR000831. Suspension concentrate containing 200 g/litre fipronil.

2.3 Is the information in this application relevant to import, manufacture or both?

(See comments under "Section 2.3 of Form" in the User Guide)

- Import only — Yes/~~No~~
- Manufacture only — ~~Yes~~/No
- Import and manufacture — ~~Yes~~/No
- If import only, indicate whether or not manufacture is likely in New Zealand — ~~Yes~~/No

2.4 If the application relates to manufacture in New Zealand, provide comparative information on the proposed manufacturing process and any alternatives for the substance(s) being applied for and for the reference substance(s) if relevant.

(See comments under "Section 2.4 of Form" in the User Guide)

NA

2.5 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?

(Optional) (See comments under "Section 2.5 of Form" in the User Guide)

Name of Approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	~~Yes/No~~/NA
Food Act 1981	~~Yes/No~~/NA
Medicines Act 1981	~~Yes/No~~/NA
Chemical Weapons (Prohibition) Act 1996	~~Yes/No~~/NA
Radiation Protection Act 1965	~~Yes/No~~/NA
Biosecurity Act 1993	~~Yes/No~~/NA
Resource Management Act 1991	~~Yes/No~~/NA
Other (please specify):	~~Yes~~/No

Section Three – Comparative 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.

The information you provide should clearly identify the similarities and differences between this substance and the previously approved substance used as a reference.

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 proposed substance(s) and of the reference substance(s).

Because comparative information is being looked for, a tabular layout might be convenient to use.

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)

The proposed substance contains 100 g/litre fipronil (CAS # 120068-37-3) in the form of a suspension concentrate. Comparison of this substance with the reference substance, a suspension concentrate containing 200 g/litre fipronil (HSR000831), is provided in Appendix 1.

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

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

- 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.

You should compare and contrast the properties of the substance(s) for which this application is made with that of the previously approved "similar" substance(s).

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

	Proposed substance	**Reference substance**
Appearance	Viscous, light brown liquid	Viscous, off white liquid
pH	7.2	6.5
Density	1.061 g/ml	1.07 g/ml
Solubility in water	Dispersible	Dispersible

3.3 Provide comparative information on the hazardous properties of the proposed substance(s) and the reference 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.

You should compare and contrast the hazardous properties of the substance(s) for which this application is made with that of the reference substance(s).

(See comments under "Section 3.3 of Form" in the User Guide).

The proposed substance is not explosive, flammable, oxidizing or corrosive.

	Proposed substance	**Reference substance**
Acute toxicity		
LD50 rat (oral):	> 1,999 mg/kg	977 mg/kg
LD50 rabbit (dermal):	> 2,000 mg/kg	2,493 mg/kg
LC50 rat (by inhalation):	> 1.7 mg/l 4 h	0.94 mg/l 4 h
Irritation		
Primary skin irritation rabbit:	Irritant.	Non-irritant.
Primary irritations of the mucous membrane rabbit:	Irritant.	Non-irritant.
Sensitization:		
Guinea pig:	Skin sensitizing effects were not observed in animal studies.	Skin sensitizing effects were not observed in animal studies.
Ecotoxicity Information on: fipronil		
Fish:	LC50 (96 h) 0.25 mg/l, *Oncorhynchus mykiss* LC50 (96 h) 0.0852 mg/l, *Lepomis macrochirus* LC50 (96 h) 0.43 mg/l, *Cyprinus carpio*	
Aquatic invertebrates:	EC50 (48 h) 0.19 mg/l, *Daphnia magna*	
Aquatic plants:	EC50 (96 h) 0.068 mg/l (biomass), *Scenedesmus subspicatus*	
Persistence and degradability Information on: fipronil		
Assessment biodegradation and elimination (H2O):	Not readily biodegradable (by OECD criteria).	

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 and check that they are the same as those on the reference substance(s). 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 if there are any risks to be assessed. See Section 4.

(Optional) (See comments under "Section 3.4 of Form" in the User Guide)

The default controls for the proposed substance match those for the reference substance.

Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001:

Code	Regulation	Description
T1	11-27	Limiting exposure to toxic substances, setting values for ADE/RfD/PDE/TEL, prohibiting use in excess of TEL
T2	29, 30	Workplace exposure
T3	5(1), 6	Record keeping
T4	7	Equipment used to handle toxic substances
T5	8	Protective clothing/equipment
T6	9	Approved handler quantities
T7	10	Carriage on passenger service vehicles

Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001:

Code	Regulation	Description
E1	32-45	Limiting exposure to ecotoxic substances, the environmental exposure limit (EEL) approach
E2	46-48	Restrictions on use of substances in application areas
E3	49	Controls relating to protection of terrestrial invertebrates, for example, beneficial insects
E4	50, 51	Controls relating to protection of terrestrial vertebrates
E5	5(2), 6	Requirements for keeping records of use
E6	7	Requirements for equipment used to handle substances
E7	9	Quantities of ecotoxic substances that require an approved handler
E8	10	Restrictions on carriage of ecotoxic substances on passenger service vehicles

Hazardous Substances (Identification) Regulations 2001:

Code	Regulation	Description
I1	6, 7, 32-35, 36(1)-(7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
I3	9	Priority identifiers for ecotoxic substances
I8	14	Priority identifiers for toxic substances
I9	18	Secondary identifiers for all hazardous substances
I11	20	Secondary identifiers for ecotoxic substances
I16	25	Secondary identifiers for toxic substances
I17	26	Use of generic names
I18	27	Requirements for using concentration ranges
I19	29-31	Additional information requirements, including multiple packaging
I20	36(8)	Durability of information for class 6.1 substances
I21	37-39, 47-50	General documentation requirements
I23	41	Specific documentation requirements for ecotoxic substances
I28	46	Specific documentation requirements for toxic substances
I29	51, 52	Signage requirements
I30	53	Advertising corrosive and toxic substances

Hazardous Substances (Packaging) Regulations 2001:

Code	Regulation	Description
P1	5, 6, 7(1), 8	General packaging requirements
P3	9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II, or III criteria
P13	19	Packaging requirements for toxic substances (class 6)
P15	21	Packaging requirements for ecotoxic substances (class 9)
PG2	Schedule 2	Packaging requirements for equivalent to UN Packing Group II

Hazardous Substances (Disposal) Regulations 2001:

Code	Regulation	Description
D4	8	Disposal requirements for toxic and corrosive substances (classes 6, 8)
D5	9	Disposal requirements for ecotoxic substances (class 9)
D6	10	Disposal requirements for packages
D7	11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge
D8	13, 14	Disposal requirements Priority identifiers for toxic substances

Hazardous Substances (Emergency Management) Regulations 2001:

Code	Regulation	Description
EM1	6, 7, 9-11	Level 1 information requirements for suppliers and persons in charge
EM6	8(e)	Information requirements toxic substances
EM7	8(f)	Information requirements ecotoxic substances
EM8	12-16, 18-20	Level 2 information requirements for suppliers and persons in charge
EM11	25-34	Level 3 emergency management requirements: duties of person in charge, emergency response plans
EM12	35-41	Level 3 emergency management requirements: secondary containment
EM13	42	Level 3 emergency management requirements: signage

Hazardous Substances (Personnel Qualifications) Regulations 2001:

Code	Regulation	Description
AH1	4-6	Approved Handler requirements (including test certificate and qualification requirements)

Hazardous Substances (Tracking) Regulations 2001:

Code	Regulation	Description
TR1	4(1), 5, 6	General tracking requirements

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

Similarity of use is not one of the criteria for a rapid assessment, but comparaive information is still required. This is because if uses are significantly different, risks may differ even if the hazardous properties are similar. Information on other aspects of "whole of life history" through to disposal are also required.

(See comments under "Section 3.5 of Form" in the User Guide)

Similarly to the reference substance, the proposed substance will be imported into New Zealand as finished product packed in plastic bottles and labelled ready for sale. The type of packaging is of a standard nature, commonly used for pesticide formulations and is UN approved.

Transportation and storage of the proposed substance will be consistent with the controls existing for the reference substance. Both the proposed substance and the reference substance are classified internationally as hazardous for transport: Class 9, UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., MARINE POLLUTANT.

The proposed substance will be used by commercial contractors around domestic, commercial, public and industrial buildings and structures. Similarly to the reference substance, the proposed substance will applied as a dilute, water based spray using conventional hand held spraying equipment, whilst taking necessary precautions and following standard safety procedures. Normally, there would be no contact with the proposed substance prior to mixing and use.

Similarly to the reference substance, the proposed substance will be stored in the original packaging until completely used, and the need to dispose of excess substance would not be expected. Any substance that requires disposal, such as spilled material, and empty containers, will be disposed of according to label advice. Empty containers will be triple rinsed and recycled where appropriate via the Agrecovery programme.

Section Four: Identification and Assessment of any Significant Variations in Risk between the Proposed Substance(s) and the Reference Substance(s)

It is noted that full risk assessments may not be required in the case of a "similar substance" rapid assessment application. It is sufficient to provide information which is able to confirm that any risks are "similar" to the risks posed by the reference substance(s).

