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The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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General information

The APVMA Gazette is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

Distribution and subscription

The APVMA Gazette is published in electronic format only and is available from the APVMA website.

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For information on how the APVMA manages personal information when you contact us, see our Privacy Policy.

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Notice of cancellation under section 45A(1)(b) of the Agricultural and Veterinary Chemicals Code – chlorthal dimethyl chemical product registrations

1) I, Sheila Logan, Executive Director, Risk Assessment Capability, pursuant to section 45A(1)(b) of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), hereby publish notice that on 9 October 2024 I cancelled the chlorthal dimethyl chemical product registrations listed in Table 1 of this notice.

2) I, Sheila Logan, Executive Director, Risk Assessment Capability, have cancelled the chemical product registrations listed in Table 1 pursuant to section 35A of the Agvet Code, as I considered it necessary to prevent imminent risk to persons of serious injury or serious illness.

3) A brief statement of reasons for the decision is included in Attachment A of this notice. The statement of reasons forms part of this notice of cancellation and sets out brief reasons for the cancellation of the chlorthal dimethyl chemical product registrations listed in Table 1 under section 35A of the Agvet Code.

Table 1: Chlorthal dimethyl product registrations cancelled pursuant to section s35A of the Agvet Code

Registration number	Name	Holder	Date of cancellation
59137	Nufarm Chlorthal-Dimethyl 900 Herbicide	Nufarm Australia Limited	9 October 2024
65212	Imtrade Pterodactyl 900 WG Pre-Emergence Herbicide	Imtrade Australia Pty Ltd	9 October 2024
67445	KDPC Prethal 750WG Herbicide	KD Plant Care Pty Ltd	9 October 2024
68349	Novaguard Chlorthal 750 WG Herbicide	Novaguard Pty Ltd	9 October 2024
69085	Ezycrop Chlorthal 750 WG Herbicide	Ezycrop Pty Ltd	9 October 2024
69626	Farmalinx Dynamo 750 Herbicide	Farmalinx Pty Ltd	9 October 2024
69680	AC Discord 750 WG Herbicide	Axichem Pty Ltd	9 October 2024
81334	MacPhersons Chlorthal 900 WG Herbicide	Eurochem Pty. Ltd.	9 October 2024
83116	Lawthal 750WG Herbicide	Nutrien Ag Solutions Limited	9 October 2024
85327	Hemani Chlorthal 750 WG Herbicide	Hemani Australia Pty Ltd	9 October 2024
88705	Titan Chlorthal 900 WG Pre-Emergence Herbicide	Titan Ag Pty Ltd	9 October 2024
93154	Dacthal 900 WG Pre-Emergence Herbicide	Agnova Technologies Pty Ltd	9 October 2024

Deemed permit and instructions

In accordance with section 45B(3) of the Agvet Code, a person who possesses, has custody of, or uses the cancelled products referred to in Table 1 of this notice in accordance with the instructions contained in this notice is taken to have been issued with a permit to possess, have custody of or use the product in accordance with those instructions.

In accordance with section 45C of the Agvet Code, if a person possesses or has custody of a cancelled product listed Table 1 with the intention of supplying it, the person may only possess, have custody of, or otherwise deal with the cancelled products according to the instructions contained in this notice.

The instructions for possession, custody, use, or otherwise dealing with the cancelled chlorthal dimethyl chemical products listed in Table 1 of this notice are:

a. **A person must not use the cancelled products referred to in Table 1 of this notice in any circumstances,** including all circumstances that are listed on the current approved labels of the cancelled products. This

immediate ban on the use of cancelled chlorthal dimethyl chemical products is considered necessary to prevent imminent risk to persons of serious injury or serious illness.

b. A person must not supply or cause to be supplied the cancelled products referred to in Table 1 of this notice.

c. A person may possess or have custody of the cancelled chemical products referred to in Table 1 of this notice.

