Australian Government

Australian Pesticides and Veterinary Medicines Authority

Public Release Summary

on the evaluation of the new active 1,4-dimethylnaphthalene in the product 1,4 SIGHT Potato Dormancy Enhancer

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This publication is available from the APVMA website.

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator responsible for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia. Before approving an active constituent and/or registering a product, the APVMA must be satisfied that the statutory criteria, including the safety, efficacy, trade, and labelling criteria, have been met. The information and technical data required by the APVMA to assess the statutory criteria of new chemical products, and the methods of assessment, must be consistent with accepted scientific principles and processes. Details are outlined on the APVMA website.

The APVMA has a policy of encouraging transparency in its activities and seeking community involvement in decision making. Part of that process is the publication of Public Release Summaries for products containing new active constituents. This Public Release Summary is intended as a brief overview of the assessment that has been conducted by the APVMA and of the specialist advice received from advisory agencies, including other Australian Government agencies and State departments of primary industries. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience to encourage public comment.

About this document

This Public Release Summary indicates that the APVMA is considering an application for registration of an agricultural or veterinary chemical. It provides a summary of the APVMA's assessment, which may include details of:

- the toxicology of both the active constituent and product
- the residues and trade assessment
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- efficacy and target crop or animal safety.

Comment is sought from interested stakeholders on the information contained within this document.

Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of [Product Name(s)] should be granted. Submissions should relate only to matters that the APVMA is required, by legislation, to take into account in deciding whether to grant the application. These matters include aspects of public health, occupational health and safety, chemistry and manufacture, residues in food, environmental safety, trade, and efficacy and target crop or animal safety. Submissions should state the grounds on which they are based. Comments received that address issues outside the relevant matters cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 16 June 2026 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- a contact name
- the company or organisation name (if relevant)
- an email or postal address (if available)
- the date you made the submission.

Please note: submissions will be published on the APVMA website unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Case Management Team – Pesticides
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Email: casemanagement@apvma.gov.au.

Further information

Further information can be obtained via the contact details provided above.

Further information on Public Release Summaries can be found on the APVMA website.

Introduction

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of 1,4SIGHTPotato Dormancy Enhancer, and approval of the new active constituent, 1,4-DIMETHYLNAPTHALENE.

Applicant

1,4GROUP, INC.

Purpose of application

1,4GROUP, INC. has applied to the APVMA for registration of the new product 1,4SIGHTPotato Dormancy Enhancer, containing 980 g/kg, as an 'Other liquids to be applied undiluted' (AL) formulation of the new active constituent 1,4-DIMETHYLNAPTHALENE.

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of the product 1,4SIGHT Potato Dormancy Enhancer, and approval of the new active constituent 1,4-DIMETHYLNAPTHALENE.

Proposed claims and use pattern

To enhance dormancy of potatoes in storage.

Mode of action

Plant growth regulator.

Overseas registrations

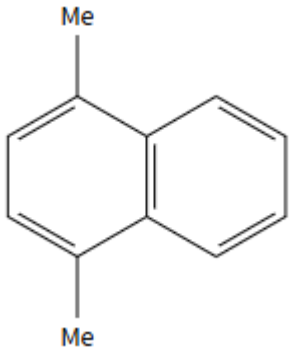
1,4-DMN is currently registered and used as a sprout inhibitor to extend potato storage in USA, Canada, Kenya, Mexico, UK and several European countries (Netherlands, Austria, Belgium, Germany, France, Ireland & Poland).

Chemistry and manufacture

Active constituent

The active constituent 1,4-dimethylnaphthalene is manufactured overseas. Details of the chemical name, structure, and physicochemical properties of 1,4-dimethylnaphthalene are listed below in Tables 1 and 2.

Table 1: Nomenclature and structural formula of 1,4-dimethylnaphthalene

Common name (ISO):	1,4-dimethylnaphthalene
IUPAC name:	1,4-dimethylnaphthalene
CAS registry number:	571-58-4
Molecular formula:	$C_{12}H_{12}$
Molecular weight:	156.23 $gmol^{-1}$
Structural formula:	

1,4-Dimethylnaphthalene is a liquid at room temperature, with a moderate vapour pressure (2.5 Pa at 25 C). It has low aqueous solubility, while being highly soluble in polar and aliphatic and aromatic non-polar organic compounds. Therefore, it has a high partition coefficient at 4.37 and is likely to be fat soluble. 1,4-Dimethylnaphthalene is not oxidising, explosive or classified as a flammable liquid.

Table 2: Key physicochemical properties of 1,4-dimethylnaphthalene

Physical form:	Clear liquid
Colour:	Pale yellow
Odour:	Slight odour of petroleum distillate
Melting point:	7.6 °C
Boiling point:	264 °C (at 744 mm Hg/99.2 kPa)
Specific gravity	1.014 (25 °C)
Stability:	Expected to remain within specification when stored for at least 2 years under normal conditions
Safety properties:	Not oxidising Not explosive Flash point (760 mm Hg, i.e. 1 atm): 122 °C, therefore not classified as a flammable liquid under the Dangerous Goods Code
Solubility in water:	5.1 mg/L (25 °C)
Organic solvent solubility (20 °C):	methanol: > 250 g/L ethyl acetate: > 250 g L/L acetone: > 250 g/L n-heptane: 239 g/L 1,2-dichloroethane: 248 g/L xylene: 248 g/L
Dissociation constant (pK_a):	Does not dissociate
PH:	5.9 (1% dilution, CIPAC MT 75.3)
Octanol/water partition coefficient (Log K_{ow}):	4.37 (calculated)
Vapour pressure (95.1% purity):	25 °C: 1.88 × 10^{-2} mm Hg (2.50 Pa) 35 °C: 3.64 × 10^{-2} mm Hg (4.85 Pa) 45 °C: 8.75 × 10^{-2} mm Hg (11.7 Pa)
Henry's law constant:	76.7 Pa m^3 /mol (25 °C)

Formulated product

The product 1,4SIGHT Potato Dormancy Enhancer will be manufactured overseas. Tables 3 and 4 outline some key aspects of the formulation and physicochemical properties of the product.

Table 3: Key aspects of the formulation of the product 1,4SIGHT Potato Dormancy Enhancer

Distinguishing name:	1,4SIGHT Potato Dormancy Enhancer
Formulation type:	Other liquids to be applied undiluted (AL)
Active constituent concentration:	980 g/kg

Table 4: Physicochemical properties of the product 1,4SIGHT Potato Dormancy Enhancer

Physical form:	Clear pale yellow liquid
PH:	5.9 (1% dilution, CIPAC MT 75.3)
Density:	1.0149 – 1.0167 g/mL
Viscosity:	6 cps at 12 rpm and 6 cps at 30 rpm.
Safety properties:	Not oxidising Not explosive Flash point (760 mm Hg, i.e. 1 atm): 122 °C, therefore not classified as a flammable liquid under the Dangerous Goods Code
Storage stability:	Expected to remain within specification when stored for at least 2 years under normal conditions

Recommendations

The APVMA has evaluated the chemistry of the active constituent 1,4-dimethylnaphthalene and the associated product 1,4SIGHT Potato Dormancy Enhancer, including the manufacturing process, quality control procedures, stability, batch analysis results and analytical methods, and found them to be acceptable. The available storage stability data indicate that the formulated product is expected to remain stable for at least 2 years when stored under normal conditions.

Based on a review of the chemistry and manufacturing details, the registration of 1,4SIGHT Potato Dormancy Enhancer, and approval of the active constituent 1,4-dimethylnaphthalene, are supported from a chemistry perspective.

Toxicological assessment

A full package of toxicological data for 1,4-dimethylnaphthalene (hereafter referred to as 1,4-DMN) was submitted by the applicant, which was sufficient to assess the toxicity of 1,4-DMN.

Evaluation of toxicology

Chemical class

1,4-DMN (CAS No. 571-58-4) belongs to the chemical family of alkylated naphthalenes and acts as a plant growth regulator preventing sprouting of potato tubers. Besides being synthetically produced, it also occurs naturally in different plant species (for example potato, rhubarb, and poppy). 1,4-DMN acts by enhancing dormancy, a natural event triggered by biochemical substances found within the potato.

