ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

ERMA New Zealand

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): NTNCS2

Applicant: BAYER 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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NEW ZEALAND

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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: Bayer New Zealand Limited
Address: 3 Argus Place, Hillcrest, North Shore City 0627
Phone: 09 443 3093
Fax: 09 443 1194

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

Address: As above

1.3 Name of the contact person for the application:

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

Name: John Messer
Position: Technical Development Manager
Address: 3 Argus Place, Hillcrest, North Shore City 0627
Phone: 09 441 8638
Fax: 09 443 1194
Email: john.messer@bayerhealthcare.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~~/**No**
• Manufacture only?	~~Yes~~/**No**
• Import and manufacture?	**Yes**/~~No~~
• If import only, indicate whether or not manufacture is likely in New Zealand	Not applicable

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)

As the product is a veterinary medicine it will be manufactured under Good Manufacturing Practice at an ACVM approved facility which has been registered for the production of the product with the ACVM. As such the manufacturing facility will be subject to regular audits of its manufacturing by ACVM. Further confidential information is provided in Appendix 1. The product is very similar to a number of products already produced in New Zealand and therefore extensive details are not provided here.

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)

See appendix 1.

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~~/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~~
	Yes/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.

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)

Mixture formulation details are provided in Appendix 1 (Confidential).

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)

Mixture characteristics (NTNCS2)

- Appearance Blue colour liquid
- Density 1.001 g/L @ 20°C
- Solubility in water the substance is miscible with water
- Flash point 88°C (PMCC)

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).

NTNCS2 : Summary table of hazardous thresholds and classification.

Hazardous property	Threshold	Classification category and criteria
Explosive	Not triggered	
Flammable Liquid	Triggered	**3.1D – PMCC flashpoint 88°C**
Oxidising agent	Not triggered	
Corrosive substance	Not triggered	
Toxic Substance		
Acute oral	Not Triggered	
Acute dermal	Not triggered	
Acute inhalation	Not triggered	
Skin irritation	Triggered	**6.3A**
Eye irritation	Triggered	**6.4A**
Sensitisation	Not triggered	
Mutagenic	Not triggered	
Carcinogenic	Not triggered	
Reproductive/ / developmental	Triggered	**6.8A / 6.8C**
Target organ/ systemic	Triggered	**6.9B**
Ecotoxic		
Aquatic	Triggered	**9.1A**
Soil	Triggered	**9.2B**
Terrestrial vertebrate	Triggered	**9.3B**
Terrestrial invertebrate	Triggered	**9.4A**

The workings and data to support these classifications are in Appendix 2.

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
6.3A	T1,T2,T4,T7 I1,I9,I16,I19,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
6.8C	T1,T2,T4,T7 I1,I9,I16,I17,I18,I19,I21,I28 P1,P3,P13,PG3 D4,D6,D7,D8 EM8
6.9B	T1,T2,T4,T7 I1,I9,I16,I17,I18,I19,I21,I28 P1,P3,P13,PG3 D4,D6,D7,D8 EM8
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
9.2B	E1,E2,E6,E8 I1,I3,I9,I11,I19,I21,I23,I29 P1,P3,P15,PG3 D5,D6,D7,D8 EM1,EM7,EM8,EM13
9.3B	E1,E2,E4,E6,E8 I1,I3,I9,I11,I19,I21,I23,I29 P1,P3,P15,PG3 D5,D6,D7,D8 EM1,EM7,EM8,EM13
9.4A	E1,E2,E3,E5,E6,E7,E8 I1,I3,I9,I11,I19,I21,I23,I29 P1,P3,P15,PG3 D5,D6,D7,D8 EM1,EM7,EM8,EM13 TR1 AH1

Composite list:

T1,T2,T3,T4,T7 F2,F6,F11,F17 E1,E2,E3,E4,E5,E6,E7,E8 I1,I3,I5,I9,I11,I13,I16,I17,I18,I19,I21,I23,I25,I28,I29 P1,P3,P13*,P15, PG2, PG3 D2,D4,D5,D6,D7,D8

EM1,EM4,EM6,EM7,EM8,EM9,EM10,EM11,EM12,EM13
TR1
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)

Production/Transportation Storage
NTNCS2 will be manufactured under conditions of Good Manufacturing Practice, at an ACVM approved manufacturing facility in Auckland. Full manufacture will be performed and the product will be shipped from this facility to a Bayer warehouse, pre-packed into 1 L, 5 L and 20 L HDPE screw top containers which would have been pre-labelled and in the case of the 1 and 5 L containers, placed in cardboard cartons for transport. The size of the 20 L container precludes putting this in cardboard cartons and instead it would be shrink-wrapped on standard shipping pallets.

