

FORM section 63A

(Modified Reassessment)

Application for a Modified Reassessment under section 63A of the Hazardous Substances and New Organisms Act 1996

Name of Substance(s): Chlorpropham

Applicant: Renovo Technologies Ltd

Signed: _____

Date: _____

Application Checklist	Tick or n/a
Mandatory sections filled out:	
All Attachments enclosed:	
Application signed and dated:	

Office use only	
Date received:	___/___/___
Application Code:	
ERMA NZ Contact:	
Application Version No:	v1.0

SECTION ONE – APPLICANT DETAILS

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

Name: Renovo Technologies Ltd
Address: PO Box 3218,
New Plymouth 4341
Phone: 06 754 6709
Fax: 06 754 8633

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

Address: 115 Mould St,
Waitara,
Taranaki

1.3 Name of the contact person for the application

Name: Mark Linton
Position: Managing Director
Phone: 027 3264539
Fax: 06 754 8633
Email: mark@reovotech.co.nz

SECTION TWO – APPLICATION TYPE

2.1 The approvals being reassessed

The approval for chlorpropham (HSR002826) is being reassessed based on a proposed change of use.

2.2 Specific aspect of the approval being reassessed

The specific aspect is a change to the use of the substance. Chlorpropham is currently approved for use as a component in another substance or product. The proposed change of use is for chlorpropham to be used in a product as a single component (ie containing only chlorpropham).

2.3 Grounds for the reassessment

An application was made on grounds for reassessment of chlorpropham as a single component (RES08008). The decision from the authority was that there are grounds for the reassessment of chlorpropham based on this change of use.

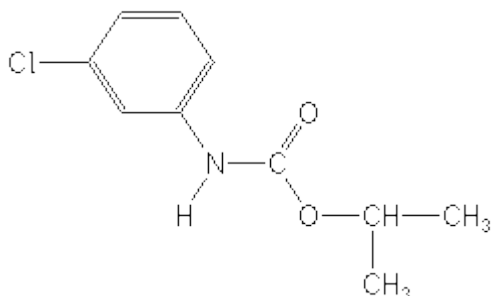
2.4 Consultation

No consultation performed to date.

SECTION THREE – INFORMATION ON THE SUBSTANCES

3.1 The unequivocal identification of the substance

Common name: Chlorpropham
HSNO Approval: HSR002826
Chemical name: isopropyl 3-chlorocarbanilate
Synonyms : 1-methylethyl (3-chlorophenyl)carbamate
CAS Registry number: 101-21-3
Molecular formula: $C_{10}H_{12}ClNO_2$
Molecular weight: 213.7
Structural formula:



3.2 Information on the chemical, physical and hazardous properties of the substance

Appearance: White/brown crystals
Density/SG: 1.18 g/mL
Vapour Pressure: 24 mPa at 25°C
Water Solubility: 110 mg/L
Melting Point: 42°C
Flash Point: Not flammable
Water/Octanol
partitioning coefficient: 3.76 at pH 7, 20°C

Hazardous Properties: 6.1E, 6.4A, 6.9B, 9.1A, 9.2A

3.3 Identification of the controls on the substances

Default controls for Chlorpropham (approval HSR002826) are listed below

Control Code	Regulation Number	Control
-----------------	----------------------	---------

Hazardous Substances (Personnel Qualification) Regulations 2001

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

Hazardous Substances (Disposal) Regulations 2001

D4	8	Disposal requirements for toxic and corrosive substances
D5	9	Disposal requirements for ecotoxic substances
D6	10	Disposal requirements for packages
D7	11,12	Information requirements for manufacturers, importers and suppliers, and persons in charge
D8	13,14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge

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

E1	32-45	Limiting exposure to ecotoxic substances through the setting of EELs
E2	46-48	Restrictions on use of substances in application areas
E5	5(2), 6	Requirements for keeping records of use
E6	7	Requirements for equipment used to handle substances
E7	9	Approved handler/security requirements for certain ecotoxic substances
T1	46692	Limiting exposure to toxic substances through the setting of TELs
T2	29,30	Controlling exposure in places of work through the setting of WESs.
T4	7	Requirements for equipment used to handle substances
T5	8	Requirements for protective clothing and equipment
T7	10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles
T8	28	Controls for vertebrate poisons