Pharmacokinetics

1,4-DMN excretion was rapid and almost completed within 48 hours with urine being the primary route and faeces being a secondary route of excretion. The parent molecule (1,4-DMN) was detected in urine only in trace amounts. 1,4-DMN metabolism was complex, and a diverse range of metabolites were generated by rats primarily via oxidation, hydroxylation, conjugation, and epoxidation of 1,4-DMN. The major metabolites identified in rat metabolism study are 1-hydroxymethyl-4- methylnaphthalene and 4-methyl-1-naphthoic acid. In an *in vitro* study, the mean total percutaneous absorption of 1,4-DMN through human skin was 2.5 %.

Acute toxicity (active constituent)

The acute toxicity of 1,4-DMN in rats is low (oral LD_{50}>2000 mg/kg bw; dermal LD_{50}>2000 mg/kg bw and inhalation LC_{50}>4.16 mg/L. 1,4-DMN was moderate eye irritant and moderate skin irritant in rabbits. 1,4-DMN was not a skin sensitiser in guinea pigs (Buehler method) and mouse local lymph node assay (LLNA).

Acute toxicity (product)

1,4SIGHT Potato Dormancy Enhancer was of low acute toxicity by oral, dermal and inhalation route in rats. 1,4SIGHT Potato Dormancy Enhancer was moderate eye irritant and moderate skin irritant in rabbits. It was not a skin sensitiser in guinea pigs and mouse LLNA.

Repeat-dose toxicity

There were no short-term repeat dose toxicity studies submitted by the applicant. In repeat dose (sub-chronic and long-term) toxicity studies in rats, kidney was identified as the target organ on histopathological examination with the key effects being chronic progressive nephropathy (CPN), basophilic tubules, mononuclear cell infiltration, karyomegaly of the cortical tubules, proteinosis in the tubules of the papilla, and papillary necrosis. CPN is a kidney alteration that has been repeatedly shown to occur spontaneously in aging rats and is not considered relevant for humans when assessing human health risk associated with exposure to 1,4-DMN. The other effects tending to set NOAELs in repeat dose studies were reduction in

food consumption and lower body weights or weight gains – a largely non-specific indicator of toxicity or general malaise.

Chronic toxicity and carcinogenicity

There was no evidence of carcinogenicity in rats, based on the absence of any neoplasia, at dietary concentrations of up to 3750 ppm (equal to 208 mg/kg bw/d), the highest dose tested. It can be concluded that 1,4-DMN is not carcinogenic in rats.

Reproductive and developmental toxicity

1,4-DMN was not a reproductive or developmental toxicant in an extended one-generation reproductive toxicity study in rats and oral developmental toxicity in rabbits.

Genotoxicity

Based on the negative results in an adequate array of genotoxicity studies both *in vitro* and in *vivo,* it can be concluded that 1,4-DMN is unlikely to have any genotoxic potential.

Neurotoxicity/immunotoxicity

The applicant did not submit any acute or repeated dose neurotoxicity/immunotoxicity study. However, there was no evidence of neurotoxicity or immunotoxicity observed in repeat dose toxicity study in rats.

Mode of action (toxicology)

No mode of action or investigative studies on 1,4-DMN were provided by the applicant.

Toxicity of metabolites and/or impurities

The applicant did not submit any toxicological studies on any metabolites and/or impurities. The major metabolites identified in rat metabolism study are 1-hydroxymethyl-4- methylnaphthalene and 4-methyl-1-naphthoic acid. It is concluded that these metabolites contribute substantially to the toxicological profile of 1,4-DMN. Overall, it is considered that the toxicity profile of metabolites is not greater than the parent compound, 1,4-DMN.

Reports related to human toxicity

No specific data have been provided. The APVMA concluded that the existing database on 1,4-DMN was adequate to characterize the potential hazards to the general population, including foetuses, infants, and children. In addition, search of the scientific literature was conducted by the APVMA using the United States National Library of Medicine (https://www.ncbi.nlm.nih.gov/pubmed) on the potential of 1,4-DMN for adverse effects (skin sensitisation and allergy) arising from occupational exposure. No relevant literature or studies were found.

Microbiological properties

Not applicable.

Infectivity/pathogenicity

Not applicable.

Sensitisation potential

Neither 1,4-DMN nor the product demonstrated skin sensitisation potential in animal study.

Health-based guidance values and poisons scheduling

Poisons Standard

1,4-dimethylnaphthalene (1,4-DMN) is included in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with no concentration cut-off or exceptions to other schedules.

Health-based guidance values

Acceptable daily intake

An Acceptable Daily Intake (ADI) for 1,4-DMN was established at 0.1 mg/kg bw/d, based on a No Observed Adverse Effect Level (NOAEL) of 11 mg/kg bw/d in a combined chronic toxicity/carcinogenicity study in rats based on histopathological changes in the kidney of female rats at the next higher dose. A safety factor of 100 was applied to the NOAEL value to establish the ADI.

Acute reference dose

An acute reference dose (ARfD) for 1,4-DMN is considered to be unnecessary due to its low acute oral toxicity, the lack of evidence for any neurological effects in repeat dose toxicity study, or developmental toxicity that might be attributable to a single dose or exposure.

Recommendations

There are no objections on human health grounds to the approval of a new active constituent 1,4-DMN.

There are no objections on human health grounds to the registration of the product 1,4SIGHT Potato Dormancy Enhancer, containing 980 g/L 1,4-DMN when the product is used as directed on the label safety directions and appropriate PPE are worn.

Residues assessment

Metabolism, analytical methodology, residue trial data, fate in storage and trade aspects have been considered for 1,4-dimethylnaphthalene.

Metabolism

Metabolism, distribution, and expression of residues of 1,4-dimethylnaphthalene in plants (potato) and livestock (hen, goat) was investigated using ^{14}C-radiolabelled 1,4-DMN (parent). In addition to the parent, two major metabolites were found in livestock, characterized as 1-hydroxymethyl-4-methylnaphthalene (M21) and 4-methyl-1-naphthoic acid (M23).

Animal metabolism

Lactating goat

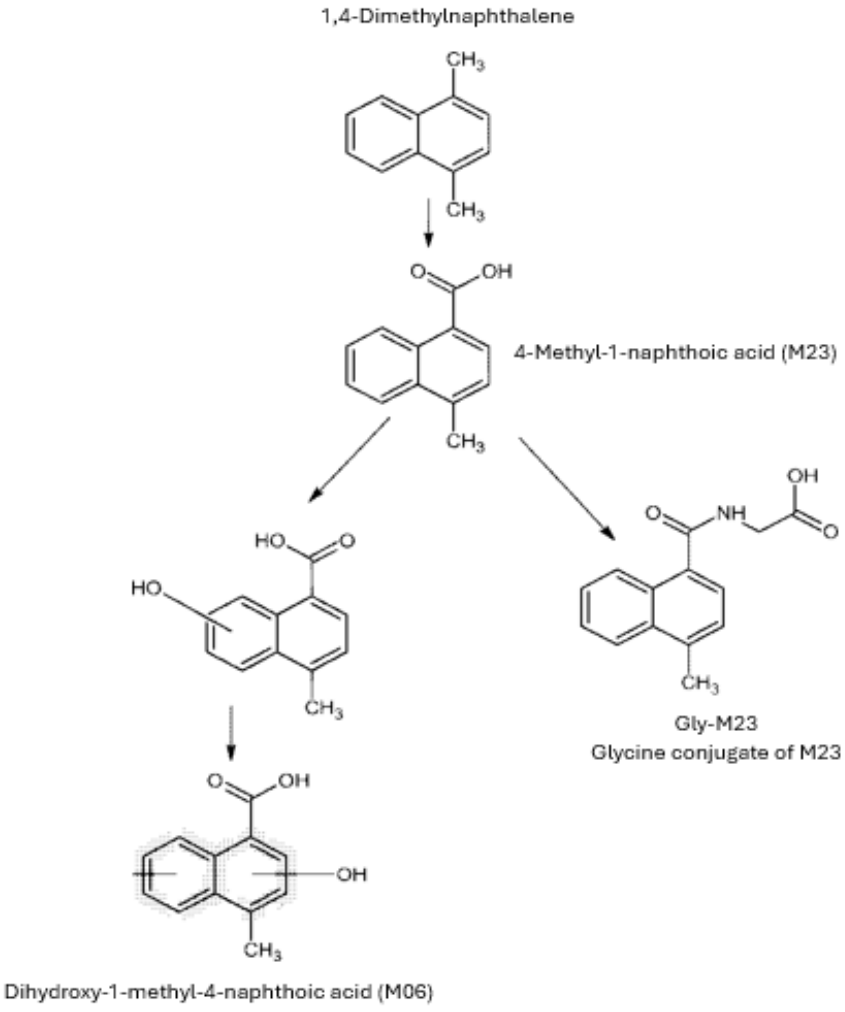
One lactating goat was orally administered ^{14}C-labelled 1,4-DMN once daily for 7 consecutive days at 12.52 ppm (0.39 mg/kg bw day). Milk was collected twice a day, and excreta (urine and faeces), blood, and plasma samples were collected once a day throughout the study period. Tissue samples were collected after sacrifice, which occurred 16 hours after the last dose. Samples collected at sacrifice included blood, bile, liver, kidney, forequarter muscle, hindquarter muscle, tenderloin muscle, omental fat, subcutaneous fat, and renal fat.