In accordance with section 45B(4) of the Agvet Code, a permit that is taken to have been issued under subsection 45B(3) of the Agvet Code remains in force until:

a. 1 year after the day of the suspension or cancellation, which is 9 October 2025; or

b. the APVMA revokes the suspension or cancellation; or

c. the APVMA, by notice published in the Gazette, declares that this subsection ceases to apply in respect of the constituent or product.

Contraventions

As specified in subsection 45C(5) of the Agvet Code, a person commits an offence under section 45C(2) of the Agvet Code if the person uses, possesses or has custody of or otherwise deals with, including supplying or otherwise disposing of, the cancelled products listed in Table 1 in a way that contravenes the instructions contained in the notice. Supplying or causing the supply of the cancelled products after 9 October 2024 is a contravention of these instructions.

It is also an offence to possess, have custody of, use, or otherwise deal with the cancelled products listed in Table 1 in a manner that contravenes the above instructions.

Sheila Logan
Executive Director, Risk Assessment Capability

With the delegated authority under sections 11, 32 and 44 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*

Attachments

Attachment A: Brief statement of reasons for the decision to cancel chlorthal dimethyl chemical product registrations under section 35A of the Agvet Code

Contact information

For any enquiries or further information about this matter, please contact:

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Attachment A – Brief statement of reasons for the decision to cancel chlorthal dimethyl chemical product registrations under section 35A of the Agvet Code

Note: This is the statement of reasons from Sheila Logan, Executive Director, Risk Assessment Capability. When 'I' is used in this statement of reasons, it means 'I, Sheila Logan, Executive Director, Risk Assessment Capability'.

Section 35A of the Agvet Code

Section 35A of the Agvet Code provides as follows:

> ***35A Suspension or cancellation of registration if imminent risk to persons of death, serious injury or serious illness***
>
> *(1) The APVMA may suspend or cancel the registration of a chemical product if the APVMA considers that doing so is necessary to prevent imminent risk to persons of death, serious injury or serious illness.*
> *Note: Section 43 deals with the effect of suspension of registration.*
>
> *(2) The APVMA may suspend or cancel the registration of the product under subsection (1) whether or not the product is being used in accordance with instructions for its use that the APVMA has approved.*
> *Note: Sections 34P and 35 do not apply to a suspension or cancellation under this section.*

Background

On 6 August 2024, the United States Environment Protection Authority (US EPA) issued an Emergency Order directing the suspension of all registrations issued under the Federal Insecticide, Fungicide and Rodenticide Act for pesticide products containing the active ingredient dimethyl tetrachloroterephthalate (DCPA). DCPA is marketed in Australia under its common name, chlorthal dimethyl, and may also be colloquially referred to as 'Dacthal'.

Following consideration by the APVMA of the reasons for the US EPA decision, along with an audit of the APVMA data holdings and information in the public domain, it was identified that there was additional information available to the US EPA which formed the basis of their decision. On 30 August 2024, the APVMA issued a written notice under section 159 (1)(d) of the Agvet Code to holders of approvals of the active constituent chlorthal dimethyl and registration of chemical products containing this active requiring the holders to give to the following information to the APVMA, on or before 27 September 2024:

1) Results of scientific investigations in relation to whether chlorthal dimethyl may interact with the endocrine system including estrogen, androgen and thyroid pathways, including comparative thyroid assays and any other scientifically relevant information.
2) Results from studies investigating potential neurotoxicity of chlorthal dimethyl (including developmental neurotoxicity).

The stated purpose of these notices was to decide whether to suspend or cancel the approvals of the active constituent chlorthal dimethyl and registration of chemical products containing this active.

The APVMA received one submission which included the results of a study investigating interactions of chlorthal dimethyl with the endocrine system, in particular thyroid pathways in rats, particularly during gestation and early development (Leggett 2022).