Hazardous Substances (Emergency Management) Regulations 2001

EM1	6,7,9-11	Level 1 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
EM6	8(e)	Information requirements for toxic substances
EM7	8(f)	Information requirements for ecotoxic substances
EM8	12-16,18-20	Level 2 information requirements for suppliers and persons in charge

Hazardous Substances (Identification) Regulations 2001

I1	6,7,32-35,36(1)-(7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
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 situations where substances are in multiple packaging
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
I3	9	Priority identifiers for ecotoxic substances
I30	53	Advertising corrosive and toxic substances
I8	14	Priority identifiers for toxic substances
I9	18	Secondary identifiers for all hazardous substances
Hazardous Substances (Packaging) Regulations 2001		
P1	5,6,7(1),8	General packaging requirements
P13*	19	Packaging requirements for toxic substances
P15	21	Packaging requirements for ecotoxic substances
P3	9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria
PG3	Schedule 3	Packaging requirements equivalent to UN Packing Group III
PS4	Schedule 4	Packaging requirements as specified in Schedule 4

3.4 The proposal to modify the approval of the substances

Chlorpropham as a single substance is currently approved for use as a component in other substances only (HSR002826). A number of other approved substances exist which contain chlorpropham as a component:

- Fruited Chloro-IPC - HSR007885;
- Emulsifiable concentrate containing 400 g/litre chlorpropham (Substance A) - HSR000823;
- Emulsifiable concentrate containing 400 g/litre chlorpropham (Substance B) - HSR000651;
- Emulsifiable concentrate containing 500 g/litre chlorpropham - HSR000637.

The majority of these substances are registered for use as a herbicide with the Agricultural Chemicals and Veterinary Medicines (ACVM) Group. This application only considers the use of chlorpropham registered for use as a plant growth regulator for stored potatoes with the ACVM Group. Two products are currently registered for this use, both under HSNO approval HSR000637:

- No Sprout (500g/L) – P4774 (HSR000637);
- Neo Stop L500 – P5616 (HSR000637).

These two products are used in potato warehouses to inhibit sprouting of potato tubers during storage. The substances are applied using a thermal fogger whereby the product is introduced into the thermal fogger and by use of high temperature combustive pulses (eg from spark plug) this causes the substance to be atomised into a evenly dispersed and small sized particulate fog. This is done directly within the contained potato storage warehouse.

A draft label for the use of single component chlorpropham as well as Neo-Stop and No Sprout are included with the application for reference. The use rate of single component chlorpropham is proposed to be 290g/20MT (bulk stores) or 430g/20MT (box stores).

The use rate of the current products containing 500 g/L chlorpropham is 570mL/20MT (bulk stores) or 850mL/20MT (box stores). This corresponds to the same application amount of chlorpropham, based on 500 g/L (existing formulations) or 980 g/kg (solid chlorpropham block).

The currently approved products for this use contain 50% chlorpropham in additional excipients (eg solvents) formulated as a liquid for ease of handling. Despite the ambient state of chlorpropham being a solid crystalline product it is possible to use the chlorpropham single component in this application due to its low melting point (42°C).

Molten chlorpropham can be distributed from a thermal fogger in exactly the same manner as the two above mentioned products. This use has become common practice overseas because of the benefits of using chlorpropham single component instead of formulated liquids. These benefits are detailed in section 4 below. Chlorpropham briquettes are currently registered for this use in Canada and USA.

The use of chlorpropham in this manner is exactly the same as for the two approved products containing 50% chlorpropham in the form of a liquid. The substances exiting the combustion chamber of the thermal fogger are in an identical state, with the only difference being the lack of excipients present from the single component chlorpropham. Greater detail will be provided regarding the mechanism of thermal foggers.

Thermal foggers utilise a pulsating combustion from ignition of fuel/air mixtures by a spark plug, generating kinetic and thermal energy (including high temperatures) to generate a particulate fog of the substance being applied. The temperatures in the combustion chamber are typically from 300-800°C depending on the model and applicator settings. The fog then cools while passing through the resonator (exhaust pipe) and exits the equipment into the area being treated. At the high temperatures in the combustion chamber the majority of solvents present in the current approved substances are instantly vaporised into a gaseous state while the chlorpropham is atomised into very small liquid particulates by the time it exits the exhaust pipe. Upon hitting the cooler ambient air the chlorpropham crystallises into a fog of very small solid particulate crystals while the solvents (as present in the currently approved products) condense on any cool surfaces (which includes walls of the warehouse and exposed potatoes). This fog then permeates throughout the potato warehouse settling on potatoes to provide an inhibition of sprouting during storage.