The majority (91.94 %) of the administered ^{14}C1,4-DMN was recovered from excreta, milk, and tissues. Urine, faeces, and cage wash contained 75.78 %, 14.09 % and 1.50 % of the total administered dose, respectively. Liver and kidney contained 0.18 % and 0.02 % of the administered dose, respectively. The Total Radioactive Residues (TRR) in liver, kidney, muscle (average) and fat (average) were 0.241 mg/kg, 0.277 mg/kg, 0.017 mg/kg and 0.018 mg/kg, respectively.

It is postulated that biotransformation occurred by carboxylation of one of the methyl groups, which was subsequently conjugated with glycine. Although the study does not provide direct evidence that hydroxylation and dihydroxylation would have occurred, the hypothesis is based on retention time comparison of peaks detected in urine with hydroxylated reference standards which did not contain the methyl moiety.

Parent 1,4-DMN was only detected as a minor residue in muscle at 4.7% TRR (0.001 mg/kg). The major metabolite was identified as conjugated M23, accounting for 17.7 and 16.6 % TRR in milk and in kidney (0.006 mg/kg and 0.05 mg/kg respectively). Although the study was performed using the 1,4-dimethylnaphthalene, whereas M21 is also present in potato tubers at levels similar to the parent, it is however concluded that this study is sufficient to address the metabolism in ruminants since M21 is the precursor of the metabolite M23, which was found as a major component in goat tissues.

Figure 1: Proposed metabolic pathway of 1,4-dimethylnaphthalene in lactating goat



Laying hen

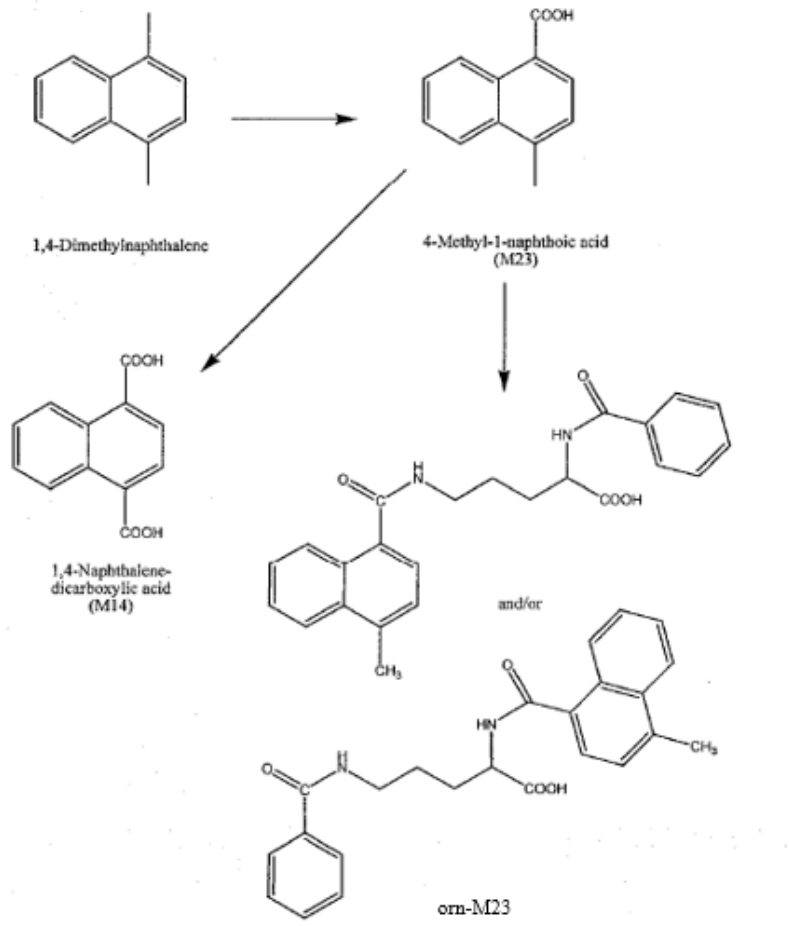
A metabolism study with laying hens was performed with 14C-labelled 1,4-DMN. The compound was administered orally once daily after the morning collection of eggs and excreta for 7 consecutive days to 10 laying hens at 10 ppm (0.82 mg/kg bw day). Eggs were collected twice daily, while excreta samples were collected once a day. Samples of breast muscle, thigh muscle, abdominal and subcutaneous fat and liver were collected after sacrifice, which occurred 6 hours after the last dose.

The majority of the administered dose was eliminated in the excreta, accounting for 99.3 %AD. A plateau was reached in egg whites after day one with residues ranging from 0.015 – 0.021 mg/kg throughout the study. Residues in egg yolks were higher compared with egg whites (0.153-0.187 mg/kg vs. 0.015–0.021 mg/kg) at Day 5 and Day 6 of the study. Whole egg TRR values were calculated from the weighted averages of yolk and white values with a calculated highest TRR at ~ 0.07 mg/kg.

In muscle tissue, residue levels accounted for 0.038 mg/kg (breast) and 0.092 mg/kg (thigh). Residues in the fat fractions were higher (0.495–0.520 mg/kg) and attributed to lipophilicity of 1,4-DMN, which was the only identified and predominant compound in fat. Residues in liver samples accounted for 0.178 mg/kg, with the liver containing 0.06% of the administered dose. In all tissue samples residues > 0.01 mg/kg were determined.

Parent 1,4-DMN was detected as a major residue in whole egg, egg yolk, fat (subcutaneous and abdominal) and thigh muscle (29–94% TRR). In addition, 1,4-DMN was detected as a minor residue in poultry breast muscle and liver (up to 7.9% TRR). The metabolic pathway of 1,4-DMN in poultry proceeds via oxidation of one methyl group to a carboxylic acid, resulting in 4-methyl-1-naphthoic acid (M23). This compound constituted 53.9% of the TRR in liver (present at 0.110 mg/kg) and was also found in egg (0.017 mg/kg, 26.2% TRR) and muscle (0.018- 0.024 mg/kg). M23 was not detected in fat. An N-benzoyl ornithine conjugate of 4-methyl-1-naphthoic acid (orn-M23) was detected in egg (0.008 mg/kg, 12.3% TRR) and liver samples (0.013 mg/kg, 6.4% TRR). orn-M23 was not detected in fat or muscle tissue. Small amounts of 1,4-naphthalenedicarboxylic acid (M14) were observed in muscle and liver samples, which is formed by the oxidation of both methyl groups to carboxylic acids.

Figure 2: Proposed metabolic pathway of 1,4-dimethylnaphthalene in laying hen



Plant metabolism

A metabolism study in post-harvest potato (Solanum tuberosum, variety Russet Burbank) was conducted with 1,4-DMN labelled with ^{14}C.

In plant metabolism studies conducted on potatoes and from a processing study with potatoes using radiolabelled 1,4-DMN, the predominant residue was parent 1,4-DMN, accounting for 27–97 percent TRR in whole potatoes.

Metabolite M21 was identified at major proportions in all potato matrices from 30 days after treatment (DAT) accounting for 41-65% TRR.

Metabolite M23 was identified in metabolism studies with potatoes as a minor metabolite (<10 percent TRR), at levels approximately 50 times lower than the parent. The metabolite was detected frequently in potatoes from supervised trials, but always about one order in magnitude lower, compared to parent.

Analytical methods and storage stability

A number of suitable analytical methods and validations for the analysis of 1,4-DMN and its metabolites in animal and plant matrices were submitted. The performance of the methods were verified by concurrent recoveries, which were generally within the boundaries of 70-110%.