You should compare and contrast the risks of the substance(s) for which this application is made with that of the reference substance(s). If the hazardous properties are similar then any difference should arise from differences in exposure scenarios.

In providing this analysis, applicants should have regard to the definition of environment and all the matters set out in Part II of the Act.

Similarly to the reference substance, the proposed substance is harmful, very toxic to aquatic organisms, toxic to terrestrial vertebrates and very toxic to terrestrial invertebrates. The potential risks to people and the environment posed by the proposed substance will be managed similarly in compliance with the approval controls already established for the reference substance, the Land Transport Rule 45001, and the New Zealand Standard for the Management of Agrichemicals NZS8409. Information covering identification, safe handling and use, emergency management and disposal will be readily available in the form of the container label, the safety data sheet (SDS) and the HazNote.

Codes of Practice that will be followed in the management of the substance are: Signage for Premises Storing Hazardous Substances (NZCIC) , Management of Agrichemicals (SNZ), Preparation of Safety Data Sheets (NZCIC), Product Labelling and Documentation Guide for Agricultural Compounds and Veterinary Medicines (Agcarm), and Hazardous Substance Storage (NZCIC).

Label instructions for the proposed substance identify a number of specific use precautions such as not to apply the substance directly onto or into water, and not to allow spray drift outside the target area, that reinforce the measures required to protect aquatic systems, edible plants, domestic vertebrates and invertebrates from a potential hazard.

Whereas the reference substance is readily available and used in a wide dispersive manner by a broad base of users, the proposed substance will only be available through a specialised distribution to a small group of trained and experienced professional users applying the material in a limited and specific manner around buildings and structures. This further mitigates the environmental impact of the proposed substance.

Accordingly, with due care, the hazards and risks associated with the proposed substance can be safely and satisfactorily managed.

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)

The active ingredient and the proposed substance have been assessed and approved by regulatory authorities in Australia, the USA and the EU. Refer to Appendix 1.

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)

NA

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.

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)

TERMIDOR®

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 for release TERMIDOR, with the active ingredient fipronil, to control certain insect pests in urban situations.

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)

The following use categories are indicated for this substance:

Main Category:	4	Wide dispersive use
Industrial category:	6	Public domain
Function/Use category:	39	Pesticides, non-agricultural

7.4 Executive Summary:

In this section, you are required to provide a summary of the significant components of the application. This information will be available for public scrutiny and as such should not contain any commercially sensitive or confidential material. The information required for this section includes a summary of:

- the identification of the substance(s), its hazardous properties and intended uses, and its disposal,
- any information on the significant risks (adverse effects) of the substance(s),
- the similarities and differences between this substance(s) and the previously approved substance(s).

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

Approval is sought, pursuant to section 28 of the HSNO Act 1996, to import the substance Termidor® for release. The proposed substance is an insecticide containing the active ingredient fipronil and is similar to a substance already approved for use in New Zealand.

The following hazard classification is indicated for the proposed substance: 6.1D (acute toxicant), 6.3B (skin irritant), 6.4A (eye irritant), 6.9A (target organ systemic toxicant), 9.lA (aquatic ecotoxicant), 9.3B (vertebrate ecotoxicant), 9.4A (invertebrate ecotoxicant).

The proposed substance is intended for use as a dilute spray around buildings and structures in urban situations for the control of certain pests. Although it has a similar hazard profile to that of the reference substance, the potential risks to people and the environment are mitigated by its manner of use. Whereas the reference substance is used in a wide dispersive manner by a broad base of users, the proposed substance will only be used by trained and experienced professional users applying the material in a limited and specific manner around buildings and structures.

The proposed substance will be managed in compliance with the approval controls, the Land Transport Rule 45001, and the New Zealand Standard for the Management of Agrichemicals NZS8409. Information covering identification, safe handling and use, emergency management and disposal will be readily available in the form of the container label, safety data sheet (SDS) and HazNote. Those handling the substance will be trained and experienced personnel. Accordingly, with due care, the hazards and risks associated with the substance can be safely and satisfactorily managed.

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CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	Yes/ NA
Initial fee enclosed	Yes
Application signed and dated	Yes
Electronic copy of application e-mailed to ERMA NZ	Yes

Signature and Statutory Declaration

I, _____[full name], of

_____ [Address],

_____[Occupation/position]
being the applicant or authorised to do so on behalf of the applicant, verify that the information contained in this application is true and correct. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

_____
Signature

Declared at _____on this _____day of _____, 200____ before me:

_____
Signature

_____
[Name] Barrister or Solicitor of the High Court of New Zealand
[or Justice of the Peace, Notary Public, or other person authorised to take a statutory declaration]