Australian Government

Australian Pesticides and Veterinary Medicines Authority

Public Release Summary on the evaluation of iodomethane in the product MIPIC 990 Soil Fumigant

Submissions received

April 2023

2022-09 APVMA Iodomethane – DOHWA Overall Concerns and Comments

Department of Health WA (DOHWA) is concerned with the overall potential registration of Iodomethane (active and product) as a soil fumigant, which must be co-injected with chloropicrin by licensed pest management technician and farmers (primarily strawberry farmers) on site. There is overall insufficient information for the combined co-fumigants, iodomethane and chloropicrin for the DoHWA to provide detailed "complete" comments for their safe use.

The Department acknowledges the APVMA scope is to review and determine whether an active and products alone as to whether it should be granted registration for safe use in Australia. However, where an active and its product is to be used in conjunction with another (registered) chemical(s), then the limited assessment scope may fall short as its review and should take into account the combine behaviour of these multiple actives and products to ultimately, determine its safe use in Australia. This limited scope is considered a serious limitation of this review. As a minimum APVMA should provide additional information to allay concerns by the regulators and eventually the users of these products that safety is not compromised by the limitations of the review.

Note, throughout this document Department refers to users as farmers (even though licensed pest management technicians) who will be accessing and applying this product as they most likely will be the users of these products with the most limited skills, knowledge and experience in fumigation and in understanding how to undertake the more complex risk assessment required when mixing iodomethane and chloropicrin for different application rates i.e. worst case scenario.

Iodomethane and Chloropicrin

More information/discussion on the combined occupational health and safety and public health risks (other than separate buffer zones) of coinjection of chloropicrin + iodomethane (eg. synergistic adverse health effects) is required. Are these two fumigants expected to behave and react independently, additively or synergistically? OR is it assumed chloropicrin will provide "advance" warning properties to indicate exposure and identify exposure risk for the combined use?

It is noted that the application label instructions for iodomethane is as a product that is always used in combination with chloropicrin. As such the DOHWA recommends that all other label instructions (and accompanying MSDS) including health risk, first aid and emergency response information and precautions (e.g. PPEC) for the combined actives. This is considered an appropriate means to better inform end users of the precautions required before deciding to purchase and use these fumigants, rather than expecting them to undertake a complex risk assessment that they may not be competent to complete.

In addition, as the label instructions assume mixing, there should be additional instructions with regards to use and availability of specialised equipment from the supplier to mix products at the correct rates, monitor for leaks and coinject the fumigants?

Most soil fumigants in Australia have been blended by the manufacturer to limit human error and minimises the specialised skills and equipment required to handle and apply the fumigants. The DOHWA is concerned regarding the additional competency requirements for mixing and coinjecting two products on site and interpreting subsequent precautions to apply for different mixes and application rates. Does APVMA know if the manufacture/ supplier intends to develop and implement a stewardship course to ensure users have competent skills and knowledge to safely use the combined fumigants?

Most strawberry growers in WA learn English as a second language and some may be illiterate in both English and their native language.

Based on the additional specialised skills, DoHWA suggests this product be limited to licensed pest management technicians in Australia or persons who have undertaken appropriate competency based training.

Iodomethane Review

Active toxicity (active constituent and product)

It is noted that iodomethane (active and product) acute inhalation toxic risk in the review is determined to be low in the review. However, the primary risk for soil fumigation has also been determined to be via inhalation with a requirement for users to wear a full-face filtered air respirator. Further elucidation of acute inhalation effects should be considered.

Label Restraints:

Reference to AS 2476 – 2008

- The risk of occupational and non-occupational exposure is expected to be mitigated by adherence to the relevant Australian Standard (AS 2476-2008 - General fumigation procedures) and its associated detection, monitoring, emergency venting and clearance provisions.

Although DoHWA supports the inclusion in the proposed label. However, we are concerned whether farmers have the competency requirements to know and understand the requirements of AS2476. In WA's *Health (Pesticide) Regulations 2011* only LPMTs are required to comply with AS2476. However, once it's on the registered label then, under the Regulations, all users are required to comply with the approved label. DoHWA is concerned that farmers may not be aware of the requirement to have a "qualified assistant" supporting them during the fumigation.

Buffer

- DO NOT use within 500 m of buildings inhabited by humans, including schools, day care facilities, nursing homes and prisons or sensitive sites e.g., playgrounds.
- DO NOT apply near buildings inhabited by humans or livestock. (General instructions)

DOHWA supports the 500m buffer restraint from any occupied buildings (eg care facilities) and sensitive sites (eg playgrounds). It is noted that it will be difficult to regulate compliance with the buffer and many farms are within 500m of sensitive receptors.

It is important to note, if heavy rains and storms are predicted within 3 days after the tarp is scheduled to be removed, then potentially the farmer's family and the workers' accommodation, may need to be vacated for a minimum of 8 days.