Animal commodities

In the dairy cattle feeding study: Samples were analysed using method 1 for animal matrices with an LOQ of 0.01 mg/kg for 1,4-DMN, M23 (except liver) and Gly-M23, 0.04 mg/kg for M23 in liver and 0.06 mg/kg for M21. Procedural recoveries for all matrices and analytes ranged mostly between 70-120% with a few samples outside of this range (low as 62% and high as 146%). However, recoveries for M23 in fat where with few exception recoveries <70%.

In the laying hen feeding study: Samples were analysed using method 1 and 3 for animal matrices with an LOQ of 0.01 mg/kg for 1,4-DMN, M23 and Orn-M23, and 0.06 mg/kg for M21. Egg yolk samples were analysed for Orn-M23 using method 2 with an LOQ of 0.01 mg/kg. Procedural recoveries for all matrices and analytes ranged mostly between 70-120% with a few samples below this range (low as 63%).

Plant commodities

Potato – residue decline study (2014)

Residues of 1,4-DMN and metabolites M21 and M23 in peel and pulp were determined using the (unbuffered) QuEChERS method and HPLC-FD with a validated limit of quantification in peel and pulp of 0.05 mg/kg for all analytes, except 1,4-DMN in 0.94 mg/kg in peel. Procedural recoveries: 1,4-DMN: 94-108% at 0.074-47 mg/kg (n=18), M21: 93-137% at 0.096-4.8 mg/kg (n=18), M23: 99-113% at 0.095-4.7 mg/kg (n=16).

Potato – residue decline study (2016)

For plant matrices, a multi-residue modified method QuEChERS was used. The method was validated (method validation study – S15-06158). In potato and its processed commodities, residues of 1,4-DMN and M21 were analysed using GC-MSD, and residues of M23 were analysed using LC-MS/MS. The limit of quantification of the analytical method was 0.05 mg/kg for each analyte and each matrix with a limit of detection set at 0.015 mg/kg.

Procedural recoveries 1,4-DMN and its metabolites M21 and M23 in the RAC and all processed commodities fortified at 0.05–50 mg/kg ranged between 71-111%.

Processing study (2012)

Raw and processed samples were homogenized in a blender and residues of 1,4-DMN and metabolite M21 were determined using the QuEChERS method with GC-MS detection and a validated LOQ of 0.07 mg/kg for fried potatoes and 0.03 mg/kg for all other matrices.

Procedural recoveries (n=32) for both analytes in the RAC and all processed commodities fortified at 0.03-10 mg/kg ranged between 78-110%.

Potato and processed commodities (2022)

Residues were determined using the QuEChERS method with GC-MS detection for 1,4-DMN and LC-MS/MS detection for metabolite M21 and M23. The validated LOQ for all analytes and matrices was equal to 0.05 mg/kg.

Procedural recoveries (n=182) for all analytes in processed commodities fortified at 0.05-25 mg/kg ranged between 63-128%.

Potato processing study (2022)

Residues were determined using the QuEChERS method with GC-MS detection for 1,4-DMN and LC-MS/MS detection for metabolite M21 and M23. The validated LOQ for all analytes and matrices was equal to 0.05 mg/kg.

Procedural recoveries (n=64) for all analytes in potato (RAC), water starch and oil fortified at 0.05-60 mg/kg ranged between 66-114%.

Stability of residues in stored analytical samples

In the residue trials submitted, all samples were maintained under freezer conditions, (i.e.–18 °C) prior to analysis and tested within 7 months of collection.

Residues of 1,4-DMN were demonstrated to be stable during frozen storage in potato tubers and processed commodity samples, including potato starch and frying oil, stored at ≤ –18 °C, up to ~13 months (400 days) which is considered acceptable.

For animal matrices, the Meeting received information on the storage stability of 1,4-DMN as well as its metabolites M21, M23 and Gly-M23 in ruminant matrices and of 1,4-DMN as well as its metabolites M21, M23 and Orn-M23 in poultry matrices stored at -20 °C.

Analytes in ruminant matrices were stable for at least 27–29 days (~1 month) in milk (whole milk, skim milk, and cream), egg white, egg yolk, liver, kidney and fat. In muscle, analytes were stable for at least 56 days (~2 months) and in whole eggs for at least 49 days (~1.5 months).

All samples from feeding studies were analysed within the tested storage stability time. This is acceptable for the purposes of the current application.

Residue definition

Toxicological evaluation of 1,4-DMN by the APVMA's Health Assessment Team (HAT) identified that the major metabolites identified in rat metabolism study were 1-hydroxymethyl-4- methylnaphthalene (M21) and 4-methyl-1-naphthoic acid (M23). The APVMA health evaluation concluded that these metabolites contribute substantially to the toxicological profile of 1,4-DMN. It was considered that the toxicity profile of metabolites is not greater than the parent compound, 1,4-DMN.

Animal commodities

In animal metabolism studies performed with laying hens, parent 1,4-DMN was detected as a major residue in whole egg, egg yolk, fat (subcutaneous and abdominal) and thigh muscle (29–94% TRR). In the poultry metabolism, M23 was the major identified metabolite in egg matrices, muscle and liver, accounting for 13–71 percent TRR, while in the ruminant metabolism M23 was not detected except in kidney at 1.3 percent TRR.

In the ruminant metabolism, Gly-M23 was the major identified metabolite in milk and kidney, accounting for 17–18 percent TRR, while in the poultry metabolism Gly-M23 was not detected. In a ruminant feeding study, residues of Gly-M23 were detected above LOQ at the relevant feeding levels in whole milk (up to 0.027 mg/kg), in liver (up to 0. 019 mg/kg), in kidney (up to 0.1 mg/kg) and in fat (up to 0.013 mg/kg).

In muscle and fat tissues of all animals investigated, residue concentrations of the sum of 1,4-DMN and metabolite M23 were ~5–26 times higher in fat compared to muscle. Similarly, levels in egg yolk compared to egg white were ~2–7 times higher.

Metabolite Orn-M23 occurred only in a poultry metabolism study (egg yolk at 16% TRR, whole egg 12% TRR and liver 6.4% TRR), at similar or lower proportions as 1,4-DMN and M23. Therefore, Orn-M23 is covered by the toxicological reference value of the parent and does not significantly contribute to the dietary exposure.

It is concluded that for dietary exposure purposes for animal commodities, based on the results of the animal metabolism and feeding studies, parent 1,4-DMN as well as metabolites M23 and Gly-M23 be included in the residue definition for animal matrices.

Definition of the residue for compliance with the MRL for animal commodities, except milk:

sum of 1,4-dimethylnaphthalene and metabolite 4-methyl-1-naphthoic acid (M23), expressed as 1,4-dimethylnaphthalene.

Definition of the residue for compliance with the MRL for milk:

glycine conjugate of 4-methyl-1-naphthoic acid (Gly-M23)

Definition of the residue for dietary risk assessment for animal commodities:

sum of 1,4-dimethylnaphthalene, metabolite 4-methyl-1-naphthoic acid (M23), and its glycine conjugate 4-methyl-1-naphthoic acid (Gly-M23) expressed as 1,4-dimethylnaphthalene.

Plant commodities

In plant metabolism studies conducted on potatoes and from a processing study with potatoes using radiolabelled 1,4-DMN, the predominant residue was parent 1,4-DMN, accounting for 27–97 percent TRR in whole potatoes.

Metabolite M21 was identified at major proportions in all potato matrices from 30 days after treatment (DAT) accounting for 41-65% TRR.

Metabolite M23 was identified in metabolism studies with potatoes as a minor metabolite (<10 percent TRR), at levels approximately 50 times lower than the parent. The metabolite was detected frequently in potatoes from supervised trials, but always about one order in magnitude lower, compared to parent.

The ADI established by the APVMA applies to the major metabolites, 1-hydroxymethyl-4- methylnaphthalene (M21) and 4-methyl-1-naphthoic acid (M23). However, M23 contributes insignificantly to the dietary exposure and does not need to be included into the residue definition for plant commodities. M21 however, adds significantly to the dietary exposure and should be included into the residue definition for risk assessment.