NTNCS2 will be stored in standard warehouse facilities prior to distribution. From there NTNCS2 would be distributed to mercantile and veterinary premised for sale to farmers. Several containers of NTNCS2 could be stored on farming premises prior to use.

Production, packaging and transportation of NTNCS2 will conform to domestic requirements for transportation. All New Zealand labelling will conform to the requirements of the Agricultural Compounds and Veterinary Medicine Group of the New Zealand Food Safety Authority. The labelling will also supply safety, handling, use, storage and disposal information as required by ERMANZ.

Uses
NTNCS2 is for the control of ectoparasites (sheep biting lice and sheep blowfly strike) on sheep. The user would apply NTNCS2 using standard equipment.

Other potential uses
None known to the applicant

Who may use the substance
Farmers, dipping contractors, veterinarians and farm workers.

Disposal of packaging and unused product
The preferable route of disposal is by use. Unused product and used packaging may be disposed of in approved landfills. Cleaned, used packaging may also be recycled via the DrumMuster program.

Destination of applied product.
The active ingredient(s) are not absorbed significantly through the skin, although small amounts are found in residue studies. Those small amounts of active ingredients absorbed are extensively metabolised prior to excretion via the urine and faeces.

The active ingredients degrade in the fleece. Shorn wool could be harvested with residues. A wool withholding period (time between treatment and shearing fleece) will be stated on the product label.

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)

Identification of potential risks

1. Transport and storage

Risk: Fire

Adverse events could potentially arise in situation where a suitable source of ignition was available in close proximity to NTNCS2 – however it is noted that with the relatively high flash point this is not a major risk.

2. Human Health

Risk: Target organ

Adverse effects could potentially arise from repeated ingestion of NTNCS2

Risk: Skin irritant

Adverse effects could potentially arise from contact of NTNCS2
Risk: Eye irritant
Adverse effects could potentially arise from contact of NTNCS2 with eyes.
Risk : Reproductive/Developmental
Adverse effects on the unborn child could potentially arise from contact by pregnant women of NTNCS2 or through the effects of NTNCS2 acquired by a child via lactation.

3. **Environmental effects**

Risk: Aquatic ecotoxicity
Adverse effects could potentially arise from release of NTNCS2 on or near water
Risk: Soil ecotoxicity
Adverse effects could potentially arise from release of NTNCS2 onto land and the subsequent effects on species such as earthworms.
Risk: Terrestrial vertebrate ecotoxicity
Adverse effects could potentially arise from release of NTNCS2 to the environment where there are vertebrate species such as small land mammals and birds
Risk: Terrestrial invertebrate ecotoxicity
Adverse effects could potentially arise from release of NTNCS2 to the environment where there are valued insect species (bees)

4. **Effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna, and other taonga.**

No new risks identified, beyond those common to any pour-on sheep ectoparasiticide. See section #4.3.

5. **Effects on New Zealand's international obligations**

Risks, costs and benefits related to New Zealand's international obligations are not assessed by the applicant.

Identification of risks

Lifecycle activity	Associated source of risk
Manufacture	Accident during manufacture resulting in spillage and release of the substance which in turn may affect an individual dealing with the spillage.
Local transport	Transport or handling incident during transportation or loading/unloading resulting in spillage and subsequent exposure of people or the environment (or contribution to fire, where a suitable ignition source is present in close proximity) • Transport accident: Spills of HDPE containers of NTNCS2 • Loading/unloading: Dropped containers spilling contents • Fire: any of the above associated with a suitable ignition source in close proximity
Storage	Incident during storage at warehouse facilities, veterinary clinics, rural merchants or end user's sites resulting in spillage and subsequent exposure of people or the environment (or contribution to fire, where a suitable ignition source is present in close proximity) • NTNCS2 could spill in storage areas (e.g. vet clinics, farms)
Use	Exposure of end users while handling the substance during use. Incident such as spillage during use and subsequent exposure of people or the environment • Chronic exposure of staff at the manufacturing site, or by frequent users on farms (e.g. dipping contractors) • Environment: Small spills on farms during use

Disposal	Disposal of substance and containers resulting in release of substance and subsequent exposure of people or the environment. Primarily disposed of by use Small amounts and empty NTNCS2 packs could be disposed of in local landfills. Small quantities of the active ingredient may be released from wool during wool scouring (wool scouring plant wastes)

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)

Risk analysis – Transport

Risk – Transport accident.