Precaution

Re-entry period

- DO NOT enter treated work areas until 5 days after treatment and until iodomethane level is less than 2ppm (12 mg/m^3).

Farmers will require access to a suitably sensitive monitoring device / leak detector which can detect very low concentrations of iodomethane (and chloropicrin) with accuracy and precision less the

2ppm. DoHWA is concerned farmers may not necessarily be competent in the selection, use, maintenance and calibration of sensitive monitoring instruments and this will effect the accuracy and precision of monitoring and may place workers and the public at risk.

- A minimum interval of 2 hours is required between perforation and tarp removal.

DoHWA notes during the "perforation" process farmers will be exposed to 2ppm (TWA of 8h), which is at the occupational airborne exposure limit. Notwithstanding, this also requires farmers to regularly be mindful of the total time period of use (or total time remaining) of the organic canister and requirement for regular periods to change canister. DOHWA is concerned for the farmers (and qualified assistant) potential exposure if they are not aware of this extremely important limitation. Noting also that compliance with respirator use, e.g. clean shaven and annual fit testing, fit checking prior to each use, will need to be adequately supervised and part of a safe system of work which relies on best work health and safety practices.

General Instructions - Important

- Non-handler entry is prohibited while tarps are being removed. Where required, a guard should be stationed at the perimeter to prevent entry of unauthorised persons, children and animals during the first day of ventilation.

Generally, DOHWA supports these statements but this indicates that there is an "extreme" risk to unauthorised people (and animals) who are not wearing suitable PPE including full face respirator with the appropriate filters especially during the first day of venting. Therefore, should this active and product be approved for general safe use on Australian farms? Normally this type of control is restricted to approved fumigants used in controlled commercial settings (with no access to visitors, children, livestock or pets), such on at the wharf for a vessel fumigation.

- A minimum interval of 2 hours is required between perforation and tarp removal.

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First Aid

- May produce severe burns. Vapour is harmful to health on prolonged exposure.
- WARNING - may cause birth defects. Use only in well ventilated area.

DoHWA supports the following statements be in red, capitalised and suggest the manufacture may wish to bold this warning.

Response from The Victorian Strawberry Industry Certification Authority (VSICA)

To

The Proposed Registration of Mipic 990 Soil Fumigant

1. Background

   VSICA is an industry body setup in 1995 for the testing, management and early-stage multiplication of pathogen-tested stock that is then distributed to commercial runner growers, and for inspection of runner crops submitted for certification. It manages the Victorian Runner Certification Scheme established by Victorian government.

   Certified runners result in the improvement of fruit yield and quality by reducing the impact of diseases and greater business certainty by reducing the variability of marketable yields.

2. Production Process

   The production of certified runners involves a five-step process to ensure that runner growers supply fruit growers with healthy planting material. At each stage in the process strict protocols involving the principles of quarantine combined with specific growing techniques and treatments mitigate against the presence of diseases.

   The final step in the production of runners for fruit growers involves the bulking up of plant material on a field scale by runner growers.

   To ensure fields are free of pathogens and weeds, soil fumigation prior to planting is mandated. Methyl bromide in combination with chloropicrin has been the only VSICA-approved treatment for many years. Methyl bromide will no longer be available for this use beyond 2023 due to commitments made by the Australian Government as a signatory to the Montreal Protocol.

3. Alternatives to Methyl Bromide

   VSICA has been closely monitoring the evaluation of methyl iodide as an alternative to methyl bromide. Subject to methyl iodide being approved by the APVMA, VSICA will mandate this product as the only approved product for use by runner growers to treat their fields for runner production.

   Methyl iodide is effectively a “drop in” replacement for methyl bromide. It will be applied at similar rates as methyl bromide in combination with chloropicrin using the same application equipment and the same application contractors.

4. Buffer Zones

   VSICA has examined the PRS in relation to the proposed registration of Mipic 990 Soil Fumigant and notes the requirement for buffer zones.

   The proposed buffer zones would prove highly impractical and would severely impact the quantity and quality of runners that could be produced.

   VSICA argues that in fact buffer zones are not required for the following reasons:

- Australian data and modelling indicate that the movement of both methyl iodide and chloropicrin from treated areas from the time of treatment to tarp removal and beyond, was below the exposure risk levels shown in the PRS.
- Australian soil types are different from those in the US (more organic matter, more clay) and daytime temperatures during treatment are lower.
- The largest runner grower field size in Australia is 6Ha which is smaller than field sizes in the US
- It would seem that an extensive reliance on US generated data and modelling was used to prescribe buffer zones for Australia.
- Label constraints imposed on other products containing chloropicrin, used for similar purposes, were determined with reference to actual agricultural practices in Australia.

5. Conclusion

   Proposed buffer zone requirements on the Mipic 990 Soil Fumigant label are not justified by Australian data, soil types and agricultural practice and would severely jeopardise the quantity and quality of runners that could be produced.