The residue definition of 1,4-dimethylnaphthalene for MRL enforcement for plant commodities is recommended as:

Definition of the residue for plant commodities for MRL enforcement: 1,4-dimethylnaphthalene

Definition of the residue for dietary risk assessment for plant commodities: sum of 1,4-dimethylnaphthalene and metabolite 1-hydroxymethyl-4-methylnaphthalene (M21), expressed as 1,4-dimethylnaphthalene.

Residues in food and animal feeds

Stored potato – MRL risk assessment

In 2015 residue decline EU trials, parent 1,4-DMN residues in whole potatoes following 6 applications at ~1× the maximum proposed rate, applied at 28-35 days re-treatment interval at 2 – 15 days after the last application, in rank order, were: 4.0, 4.3, 5.6, 5.9, 6.3, 7.8, 8.0, 8.2, 8.4 and 8.7 mg/kg (n=10).

In two residue decline studies conducted in the Netherlands in 2011, parent 1,4-DMN residues in whole potatoes following 6 applications at 19.93 g ai/1000 kg (~1× the proposed rate), applied at 28-29 days interval and 3 days after last application, in rank order, were: 9.6 and 10.9 mg/kg (n=2).

The combined dataset suitable for MRL estimation is, in rank order, 4.0, 4.3, 5.6, 5.9, 6.3, 7.8, 8.0, 8.2, 8.4, 8.7, 9.6 and 10.9 mg/kg (n=12). The STMR was 7.9 mg/kg. The OECD MRL calculator estimates an MRL of 30 mg/kg. (Unrounded MRL = 21.9 mg/kg).

Based on the available information, a 1,4-dimethylnaphthalene MRL of 20 mg/kg for [VR 0589] Potato is recommended to cover 1,4-DMN residues arising in stored potatoes as a result of the proposed use.

Stored potato - dietary exposure risk assessment

In the 2015 EU trials, total 1,4-DMN (sum of parent 1,4-DMN and metabolite 21) residues following 6 applications at ~1× the proposed rate, applied at 28-35 days re-treatment intervals at 2-30 days after the last application, in rank order, were:

Whole potatoes: 5.82, 6.75, 8.94, 9.62, 10.61, 10.66, 11.85, 12.74, 13.95 and 17.29 mg/kg (n=10).

Potato peel: 23.81, 26.27, 29.17, 36.99, 36.71, 37.72, 53.62, 54.62, 54.79 and 55.8 mg/kg (n=10).

Potato pulp: 1.41, 1.81, 1.87, 1.88, 2.06, 2.21, 2.40, 2.63, 3.42 and 3.74 mg/kg (n=10).

In the 2011 trials, total 1,4-DMN residues following 6 applications at 1× the proposed rate, applied at 28-29 days interval and 3 days after last application, in rank order, were:

Whole potatoes: 11.4 and 14.2 mg/kg (n=2).

Potato peel: 70.5 and 95.7 mg/kg (n=2).

Potato pulp: 2.46 and 4.46 mg/kg (n=2).

The combined dataset for whole potatoes, in rank order, is: 5.82, 6.75, 8.94, 9.62, 10.61, 10.66, 11.4, 11.85, 12.74, 13.95, 14.2 and 17.29 mg/kg (n=12). STMR = 11.03 mg/kg.

The combined dataset for potato peel, in rank order, is: 23.81, 26.27, 29.17, 36.99, 36.71, 37.72, 53.62, 54.62, 54.79, 55.8, 70.5 and 95.7 mg/kg (n=12). STMR = 45.67 mg/kg.

The combined dataset for potato pulp, in rank order, is: 1.41, 1.81, 1.87, 1.88, 2.06, 2.21, 2.40, 2.46 2.63, 3.42, 3.74 and 4.46 mg/kg (n=12). STMR = 2.30 mg/kg.

Processing studies

The submitted processing studies showed that total 1,4-DMN (parent 1,4-DMN or the metabolite M21) residues didn't concentrate in peeled or unpeeled baked, boiled, microwaved, fried or canned potatoes.

A median processing factor for total 1,4-DMN in dry pulp was calculated at 3.2× the total 1,4-DMN residues in RAC. Taking the HR of 17.29 mg/kg (STMR = 11.03 mg/kg) in whole potatoes and processing factor of 3.2×, the estimated total residues of 1,4-DMN in dried pulp equates to 55.33 mg/kg (STMR-P = 35.30 mg/kg).

Total 1,4-DMN (parent 1,4-DMN or the metabolite M21) residues didn't concentrate in potato process waste (median Pf = 0.28×). HR-P is estimated at 4.84 m/kg and STMR-P is estimated at 3.09 mg/kg.

Residues in animal commodities

Animal commodities and MRLs

According to the OECD feed calculator, potato culls and dried potato pulp may be fed to beef and dairy cattle at up to 10% and 5% in Australia. Potato process waste may be fed to beef cattle at up to 5% of the diet.

The estimated maximum dietary burden for beef and dairy cattle as a result of the proposed use in stored potatoes is calculated at 10.7 mg/kg.

Note: The total residue of parent + M21 has been used to calculate the livestock dietary burden. While M21 is not in the residue definition for 1,4-DMN in animal commodities it is a likely intermediate in the formation of M23 and Gly-M23 which are in the animal commodity definitions.

Mammalian commodity MRLs are estimated below based on extrapolation from a submitted dairy cattle animal transfer study:

Cattle

Feeding level (ppm)	Milk	Muscle	Liver	Kidney	Fat
	(Gly-M23)	(MRL enforcement: Sum of 1,4-DMN and metabolite M23) 1,4-DMN residue (mg/kg)			
38.7 (actual)	0.027	<0.02	0.378	0.216	0.024
10.7 – beef, estimated burden	-	<0.02	0.105	0.06	0.007
10.7 – dairy, estimated burden	0.007	-	-	-	-
Recommended MRLs	*0.02	*0.02	0.2		*0.02

It is recommended that the following 1,4-DMN MRLs for animal commodities be established in the MRL Standard.

Edible offal (mammalian)	0.2 mg/kg
Meat (mammalian) [in the fat]	*0.02 mg/kg
Milks	*0.02 mg/kg

Poultry livestock burden

Potato or potato processed products are not fed to poultry in Australia. Therefore, 1,4-DMN residues are not expected in poultry commodities as a result of the proposed use in stored potatoes.

It is recommended to establish the following poultry MRLs in the MRL Standard.

Eggs	*0.02 mg/kg
Poultry meat [in the fat]	*0.02 mg/kg
Poultry, edible offal of	*0.05 mg/kg

Dietary risk assessment

The chronic dietary exposure to 1,4-dimethylnaphthalene is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the chemical and the mean daily dietary consumption data derived primarily from the 2011-12 National Nutritional and Physical Activity Survey. The NEDI calculation is made in accordance with WHO Guidelines and is a conservative estimate of dietary exposure to chemical residues in food.

The NEDI for 1,4-dimethylnaphthalene is <15% of the ADI. It is concluded that the chronic dietary exposure to 1,4-dimethylnaphthalene is acceptable.

The acute dietary exposure is estimated by the National Estimated Short-Term Intake (NESTI) calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR with 97.5th percentile food consumption data derived primarily from the 2011-12 National Nutritional and Physical Activity Survey. NESTI calculations are conservative estimates of short-term exposure (24-hour period) to chemical residues in food.

An ARfD was considered unnecessary by the APVMA and the JMPR. Therefore, acute dietary exposure assessment is not required.

Recommendations

The following amendments are required to be made to the APVMA MRL Standard (Table 5).

Table 5: Amendments to the APVMA MRL Standard

Amendments to Table 1		
Compound	**Food**	**MRL (mg/kg)**
Add:		
1,4-dimethylnaphthalene		
MO 0105	Edible offal (mammalian)	0.2
PE 0112	Eggs	*0.02
MM 0095	Meat (mammalian) [in the fat]	*0.02
ML 0106	Milks	*0.02
VR 0589	Potato	20
PM 0110	Poultry meat [in the fat]	*0.02
PO 0111	Poultry, edible offal of	*0.05

Amendments to Table 3	
Compound	**Residue**
Add:	
1,4-dimethylnaphthalene	Commodities of plant origin for MRL enforcement: 1,4-dimethylnaphthalene. Commodities of plant origin for dietary exposure: sum of 1,4-dimethylnaphthalene and metabolite 1-hydroxymethyl-4-methylnaphthalene (M21), expressed as 1,4-dimethylnaphthalene. Commodities of animal origin, except milk: sum of 1,4-dimethylnaphthalene and metabolite 4-methyl-1-naphthoic acid (M23), expressed as 1,4-dimethylnaphthalene. Milk: glycine conjugate of 4-methyl-1-naphthoic acid (Gly-M23). Commodities of animal origin for dietary exposure: sum of 1,4-dimethylnaphthalene, metabolite 4-methyl-1-naphthoic acid (M23), and its glycine conjugate 4-methyl-1-naphthoic acid (Gly-M23) expressed as 1,4-dimethylnaphthalene.