The APVMA has now reviewed the submitted information taking into consideration the detailed evaluation conducted by the US EPA, as well as considering the relevance of the study. In addition to evaluating this pivotal study, the APVMA

has evaluated the potential exposure likely to result from use of the products in the circumstances currently approved in Australia, considering current label instructions and the possible additional risk mitigation measures that could be put into place. This included conducting a risk assessment based on the identified hazard, and likely exposure, to determine whether the risk of exposure by users, workers re-entering treated areas, and the general public is considered to be acceptable.

Material relied on for this decision

In making this decision I have relied on the following information:

1) United States Environment Protection Authority. DCPA – Data Evaluation Record (DER) of a submitted definitive study to fulfill the Comparative Thyroid Assay (CTA) study requirement. EPA-HQ-OPP-2011-0374-0080.
2) Leggett, A. M. (2022) DCPA: Main Pre and Post Natal Developmental Comparative Thyroid Study in CD Rats by Oral Administration. Labcorp Early Development Laboratories Ltd, Eye, Suffolk. Laboratory Project ID: 8432592, June 20, 2022. MRID 51957801. Unpublished
3) A/g Director, Health Assessment Team, APVMA. 30 September 2024. Minute: update on recent US EPA regulatory action on chlorthal dimethyl (and accompanying attachments, including OPHEC calculations and residential turf post application calculations)

Material facts and findings

I make the following findings having considered the material referred to above.

Hazard assessment

No Observed Adverse Effect Level (NOAEL) – developmental effects

I find that a NOAEL for chlorthal dimethyl following administration to pregnant female rats for developmental effects in their pups is identified as 0.1 mg/kg bw/day. After the pregnant female rats were dosed at 1.0 mg/kg bw/day for 15 days during gestation, the effects on the thyroid hormones were seen in pups on gestational day 20 (prior to birth). However, no effect on thyroid hormones were observed in pups where the pregnant female rats were treated at the next lowest dose used in the study, which was 0.1 mg/kg bw/day (this is the NOAEL I identified).

In the study, in gestational day 20 foetuses, the effect of doses greater than or equal to 1.0 mg/kg bw/day on the thyroid hormones included a 35–52% decrease in triiodothyronine (T3) and a 29–66% decrease in thyroxine (T4). These changes in T3 and T4 were considered adverse.

I consider that the effects related to exposure of pups during gestation from dosing of the pregnant female rats are relevant to the exposure to unborn children, where pregnant people are exposed to chlorthal dimethyl. Rats are considered a suitable animal model for assessment of effects on humans as an established scientific practice. Risks to unborn children resulting from perturbation of thyroid levels can include low birth weight and irreversible and life-long impacts can include impaired brain development and motor skills.

I consider that the NOAEL of 0.1 mg/kg bw/day in rats is a suitable endpoint against which to assess worker exposure, based on the potential for people who may be pregnant to be exposed through use of the products (including mixing, loading and applying the products), or interacting with treated areas (such as mowing or handling treated turf). The selection of the endpoint relating to developmental toxicity is relevant for workers as there is a potential for them to be pregnant, and therefore for there to be exposure to the unborn child. The use of chlorthal dimethyl products in all

situations, including activities following treatment of an area, can result in potential exposure through deposition of the chemical on the surface of the skin and through inhalation. The deposition of product on the skin can result in systemic exposure through absorption of the chemical through the skin, and therefore exposure to the unborn child.

NOAEL – offspring toxicity

I find that the NOAEL for the effects on offspring toxicity is identified as 10 mg/kg bw/day, which relates to the exposure of pups after birth. This is because there were no effects seen at this dose in the comparative thyroid study.

I consider that the NOAEL of 10 mg/kg bw/day is a suitable endpoint against which to assess exposure of children who may be exposed to treated turf, including through play activities which may include exposure directly to the skin, as well as oral exposure through 'hand to mouth' activities common in toddlers and young children. The NOAEL for offspring toxicity is considered suitable for exposure to children, particularly toddlers and young children, as they are extremely unlikely to be pregnant and therefore the developmental NOAEL is not relevant.