The single component chlorpropham is expected to replace the current liquid products in the market for this use. It will be impossible for the single component to replace the other liquid chlorpropham products used as a herbicide for two reasons:

- Single component chlorpropham is a solid crystalline substance which is immiscible with water so it cannot be applied in a widely dispersive manner in water as the other liquid chlorpropham agricultural herbicides are.
- Each products use is controlled by the registered label use approved by the ACVM Group which will restrict the use of solid chlorpropham to the specific use described in this application.

Additionally, the product will not be for sale to the general public, further reducing the risk of this occurring.

3.5 Commercial sensitivity

Some commercially sensitive data is included with this application in confidential appendices.

SECTION FOUR: RISKS, COSTS AND BENEFITS

4.1 Identification of all the effects associated with the reassessment proposal (section 63A(6)(a))

The primary effect is that single component chlorpropham will be used in a manner where it is released. However, this effect is mitigated by the fact that chlorpropham is already released after use in an identical manner, the difference being the composition of the products prior to use and that additional excipients are also released when used currently (eg solvents in the existing liquid formulations). No other significant effects are anticipated.

A lifecycle summary table has been prepared and is provided below.

Life cycle step	Potential risk event	Possible consequence	Likelihood
Arrival into NZ (product) and Transport & Storage within NZ (product)	<ul style="list-style-type: none"> • Packaging damaged or leaking • Spillage from transport accident • Fire • Containers opened (unauthorised people) 	<ul style="list-style-type: none"> • Release into environment (water) • Release into environment (water) • Release of fumes, smoke • Contact with people, animals, foodstuffs 	<ul style="list-style-type: none"> • Low – product is a solid block so easily contained if packaging damaged • Low – as above • Low – no increased fire risk from product. • Low – product contained in steel drums and exposure risk from solid block low
Product use	<ul style="list-style-type: none"> • Unintended contact with skin, eyes • Inhalation of fog • Use on plants (off label use) • Release into environment 	<ul style="list-style-type: none"> • Exposure to chlorpropham • Exposure to chlorpropham • Off target damage from unapproved use. • Contamination of waterways 	<ul style="list-style-type: none"> • Low – only trained contractors apply the product in contained warehouses. • Low – as above. • Low – as described in 3.4. • Low – product is used and released in contained warehouses.
Disposal	<ul style="list-style-type: none"> • Reuse of containers for other uses • Unused product or containers / packaging into waterways 	<ul style="list-style-type: none"> • Release into environment (water) • Skin or eye contact with product 	<ul style="list-style-type: none"> • Moderate – product is only applied by a small number of trained contractors so empty containers will be disposed of correctly. • Low – empty drums will be disposed of by

			companies experienced in hazardous substances.
--	--	--	--

4.2 Assessment of the risks associated with the reassessment proposal

A summary of the hazard classifications for single component chlorpropham and the existing formulations (approval HSR000637) are listed below.

Hazardous Property	Single Component Chlorpropham	HSR000637 Reference Substance
Class 1 Explosiveness	Not triggered	Not triggered
Class 3 Flammability	Not triggered	3.1C
Class 5 Oxidising	Not triggered	Not triggered
Class 6 Toxicity		
6.1 Acute toxicity	6.1E	Not triggered
6.3 Skin Irritation	Not triggered	Not triggered
6.4 Eye Irritation	6.4A	6.4A
6.5 Sensitisation	Not triggered	Not triggered
6.6 Mutagenic	Not triggered	Not triggered
6.7 Carcinogenic	Not triggered	Not triggered
6.8 Reproductive and/or developmental	Not triggered	Not triggered
6.9 Target organ or system effects	6.9B	6.9B
Class 8 Corrosiveness	Not triggered	Not triggered
Class 9 Ecotoxicity		
9.1 Aquatic	9.1A	9.1B
9.2 Soil	9.2A	9.2A
9.3 Terrestrial Vertebrates	Not triggered	Not triggered
9.4 Terrestrial Invertebrates	Not triggered	Not triggered

It can be seen from this comparison that single component chlorpropham has a lower flammability hazard, higher acute toxicity and higher aquatic toxicity hazards. However, these increased hazards are merely the result of a dilution effect in HSR000637 and are less significant when the use rates are included considering that the same amount of chlorpropham is applied for each product. The higher flammability hazard of HSR000637 is significant when considering that the products are applied through a high temperature thermal fogger.