Assessment of overseas trade aspects of residues in food

Commodities exported and main destinations

Potatoes are not considered a major export commodity. However, commodities of animal origin, such as meat, offal and dairy products are considered major export commodity, which may be derived from livestock fed feeds produced from treated potatoes. Residues in these commodities resulting from the use of 1,4SIGHT Potato Dormancy Enhancer may have the potential to unduly prejudice trade.

Overseas registrations and approved label instructions

The applicant indicated that 1,4-dimethylnaphthalene is exempt from the requirement of tolerance for residues on potatoes, root and tuber crops when treated post-harvest in the United States of America and that an MRL of 15 mg/kg (now 20 mg/kg) is set for 1,4-DMN on potatoes in the EU in conjunction with a 30 days interval between application and storage unloading.

Comparison of Australian MRLs with Codex and international MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. CXLs are primarily intended to facilitate international trade and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. 1,4-DMN has been considered by Codex. The following relevant Codex CXLs and international MRLs have been established for 1,4-DMN.

Table 6: Proposed Australian and current international MRLs for 1,4-dimethylnaphthalene

Commodity	Tolerance for residues arising from the use of chlorantraniliprole (mg/kg)							
	Australia (PROPOSED)	Codex[1]	EU[2]	China[3]	Japan[4]	South Korea[5]	Taiwan[6]	USA[7]
Residue Definition	For compliance with the MRL for plant commodities: 1,4-DMN For dietary risk assessment for plant commodities: Sum of 1,4-DMN and its metabolite M21, expressed as 1,4-DMN For compliance with the MRL for animal commodities, except milk: Sum of 1,4-DMN and its metabolite M23, expressed as 1,4-DMN For compliance with the MRL for milk: metabolite M02.	For compliance with the MRL for plant commodities: 1,4-DMN For dietary risk assessment for plant commodities: Sum of 1,4-DMN and its metabolite M21, expressed as 1,4-DMN For compliance with the MRL for animal commodities, except milk: Sum of 1,4-DMN and its metabolite M23, expressed as 1,4-DMN For compliance with the MRL for milk: metabolite M02.	Sum of 1,4-DMN and its metabolite M23 free and conjugated, expressed as 1,4-DMN	-	1,4-DMN	-	-	An exemption from the requirement of a tolerance is established for the residues of the plant growth regulator, 1,4-dimethylnaphthalene (1,4-DMN), when applied postharvest to all sprouting root, tuber, and bulb crops in accordance with good agricultural practices.

[1] Food and Agriculture Organisation of the United Nations, Codex Alimentarius - International Food Standards, accessed July 2025.
[2] European Commission Pesticide residue(s) and maximum residue levels (mg/kg), accessed May 2025
[3] USDA - National Food Safety Standard for MRL – 03-27-2023, accessed August 2025
[4] The Japan Food Chemical Research Foundation, Maximum Residue Limits (MRLs) List of Agricultural Chemicals in Foods, The Japan Food Chemical Research Foundation website, accessed May 2025
[5] Ministry of Food and Drug Safety Korea, MRLs in Pesticides, accessed August 2025
[6] Laws & Regulations Database of the Republic of China (Taiwan), Standards for Pesticide Residue Limits in Foods, accessed August 2025
[7] Code of Federal Regulations (eCFR)- USA National Archives accessed July 2025

Commodity	Tolerance for residues arising from the use of chlorantraniliprole (mg/kg)							
	Australia (PROPOSED)	Codex[1]	EU[2]	China[3]	Japan[4]	South Korea[5]	Taiwan[6]	USA[7]
	For dietary risk assessment for animal commodities: Sum of 1,4-DMN and its metabolites M23 and M02, expressed as 1,4-DMN	For dietary risk assessment for animal commodities: Sum of 1,4-DMN and its metabolites M23 and M02, expressed as 1,4-DMN						
Edible offal (mammalian)	0.2	0.5	2 (bovine liver and kidney) 3 (sheep/goat liver and kidney) 1.5 (swine liver and kidney)	-	-	-	-	-
Eggs	*0.02	0.03	0.4					
Meat (mammalian) [in the fat]	*0.02	0.03 (fat)	0.03 (bovine, sheep and goat) 0.03 (swine)	-	-	-	-	-
Mammalian fats	-	0.03 (mammalian fats except milk fats)	0.5 (bovine) 0.6 (sheep/goat) 0.3 (swine)		-	-	-	-
Milks	*0.02	0.03	0.3 (cattle) 0.3 (sheep/goat)	-	-	-	-	-

Commodity	Tolerance for residues arising from the use of chlorantraniliprole (mg/kg)							
	Australia (PROPOSED)	Codex[1]	EU[2]	China[3]	Japan[4]	South Korea[5]	Taiwan[6]	USA[7]
Poultry meat [in the fat]	*0.02	0.3 (fat)	0.3 (meat)	-	-	-	-	-
Poultry, edible offal of	*0.05	0.2	1.5	-	-	-	-	-
Poultry fat	-	0.3	1.5	-	-	-	-	-

Potential risk to trade

Export of treated produce containing finite (measurable) residues of 1,4-DMN may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

The proposed residue definition for 1,4-DMN for animal commodities, except milk is the same as established by Codex and includes sum of 1,4-DMN and its metabolite M23. The residue definition for milk established by the Codex and proposed here for Australia is the glycine conjugate of the metabolite Gly-M23 (= M02) only. The EU residue definition for 1,4-DMN is parent plus free (M23) and conjugate metabolite Gly-M23 (= M02).

The US has established an exemption from the requirement of a tolerance for the residues of 1,4-DMN when applied postharvest to all sprouting root, tuber, and bulb crops. Japan has established an MRL of 15 mg/kg for 1,4-DMN on potatoes with a residue definition of parent 1,4-DMN. The other international markets, for e.g., China, Korea and Taiwan have not considered 1,4-DMN for residue definition or maximum residue limits.

Detectable residues are not expected to occur in poultry so the risk to trade in commodities from poultry is low.

The proposed mammalian offal MRL at 0.2 mg/kg is lower than the MRLs established by the Codex and the EU. Finite residues are not expected to occur in milk, mammalian muscle and fats. The Codex and the EU have established animal commodity MRLs at finite levels, higher than the proposed MRLs. Therefore, the risk to trade in mammalian commodities is low.

In a lactating cow study, following a 7-day depuration period after feeding at 624 ppm, no quantifiable residues were observed in animal tissues, except in kidney (M23 residues at 0.0133 mg/kg) which is slightly above the LOQ of 0.01 mg/kg. Noting that the feeding level at 624 ppm was significantly higher than the estimated maximum dietary burden of 10.7 ppm, finite residues in livestock tissues are not expected, as a result of the proposed use, following a 7-day depuration. For the livestock destined for export markets that do not have established animal commodity MRLs or default to 0.01 mg/kg in the absence of an MRL, a 7-day export slaughter interval is considered appropriate to mitigate the trade risk in animal commodities.

It is recommended to add the following Export Slaughter Interval Statement on the proposed label.

LIVESTOCK DESTINED FOR EXPORT MARKETS

The withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the withholding period, the export slaughter interval is observed before stock are sold or slaughtered.

Recommendations

Comment is sought on the potential for the proposed uses to prejudice Australian trade.

Work health and safety assessment

Health hazards

1,4SIGHT Potato Dormancy Enhancer was of low acute toxicity by oral, dermal and inhalation route in rats. 1,4SIGHT Potato Dormancy Enhancer was moderate eye irritant and moderate skin irritant in rabbits. It was not a skin sensitiser in guinea pigs and mouse LLNA.