Exposure estimates and risk assessment

The APVMA has assessed likely exposure of workers using chlorthal dimethyl products, workers re-entering and working in treated areas, and children exposed to chlorthal dimethyl through play on treated turf. These assessments have been carried out based on the lowest rate approved on the chlorthal dimethyl labels. For efficiency, only the lowest label rate was assessed, as an unacceptable exposure for the lowest rate would indicate that higher label rates would be similarly unacceptable given the same routes of exposure.

Occupational handler exposure

Worker exposure was modelled using the US EPA Occupational Pesticide Handler Exposure Calculator (OPHEC), an internationally accepted model which is routinely used by the APVMA for worker exposure assessments. This calculator utilises the rates of use proposed on the label, as well as default treatment areas, to determine estimated exposure of each worker who may be mixing, loading and applying the chemical product.

The estimated exposure is considered against the endpoint which did not produce any effects in the developmental toxicity study in rats to determine whether exposure was acceptable. This endpoint is 0.1 mg/kg bw/day for workers using chlorthal dimethyl products, based on the NOAEL for developmental effects.

Consistent with international best practice, the APVMA considers that a margin of exposure of 100 to the selected end point is protective based on a 10-fold level of uncertainty for inter species variability and a 10-fold level of uncertainty for intra species variability. On this basis, a maximum estimated worker exposure to 0.001 mg/kg bw/day and a maximum estimated exposure to children of 0.1 mg/kg bw/day would be acceptable.

For workers using chlorthal dimethyl products, the maximum acceptable level of exposure was exceeded in all exposure estimates, even with the application of the maximum risk mitigation measures. Assuming a single person mixes, loads and applies the chemical product while wearing protective clothing and gloves, and using a respirator, a margin of exposure of <5 was calculated for all current approved uses of chlorthal dimethyl, at the lowest application rate. For many chlorthal dimethyl uses, at the lowest application rate a margin of exposure of <1 was calculated.

Based on the approved uses of these products, I consider that the maximum protection considered possible includes protective clothing, gloves and the use of a respirator. I do not consider additional risk mitigation measures, such as the use of closed mixing and loading, to be appropriate given the formulations available and the high application rate of the products. I also note that if one person mixes and loads the product and a second person applies the product, an unacceptable margin of exposure is still calculated at the lowest application rate for both persons.

Exposure from re-entering and working in treated turf

Post application exposure modelling for individuals undertaking medium contact activities following use on turf (such as mowing turf or golfing) also resulted in unacceptable exposure. The endpoint for the post application exposure of adults or workers is 0.1 mg/kg bw/day, based on the NOAEL for developmental effects, and I consider applying a margin of exposure of 100 to this endpoint to be protective. A post application margin of exposure of <1 was calculated for high contact lawn activities, <5 for golfing, and <20 for mowing turf.

I do not consider reduction of exposure through the use of personal protective equipment to be appropriate for these activities, particularly as they may be undertaken by members of the public who are unaware of the risk associated with activities being undertaken in areas that have been treated.

Exposure from toddlers on turf

Assessment of exposure for young children exposed through playing on treated recreational turf was undertaken. The endpoint is 10 mg/kg bw/day for young children exposed to chlorthal dimethyl through play on treated turf, based on the NOAEL for offspring toxicity. I consider applying a margin of exposure of 100 to this endpoint to be protective.

Exposure of children aged 1–2 years was not acceptable; however, it was noted that the margin of safety for such children was higher than for adults or workers based on the higher NOAEL. A post application margin of exposure of 91 was calculated for hand to mouth activities in children 1–2 years of age.

Conclusions

I have considered the assessments conducted by the APVMA staff in the Health Assessment Team and agree with all findings and the conclusions and reasons on which these are based.