It is possible that at some stage, a vehicle carrying NTNCS2 will be involved in a transport accident.

- The finished product will be transported in large quantities under the Dangerous Goods for transport rules and will therefore be appropriately placarded including Dangerous Goods information on the immediate packaging and will be accompanied by appropriate documentation with information including emergency telephone contact numbers and information on how to contain and dispose of spilled material. The transport company hired to perform transportation operations will be a large an experienced company which handles many veterinary medicines and agricultural compounds.
- Smaller quantities are likely to be transported from mercantile outlets to individual farm properties under small package of dangerous goods rule or in some situations dangerous goods in limited quantities – therefore the risk of effects from a transport accident involving such smaller quantities are greatly reduced.
- The packaging of the NTNCS2 is of standard appropriately strong HDPE packaging, and in the case of 1 and 5L pack sizes additionally packaged in cardboard cartons. Packaging will be existing 'off the shelf' material which has been proved over many years to be suitable for its purpose.
- The greatest individual container size transported will be a 20L container and therefore even where large quantities are transported, it is unlikely that spillage of all containers will occur.

Such risks are likely to result either in human or environmental exposure and as such are analysed below.

Risk analysis – Human exposure

Risk: Repeated exposure (ingestion) – Target Organ / reproductive - developmental effects

Repeated ingestion by humans causing either target organ or reproductive / developmental effects is VERY UNLIKELY to occur.

- The finished product will be stored in a secure warehouse initially at the manufacturing facility prior to shipment to a Bayer controlled warehouse. The only persons with access are trained workers at the manufacturing plant or trained warehouse staff.
- Smaller quantities would also be stored at veterinary clinics and mercantile outlets or on farms (places of work). Even though the product is an over the counter product, it is not likely to be purchased by general consumers. Personnel employed at veterinary clinics, mercantile outlets and farming operation are generally aware of the risks of ingestion of such products.

- The NTNCS2 is packaged and labelled at manufacture and so will be clearly identified at all times subsequent to manufacture so the risk of confusion by consumers leading to oral ingestion is extremely unlikely
- The product will leave the manufacturing facility firmly closed (screw cap containers – small pack sizes will also be induction sealed). With the exception of the 20L container, the majority of the pack sizes would be expected to be used completely at the one time once the container was broached.
- The only persons likely to have access to NTNCS2 on a regular basis are (i) staff at manufacturing plant (ii) persons dipping sheep frequently such as dipping contractors or farm workers. These people are skilled and experienced at handling agricultural chemicals. The daily contact with / ingestion of many mLs of NTNCS2 that is required for chronic toxic effects and reproductive/ developmental effects by adult workers is not at all likely.
- Storage and use is limited to 'places of work'
- The label will state "KEEP OUT OF REACH OF CHILDREN – FOR ANIMAL TREATMENT ONLY"

Likelihood of risk: VERY UNLIKELY
Magnitude: Initially mild and reversible; potentially severe

Risk – Skin irritancy
Exposure of NTNCS2 to skin is UNLIKELY to occur.
In addition to the features of the product described above which limit its availability to 'places of work' and to users who are experienced with the product, the additional factors are relevant to this risk:

- The label will give advice to users to avoid contact with skin and eyes. Further advice will be given in the event of contact with skin and eyes "If on skin remove contaminated clothing and wash with plenty of soap and water.." – spills on skin can be successfully washed of with water.
- The product will be applied through a closed system applicator which will minimise the chance of skin contact. The product applicator directs the NTNCS2 directly to the sheep and away from the person applying the product.
- The main risk period will be during decanting between (for example) a 20L container and a 5 L backpack – to mitigate this risk, a decanting tap will be provided with every applicator which will ameliorate the risk of spillage which may have occurred if a funnel was used for decanting.

Likelihood of risk: Spills on skin are UNLIKELY
Magnitude: Low, localised, reversible.

Risk – Eye irritancy
Exposure of NTNCS2 in the eye is VERY UNLIKELY to occur.
The features of the product described above which limit its availability to 'places of work' and to users who are experienced with the product, and the features which will reduce the risk of skin irritancy are also expected to reduce the risks arising from eye irritancy.

- The label will carry the warning: "If in eyes rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing"

Likelihood of risk: VERY UNLIKELY
Magnitude: Low, localised, reversible, but in extreme cases may be severe.

Risk analysis – Environmental Risks

Risk – Ecotoxicity following accidental or intentional release.