Occupational exposure

Exposure during use

1,4-SIGHT Potato Dormancy Enhancer containing 980 g/L 1,4-DMN in a liquid (LD) formulation, is intended for use to enhance dormancy of potatoes in storage and prevent them from sprouting. 1,4SIGHT Potato Dormancy Enhancer is intended for professional use and will be applied via specialist thermal fogging equipment to stored potatoes that will be processed commercially. The product will be applied within enclosed areas and never field applied. 1,4SIGHT Potato Dormancy Enhancer is to be applied at a rate of 20 mL/1000 kg of stored potatoes, with a maximum of 6 applications at intervals of 4-6 weeks.

1,4SIGHT Potato Dormancy Enhancer will be applied automatically using specialist thermal fogging equipment therefore, no mixing and loading is required. The fogger is outside the shed, and the product is fogged into the airtight/sealed shed through a hole in either the door or the wall of the storage where the fog is introduced into the air circulation equipment of the storage building. Users/ applicators will remain outside of sealed shed/storage room during automated product application and are not allowed to enter the shed while potatoes are treated with 1,4SIGHT Potato Dormancy Enhancer. Based on the product use pattern (automated application system), user /applicator exposure to the product is expected to be minimal.

1,4-DMN is a plant growth regulator preventing sprouting of potato tubers. 1,4-DMN occurs naturally in different plant species (for example potato, rhubarb, poppy). The acute toxicity database on 1,4-DMN indicates that it has low toxic potential by the oral, dermal, and inhalational route. 1,4-DMN was a moderate eye irritant and moderate skin irritant and not a skin sensitiser. There is no evidence that 1,4-DMN is a reproductive or developmental toxicant, or is neurotoxic, immunotoxic, mutagenic and carcinogenic. Taking into consideration all available information, a quantitative risk assessment for 1,4-DMN is considered not necessary to manage the limited risk resulting from repeated systemic exposure while using the product. The main risk from using 1,4SIGHT Potato Dormancy Enhancer will be associated with its acute hazards and will be adequately mitigated by displaying the corresponding hazards, precautions, and PPE on the product label.

Exposure during re-entry or rehandling

Workers performing post application activities (e.g., clean up, maintenance and repair) in treated sheds prior to ventilation or prior to settling of aerosol fog may be exposed to the 1,4-DMN via dermal and inhalation routes. However, a re-entry into the potato storage immediately after application is not allowed and is not necessary as the application process is run entirely from the outside of the storage building. The building is completely sealed off and remains closed for 24-48 hours after treatment. Thereafter, the store is only entered after at least half an hour of ventilation with outside air. Worker exposure and risks during re-entry activities are considered negligible and can be adequately managed by displaying appropriate re-entry statements on the product label.

Public exposure

The product is intended for professional use and is not expected to be handled by members of the public.

Recommendations

The following first aid instructions, safety directions and precautionary (warning) statements are recommended for the product label.

First aid instructions

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766.

Safety directions

Will irritate the eyes and skin. Do not inhale vapour. Avoid contact with eyes and skin. When opening the container and using the product, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves and face shield or goggles. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use, wash gloves, face shield or goggles, and contaminated clothing.

Precautionary (warning) statements

Not required.

Restraints/Restrictions

DO NOT treat wet, damaged, or rotting potatoes.

DO NOT use on or near seed potatoes within 30 days of seed planting.

DO NOT apply to field potatoes.

DO NOT allow spray to directly contact potatoes.

Re-entry or Re-handling Statement

DO NOT enter storage areas during application or treatment (prior to ventilation) unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) goggles, respirator and chemical resistant gloves and footwear. Clothing must be laundered after each day's use.

After the treatment period, allow the storage area to ventilate for at least 30 minutes.

DO NOT allow workers to enter for normal activities until ventilation is complete.

Environmental assessment

Environmental fate and hazard was based on study summaries from overseas assessment reports (EFSA) supplemented by evaluation of additional studies.

Fate and behaviour in the environment

1,4-DMN is moderately volatile and rapidly volatilises from soil and aquatic systems. It reacts rapidly with hydroxyl radicals in the air (DT_{50} 2.2 h) and therefore is not subject to long-range transport.

Effects and associated risks to non-target species

1,4-DMN has low toxicity to mammals (LD_{50} 2730 mg ac/kg bw, *Rattus norvegicus*) and birds (LD_{50} >2000 mg ac/kg bw, *Colinus virginianus*). In a developmental toxicity study in mammals, decreased body weight gain and food consumption was observed at doses as low as 250 mg ac/kg bw/d (NOAEL 80 mg ac/kg bw/d, *Oryctolagus cuniculus*).

1,4-DMN has moderate toxicity to fish (lowest LC_{50} 0.67 mg ac/L, *Oncorhynchus mykiss*), aquatic invertebrates (EC_{50} 0.54 mg ac/L, *Daphnia magna*), algae (E_rC_{50} 0.62 mg ac/L, *Pseudokirchneriella subcapitata*), and aquatic plants (EC_{50} 1.1 mg ac/L, *Lemna gibba*). Following long-term exposure under flow-through conditions, reduced growth rate of juvenile fish was observed at concentrations as low as 0.21 mg ac/L (NOEC 0.090, *Oncorhynchus mykiss*) and reduced reproduction of aquatic invertebrates was observed at 0.34 mg ac/L (NOEC 0.16 mg ac/L, *Daphnia magna*).

1,4-DMN has low toxicity to bees by contact exposure (LD_{50} >100 µg ac/bee, *Apis mellifera*) and oral exposure (LD_{50} >87 µg ac/bee, *Apis mellifera*).

Upon ventilation after treatment, 1,4-DMN is not expected to be transported long distances through the air based on its predicted rapid reaction with hydroxyl radicals. Exposure of non-target species to 1,4-DMN is expected to be negligible. Therefore, risks to non-target species are acceptable and no protection measures are required.

Recommendations

Based on the LC/EC_{50} values <1 mg ac/L for aquatic species, a ‘very toxic to aquatic life’ statement on the label is advised to identify the hazard. However, no protection measures are required under the proposed conditions of use.

Efficacy and safety assessment

Proposed product use pattern

The proposed new product, 1,4SIGHT Potato Dormancy Enhancer, is a 980 g/kg liquid formulation of 1,4-dimethylnapthalene to enhance dormancy of potatoes in storage (NOT seed potatoes). The product will be applied mechanically via specialist thermal fogging equipment and is only intended for enclosed situations. The proposed product rate is 20 ppm as 20mL per 1000 kg.

Efficacy and target crop/animal safety

Efficacy and crop safety trials done overseas in the US, Germany and the UK were provided to support label claims as a plant growth regulator to enhance the dormancy of potatoes in storage, as well as two trial reports from Tasmania. Expert statement from Germany was also provided based on findings from various studies in Netherland, France and Belgium. One trial was done in Tasmania but was discontinued due to an infection of *Clostrdium*. Trials included untreated controls and compared to CIPC as a standard sprout inhibitor. Given the proposed product use is in an enclosed situation with same principles of storage environments, and the overseas trials adhered to the standardized protocol following appropriate principles of handling and storage of potato, overseas data are considered acceptable to support the efficacy of the product use in Australia.

In the trials, 1,4SIGHT Potato Dormancy Enhancer was applied according to the label recommendations under similar situation (storage condition). Application rates included label rate (20ppm), as well as rates lower and higher than label rate. The product was applied multiple times (4-6 applications) at intervals during the storage period.

Efficacy

The efficacy trials demonstrate sprout control to result in extended dormancy in several potato cultivars, with variety-dependent control level. The efficacy of 1,4-DMN was generally similar or often better to standard product CIPC in certain varieties studied. The observed efficacy is supportive of the proposed use of 1,4SIGHT Potato Dormancy Enhancer applied at the single rate of 20 mL/1000 kg with six applications during the storage period.

Crop safety

Trials demonstrated the safety of the product by measuring different variables when product applied at 20 ppm and above, with up to six applications (but not at 2x label rate). The trials from the UK show no deleterious effects from the use of 1,4-DMN were observed in relation to processing quality of chips and was similar to tubers treated with CIPC. The data from Germany demonstrated no adverse effect on tubers with no weight loss and fry quality with up to 5 applications of the product. The trials from USA observed no issues on processing quality from all treatments of 1,4-DMN.