Furthermore, the risk of unintended contamination of the aquatic environment in the case of a spill or accident is reduced with single component chlorpropham because it is solid at ambient temperature, therefore is considerably easier to contain than the liquid formulations in HSR000637.

It is intended that this product will ultimately replace the existing product in the market
Category 4.1 details risks in the lifecycle summary table

4.3 Assessment of the costs associated with the reassessment proposal

Costs associated with this reassessment proposal are expected to be administrative in nature only.

4.4 Assessment of the benefits associated with the reassessment proposal

A primary benefit is the reduction in solvent which is ultimately released during thermal fogging. Application of the product is safer because of lower flammability risk (due to lack of solvents). A benefit is also the reduction in packaging because the applied product is more concentrated (eg 98% pure compared to 50% pure). In the case of an accidental spill of the product prior to application (eg during transport) containment of the spill is more straightforward due to it being a solid rather than liquid and the chance of accidental contamination of the environment is reduced.

4.5 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

None

SECTION FIVE – INTERNATIONAL CONSIDERATIONS

5.1 The best international practices and standards for the safe management of the substance (section 63A(6)(b))

Single Component Chlorpropham is currently used for sprout inhibition of stored potatoes in a number of overseas countries. Example registrations are as follows:
Canada; registration numbers 27402, 27213, 29031, or 29037
United States; EPA registration numbers 2792-70, 2749-520, 65726-3

5.2 International obligations and treaties

None known.

SECTION SEVEN – SUMMARY OF PUBLIC INFORMATION

7.1 Name of the substance for the public register

Chlorpropham

7.2 Purpose of the application for the public register

Modified reassessment of the approval for chlorpropham to permit its use as a sprout inhibitor for stored potatoes.

7.3 Executive summary

Chlorpropham use is proposed to be modified to include the use as a solid, crystalline single component for inhibiting sprout growth on stored potatoes. Currently chlorpropham is approved to be used for this purpose as a component in liquid formulations only containing 50% chlorpropham (HSR000637).

Chlorpropham is applied to potatoes to inhibit sprout growth using a thermal fogger. After the product is introduced into the thermal fogger and by use of high temperature combustive pulses (eg from spark plug) the product is atomised into a evenly dispersed and small sized particulate fog. This is done directly within the contained potato storage warehouse.

The use rate of single component chlorpropham is proposed to be 290g/20MT (bulk stores) or 430g/20MT (box stores).

The use rate of the current products containing 500 g/L chlorpropham is 570mL/20MT (bulk stores) or 850mL/20MT (box stores). This corresponds to the same application amount of chlorpropham, based on 500 g/L (existing formulations) or 980 g/kg (solid chlorpropham block).

The hazards of solid single component chlorpropham are 6.1E, 6.4A, 6.9B, 9.1A, 9.2A. The hazards of the currently approved liquid formulations (HSR000637) are 3.1C, 6.4A, 6.9B, 9.1B, 9.2A.

Single component chlorpropham has a lower flammability hazard, higher acute toxicity and higher aquatic toxicity hazards than HSR000637. However, these increased hazards are the result of a dilution effect of chlorpropham in HSR000637. They are proposed to be less significant when the use rates are included considering that the same amount of chlorpropham active ingredient is applied for each product..

The benefits to using chlorpropham single component over the existing formulations' use are a safer application process, reduced transportation (higher concentration), less solvents used and released to the environment, reduced packaging, and reduced unintended effects in the case of a spill.

While the single component chlorpropham has a higher hazard for aquatic toxicity, the risk of accidentally contaminating the aquatic environment is lower due to it being a solid, block product which cannot spill and flow down drains directly into the aquatic environment, eg it is easier to contain than the currently used liquid products (HSR000637). The higher flammability hazard of HSR000637 is significant when considering that the products are applied through a high temperature thermal fogger. Other risks between single component chlorpropham and the existing liquid formulations are similar.