Risk – Aquatic species

Access to waterways or bodies of water could occur:

- Following accidental spillage during transport.
- Disposal of unused product near waterways
- Disposal of effluent from wool scouring plants (Note: a wool withholding time will be set by the ACVM Group and stated on the product label)

Risks are no greater than for other pour-on ectoparasiticides currently marketed. One of the major mitigating factors for spillage is that bulk material will not leave the manufacturing plant. The highest single volume container to be transported will be 20 L. Economic effects and the product cost will reduce the likelihood that unused product will be disposed of inappropriately as the cost will ensure that there is a strong incentive to use all of the product through direct animal treatment.

Likelihood of small spill:	Localised spills are EQUALLY LIKELY/UNLIKELY
Magnitude:	Low, localised, minor
Likelihood of large spill	Large spills are VERY UNLIKELY
Magnitude:	Minor to moderate environmental effects

Risk – soil

Access to soil and terrestrial invertebrates could occur:

- Following accidental spillage during transport.
- Disposal of unused product in local landfills
- Disposal of unused product on farmland

Risks are no greater than for other pour-on ectoparasiticides currently marketed. One of the major mitigating factors for spillage is that bulk material will not leave the manufacturing plant. The highest single volume container to be transported will be 20 L. Economic effects and the product cost will reduce the likelihood that unused product will be disposed of inappropriately as the cost will ensure that there is a strong incentive to use all of the product through direct animal treatment.

Likelihood of small spill:	Localised spills are EQUALLY LIKELY/UNLIKELY
Magnitude:	Low, localised, minor
Likelihood of large spill	Large spills are VERY UNLIKELY
Magnitude:	Moderate environmental effects

Risk – terrestrial invertebrates – bees

Due to the use pattern and packaging of the product, it is highly unlikely that significant quantities of active ingredient could be released where bees are working. Applying the pour-on onto sheep would not be done in areas were bees would be working (sheep yards). The use pattern of NTNCS2 does not put bees at risk.

Likelihood of risk:	VERY UNLIKELY
Magnitude:	Minor.

Risk – terrestrial vertebrates

Access to soil and terrestrial vertebrates could occur:

- Following accidental spillage during transport.
- Disposal of unused product in local landfills

- Disposal of unused product on farmland

Risks are no greater than for other pour-on ectoparasiticides currently marketed. One of the major mitigating factors for spillage is that bulk material will not leave the manufacturing plant. The highest single volume container to be transported will be 20 L. Economic effects and the product cost will reduce the likelihood that unused product will be disposed of inappropriately as the cost will ensure that there is a strong incentive to use all of the product through direct animal treatment.

Likelihood of small spill: Localised spills are EQUALLY LIKELY/UNLIKELY
Magnitude: Low, localised

Likelihood of large spill Large spills are VERY UNLIKELY
Magnitude: Moderate to severe environmental effects

Risk – Summary

NTNCS2 is very similar to existing products already on the market. Its presence in the NZ market will be beneficial in terms of the increased choice of this type of product and it will not impose any extra costs which are not already apparent in the existing products on the market.

Further risk mitigating factors are discussed further in Appendix 1.

Exposure Route	Potential Effect	Likelihood of Adverse Effect Occurring	Magnitude of Adverse Effect	Level of Risk
Spillage during transport, storage, use or disposal resulting in substance entering a water body, soil or exposing animals.	Death or adverse effect on aquatic and terrestrial organisms. Death or adverse effect on animals or people	Very unlikely	Minor	Low
Inadequate storage allowing access to children	Adverse effect on the child	Very unlikely	Minimal	Insignificant
Prolonged chronic exposure during use	Health effects in users	Very unlikely	Minimal	Insignificant
Eye exposure during use	Eye irritation	Very unlikely	Minimal	Insignificant
Skin exposure during use	Skin irritation	Unlikely	Minimal	Low
Active ingredients entering aquatic environment via wool scour effluent	Death or adverse effect on aquatic organisms	Unlikely	Minor	Low

Costs

Costs – Human health

Any health costs would be borne by workers and the community generally

Costs – Environment

Costs of cleaning up spillage would be borne by the wider community. Costs of disposal would be borne by end-users.

Benefits

Benefits – human health

While NTNCS2 is not expected to have any direct benefit to human health, the control of ectoparasites on sheep improves sheep farm productivity, increasing the export earnings which are necessary to fund

health care of New Zealanders generally. There may also be a psychological benefit to farmers who appreciate having new and improved animal health formulations available to treat their sheep – and the resulting decreases in stress levels that this produces.