Based on the above findings, I conclude that use of all currently registered chlorthal dimethyl products (listed in Table 1 of this notice) in accordance with the label directions is not able to be carried out without exposing unborn children to unacceptable levels of chlorthal dimethyl. Further, I conclude that any possible variations to the label to include additional mitigation measures will not result in acceptable risk and allow the products to continue to be used. Therefore, the continuing registration of the products cannot be supported.

On the basis that I am satisfied that the imminent risk to persons of serious injury or serious illness associated with the use of these products cannot be appropriately mitigated, I have decided to cancel all currently registered chlorthal dimethyl products, which are listed in Table 1 of this notice.

Reasons

In order to cancel the registration of the chemical products listed in Table 1 of this notice under section 35A, I must consider that doing so is necessary to prevent imminent risk to persons of serious injury or serious illness.

Why it is necessary?

I have identified that there is an imminent risk of serious injury or serious illness to unborn children associated with the use of products containing chlorthal dimethyl. I consider that action of cancelling the registrations under section 35A of the Agvet Code is necessary to prevent the continued use of the products, thereby ensuring that exposure to chlorthal dimethyl from the use of the agricultural chemical products listed in Table 1 of this notice ceases immediately.

The human health assessment undertaken by the APVMA identified that, based on the use situations and application methods for chlorthal dimethyl, the risks to the health of occupational handlers are such that there are no registered uses

that can be supported. Further, there are no practical mitigation measures that can be put in place to allow the continued use of the products without exposing workers to unacceptable levels of chlorthal dimethyl, as there is a potential for these workers to be pregnant. Our findings are consistent with the recent emergency order issued by the US EPA.

Why the risk to persons is of serious injury or serious illness?

The risk of serious injury or serious illness is to unborn children, noting that workers or adults who are pregnant may be exposed to unacceptable levels of chlorthal dimethyl. This exposure of people who are pregnant to agricultural chemical products containing chlorthal dimethyl creates the risk of changes to foetal thyroid hormone levels that are significant enough to cause a serious adverse effect on an unborn child. The decrease in foetal thyroid hormone levels has been linked to low birth weight, impaired brain development, decreased IQ, and impaired motor skills later in life, some of which may be irreversible.

I consider these adverse effects to unborn children constitute serious injury or serious illness, particularly as they may be life long and irreversible.

Why the risk is imminent?

The identified imminent risk is that any continued use of products containing chlorthal dimethyl may expose people who are pregnant to unacceptable levels of chlorthal dimethyl, which has the potential to have a serious adverse effect on an unborn child. The potential adverse effect is a decrease in foetal thyroid hormone levels, which are generally linked to adverse effects including low birth weight, impaired brain development, decreased IQ, and impaired motor skills later in life, some of which may be irreversible. It is also noted that there is insufficient data to confirm at what stage of pregnancy an unborn baby may be at most risk of changes to foetal thyroid hormone levels.

There is the potential for people to be exposed to chlorthal dimethyl without their knowledge through activities including working or entering treated areas. No mitigation strategies have been identified, that can be reasonably put into place to prevent unacceptable levels of exposure by people using the agricultural chemical products.

The agricultural chemical products in Table 1 of this notice are used seasonally and key application times are in spring, increasing the need to act immediately to prevent possible serious injury or serious illness to unborn children.

Why it is preventative?

The instructions for possession, custody, use, or otherwise dealing with the cancelled chlorthal dimethyl chemical products listed in Table 1 of this notice are listed in the notice. These include an immediate ban on all use of chlorthal dimethyl chemical products listed in Table 1, and immediate ban on the supply of the of chlorthal dimethyl chemical products listed in Table 1.

Consequently, no persons will be lawfully exposed to the chemical through its use as an agricultural chemical after the date of this decision.

Decision

Given the material facts and findings and reasons set out above, I have cancelled the registration of the chemical products listed in Table 1 of this notice pursuant to section 35A of the Agvet Code to prevent imminent risk to persons of serious injury or serious illness.

Further, I have decided it is not appropriate to allow continued use or supply of the chemical products listed in Table 1 of this notice, including any phase out period for existing stock.