Recommendations

Based on the trials and evidence provided, a label claim for plant growth regulator to enhance the dormancy of potatoes in storage when applied according to the label recommendations using the proposed new product is supported. The presented studies/trials also demonstrated tuber safety data of the recommended application rate of 1,4SIGHT Potato Dormancy Enhancer for single application, intervals of application and number of applications

Labelling requirements

CAUTION

KEEP OUT OR REACH OF CHILDREN

READ THE DIRECTIONS BEFORE OPENING OR USING

1,4 Sight Potato Dormancy Enhancer

ACTIVE CONSTITUENT: 980 g/kg 1,4-DIMETHYLNAPHTHALENE

To enhance dormancy and control sprouting of potatoes in storage as per the Directions for Use Table

Contents: 10L - 20L

DIRECTIONS FOR USE

RESTRAINTS
DO NOT treat wet, damaged or rotting potatoes.
DO NOT use on or near seed potatoes within 30 days of seed planting.
DO NOT apply to field potatoes.
DO NOT allow spray to directly contact potatoes

Crop	Rate	Critical Comments
Potatoes (post harvest use) NOT seed potatoes	20 mL per 1000 kg of stored potatoes	This product is applied via specialised hot or cold thermal fogging equipment. Apply any time after potatoes are placed into the storage area and are dry. Potatoes can be retreated as necessary for effective control but DO NOT exceed a maximum of 6 treatments at 4 to 6-week intervals. DO NOT exceed a total dose of 120 mL/1000 kg per season.

NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION

WITHHOLDING PERIOD – NOT REQUIRED WHEN USED AS DIRECTED

LIVESTOCK DESTINED FOR EXPORT MARKETS
The withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the withholding period, the export slaughter interval is observed before stock are sold or slaughtered.

EXPORT SLAUGHTER INTERVAL:
Livestock that has been fed treated potatoes should be placed on clean feed for 7 days prior to slaughter

GENERAL INSTRUCTIONS

1,4SIGHT® is applied via specialised fogging equipment to stored potatoes to enhance dormancy and prevent sprouting. For specific details about the application equipment please contact your distributor/supplier of 1,4SIGHT®.
Important Note: This sprout suppressant and dormancy enhancing product has not been tested on all potato cultivars grown in Australia.

Application Timing and Rates
Application:

1,4SIGHT® must ONLY be applied to stored ware potatoes or to stored potatoes that will be processed commercially.

1,4SIGHT® must ONLY be applied through hot or cold fogging equipment that permits accurate monitoring and control of the throughput during application.

Application Timing: Application of 1,4SIGHT® can be made any time after the potatoes are placed in the storage area and the potatoes have dried. Ideally, apply before signs of sprouting.
The treatment may be applied before, during, or after the wound healing period.
Application Rates: Apply at a rate of 20 mL per 1000 kg of stored potatoes, with a maximum of 6 applications and at intervals of 4-6 weeks.

Application Guidelines

Preparation of storage space and treatment
1. Potatoes intended for storage must be mature and free of disease.
2. Stores should be filled to designed capacity to ensure efficient use of product.
3. For improved efficacy and efficiency, potatoes should be dry (minimum surface moisture) and as free from soil as possible. This ensures optimal absorption of the active substance into the potato.
4. It is not necessary that the wound healing is finalised before treatment with 1,4SIGHT®.
5. Prior to application of 1,4SIGHT®, ensure store air, fridge (if fitted) and store fabrics are all about the same temperature. This will avoid 1,4SIGHT® from condensing in store, which may cause damage on potatoes and materials.
6. Ensure all doors, louvers and ducts are sealed prior to application to avoid leakage.
7. If appropriate, during application, use air recirculation within the store to aid distribution.
The most effective way of doing this is with adjustable fans to reduce the air speed.
8. Ensure 1,4SIGHT® is applied as a dry fog, to ensure vaporisation and distribution. This will reduce the risk of precipitation and fallout.
9. After application run store fans for 10-30 minutes to aid distribution of 1,4SIGHT®.
10. Store must remain closed for at least 24-48 hours after treatment. This ensures the maximum absorption of the vapour into the potatoes. Automated regular internal air circulation at reduced speed is helpful, without refrigeration for at least 24 hours.
11. Make sure that neither persons nor animals are in the room during treatment. Take every precaution necessary to prevent unauthorized entry of the store during the sealing period (24-48 hours) after treatment.

1,4SIGHT® has a melting point of 7 to 8°C. Store at 2- 8°C and transport above 8°C. Insulate 1,4SIGHT® container during transportation and use if required

Use of equipment

1. Check and maintain fogging equipment/nozzles at regular intervals. The application equipment must be free of residues from previous applications. Follow application equipment manufacturers' recommendations for cleaning.

2. Prepare and use thermal application equipment outside the store.

3. If possible, place output of the applicator directly into the store via the application port. When using a hose from applicator to store, keep the length to the minimum required and secure to avoid movement during the application. This is usually required nearest the fans but can vary depending on positioning of the application port and of the individual store.

Cross contamination
During application: 1,4SIGHT® is a volatile product. Avoid movement of atmosphere from treated stores to untreated stores used for seed potatoes, seeds, bulbs, or other crops which can lead to cross contamination.
After application: Cross contamination can also occur when untreated potatoes, seed potatoes, seeds, bulbs, or other crops are stored near potatoes, boxes or stores previously treated with 1,4SIGHT®.

PRECAUTION
Re-entry Period
DO NOT enter storage areas during application or treatment (prior to ventilation) unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) goggles, respirator and chemical resistant gloves and footwear. Clothing must be laundered after each day's use.
After the treatment period, allow the storage area to ventilate for at least 30 minutes with outside air.
DO NOT allow workers to enter for normal activities until ventilation is complete.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT
Very toxic to aquatic life. DO NOT contaminate streams, rivers or watercourses with the chemical or used containers.

STORAGE AND DISPOSAL
Store in the closed, original container in a cool well-ventilated area. Do not store for prolonged periods in direct sunlight. Triple-rinse containers before disposal. Dispose of rinsate according to state/territory legislative requirements. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, dispose of empty container or unused product in compliance with relevant local, state or territory government regulations. DO NOT burn empty containers or product.

SAFETY DIRECTIONS

Will irritate the eyes and skin. Do not inhale vapour. Avoid contact with eyes and skin. When opening the container and using the product, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves and face shield or goggles. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use, wash gloves, face shield or goggles, and contaminated clothing.

FIRST AID
If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 13 11 26 New Zealand 0800 764 766.

Acronyms and abbreviations

Shortened term	Full term
ACCS/ACMS	Advisory Committee for Chemicals Scheduling/Advisory Committee for Medicines Scheduling
ADI	Acceptable daily intake (for humans)
ARfD	Acute reference dose
bw	Bodyweight
d	Day
DT_{50}	Time taken for 50% of the concentration to dissipate
EA	Environment Australia
EC_{50}	Concentration at which 50% of the test population are immobilised
E_rC_{50}	Concentration at which the rate of growth of 50% of the test population is impacted
ESI	Export slaughter interval
g	Gram
GAP	Good Agricultural Practice
HPLC	High pressure liquid chromatography *or* high performance liquid chromatography
in vitro	Outside the living body and in an artificial environment
in vivo	Inside the living body of a plant or animal
kg	Kilogram
L	Litre
LC_{50}	Concentration that kills 50% of the test population of organisms
LD_{50}	Dosage of chemical that kills 50% of the test population of organisms
Log K_{OW}	Log to base 10 of octanol water partitioning co-efficient, synonym P_{OW}
LOQ	Limit of quantitation – level at which residues can be quantified
mg	Milligram
mL	Millilitre
MRL	Maximum Residue Limit
NEDI	National Estimated Daily Intake

Shortened term	Full term
NESTI	National Estimated Short-Term Intake
ng	Nanogram
NOEC/NOEL	No observable effect concentration level
NOAEL	No observed adverse effect level
OC	Organic carbon
OM	Organic matter
po	Oral
PPE	Personal protective equipment
ppm	Parts per million
RAL	Regulatory Acceptable Level
s	Second
sc	Subcutaneous
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
µg	Microgram
WHP	Withholding period

Glossary

Term	Description
Active constituent	The substance that is primarily responsible for the effect produced by a chemical product
Acute	Having rapid onset and of short duration
Carcinogenicity	The ability to cause cancer
Chronic	Of long duration
Efficacy	Production of the desired effect
Formulation	A combination of both active and inactive constituents to form the end use product
Genotoxicity	The ability to damage genetic material
Metabolism	The chemical processes that maintain living organisms
Subcutaneous	Under the skin
Toxicology	The study of the nature and effects of poisons