Benefits – Environment
While NTNCS2 is not expected to have any direct benefit to the environment, a product which more effectively controls ectoparasites in sheep may actually serve to decrease the overall requirement for chemicals particularly those which are required to treat active fly strike in sheep (and these chemicals are often older organophosphate based products) – so indirectly the use of NTNCS2 may decrease the quantity of other chemicals used on sheep and thus at risk of entering and affecting the environment.

Other benefits

Benefit	Impact	Action Through
Improvement of animal health	Direct	More effective treatment and control of ectoparasites
Improvement of the livestock and animal products that New Zealand can offer at home and overseas	Direct Indirect	Having healthy animals improved the quantity and quality of farm produce.
Improvement of overall farm production	Indirect	Having healthy animals improved the quantity and quality of farm produce
Increased choice of this type of product in the NZ market	Direct	Increased choice of this type of product is likely to promote competition which in turn may lead to a decreased cost for New Zealand farmers.

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)

When use as directed, and noting the nature of the product and packaging, it is assessed that this product will have an insignificant effect on the environment and other cultural interests of Maori. Although direct consultation with Maori has not taken place, it is anticipated that there are unlikely to be any particular aspects of this product likely to affect Maori tradition or culture

Further comments in confidential Appendix 1.

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)

Risks to New Zealand's international obligations with regard to food and fibre residues are to be assessed by the ACVM Group of NZFSA. Other risks, costs and benefits related to New Zealand's international obligations are not assessed by the applicant.

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)

Flammable properties

The default controls are F2, F6, F11, F17

Toxic properties

The proposed controls are: T1, T2, T4, T7.
The combination of the controls and the label instructions will adequately control risks for users.
The default control T3 (records of use) is not required for similar products.

Ecotoxic properties

The proposed controls are: E1, E6 & E8
The control E2 is not required for veterinary medicines. E3 is not necessary as there is no exposure pathway for bees. E4 is not necessary as there is no exposure pathway to terrestrial vertebrates. The controls for records of use (E5), approved handlers (E7 & AH1) and tracking (TR1) should not be required as these have been deleted for similar products.

Identification

The default controls for identification (I1,I3,I5,I9,I11,I13,I16,I17,I18,I19,I21,I23,I25,I28,I29) control the risk associated with identification of the hazardous properties of the substance. This will be achieved in the labelling proposed for the product and by the provision of an appropriate Safety Data Sheet.

Packaging

The proposed controls are P1,P3,P13*,P15, PG3. Similar products in the market which have a similar Dangerous goods Class 9 are not packaging Group 2 (PG2) for transport.

Disposal

The default controls for disposal (D2,D4,D5,D6,D7,D8) control the risks associated with disposal of unused product and containers as well as used containers.

Emergency Management

The default controls for emergency management (EM1, EM4, EM6, EM7, EM8, EM9, EM10, EM11, EM12, EM13) control the risks which require emergency management.

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)

The direct benefits to animal welfare and indirect benefits to the New Zealand economy outweigh risks associated with improper handling, accidental spillage or inappropriate disposal. Such events

are unlikely to occur due to the proposed controls as a result of the hazard assessment of NTNCS2

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)

NTNCS2 has been successfully considered by ERMANZ for manufacture into containment (HSC000301) and the ACVM Group of NZFSA for Provisional Registration (A10235).

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)

NTNCS2

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)

This application proposes the manufacture and distribution for release of NTNCS2 which is a veterinary medicine to control ectoparasites on sheep after external application.

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. Non dispersive use
Industry category: 1. Agricultural industry
Function/Use category: 41. Pharmaceuticals (Subcategory) veterinary medicines

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 proposes the manufacture and distribution of the mixture NTNCS2 in New Zealand.

NTNCS2 breaches HSNO thresholds for flammability, skin irritation, eye irritation, reproductive/developmental effects, target organ toxicity, aquatic and soil ecotoxicity and terrestrial vertebrate and invertebrate ecotoxicity.

NTNCS2 is to be used on farms to control ectoparasites on sheep. It would be sold as a ready to use formulation and have a dedicated applicator to allow effective product application by an end-user.

Risks to humans are relatively low and can be managed by careful application including the use of the dedicated applicator with the use of protective equipment. Risks to the environment can be managed by careful use, transportation under Dangerous Goods rules and appropriate disposal. Risks to bees are limited by the lack of exposure pathways.

The main risks associated with the use of this product are to the user if NTNCS2 were not handled appropriately – this risk is judged to be unlikely. The main risk to the environment is the risk to aquatic organisms in the case of accidental spills or inappropriate disposal. These events are judged to be very unlikely.

CHECKLIST

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

Signed Date