



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**



Molinate proposed regulatory decision

Submissions received

February 2022



14 January 2022

SunRice Group

Submission in relation to the proposed regulatory decision for the approval of Molinate in Australian rice production

Delivered to:

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Delivered by email: chemicalreview@apvma.gov.au

Introduction

SunRice welcomes the opportunity to provide comment to the Australian Pesticides and Veterinary Medicines Authority (APVMA) on the preliminary review decision for Molinate.

Barnyard grass is one of the most competitive weeds in Riverina rice crops. If it is not controlled, the weed competition will result in significant yield reduction, even crop failure. Molinate has been the linchpin of reliable barnyard grass control in water-seeded rice production for more than 40 years.

There are alternate chemicals for the control of grass weeds in rice however they all have their limitations. These range from the potential for crop damage, weed resistance development or their effectiveness when water or weather conditions are not ideal. This means that the availability of Molinate is critical to ensure long term protection of rice from grass weeds.

1.1 The SunRice position

SunRice supports the APVMA's proposed regulatory decision to approve the continued registration of Molinate for the control of grass weeds in Australian rice crops. SunRice has worked closely with the Ricegrowers' Association of Australia (RGA) in assisting with the review into safe methods of use and continues to work with rice growers to ensure that these practices are understood within the rice industry. SunRice is aware of the separate RGA submission to this review, and is supportive of that submission.

1.2 The APVMA Molinate review and the RGA response

In 2013 the APVMA started a review into the safe use of Molinate and the potential removal of its registration for use in Australian rice crops. In response the RGA began discussions with the APVMA highlighting that the currently available operator exposure data was out of date and not based on current best practice. It was agreed that a research project be established to identify the operator exposure risk during closed system loading and using the Soluble Chemical Water Injection in Rice Technique (SCWIIRT or Bickley boom application).

This research related to:

- The safety of people exposed to it during handling;
- The likelihood of it being harmful to human beings; and
- The likelihood of an unintended effect that is harmful to animals, plants, things or to the environment.

The research was used to support three submissions to the APVMA for consideration.

Submissions received from holders or members of the public; *Molinate Technical Report October 2021 page 3*

Submitted by	Contents	Review comments
Ricegrowers' Association of Australia October 2014	<i>Mixer and Loader Exposure Study with Molinate</i> . Preliminary trial with 3 operators (3 replicates) to assess the extent of dermal exposure when wearing specified personal protective equipment (PPE) during mixing and	Preliminary indication that aerial application of Molinate could be supported with appropriate restrictions. Further replicates required to confirm preliminary outcomes.

	loading (Agriseach 2014).	
Ricegrowers' Association of Australia April 2016	Submission of collated water monitoring data for 2010–11 to 2014–15 growing seasons (RGA 2016).	Detections of Molinate declined with one detection in the 2013–14 season and zero detections above the environmental guideline in the 2014–15 season.
Crop Care Australasia Pty Ltd/Nufarm Australia February 2017	<i>Mixer/Loader and Applicator Exposure Study with Molinate – Final Study.</i> Worker exposure study for mixing/loading and application by aircraft (Bickley Boom*; Agriseach 2016).	Continued use of Molinate is supported with restrictions to the amount of Molinate that can be mixed and applied per day.

The Molinate Technical Report October 2021 states that:

“The additional information received has been considered and based on the evaluation of this information, the APVMA is currently satisfied that the instructions for use for agricultural Molinate products can be varied to satisfy the requirements for continued registration.” Molinate Technical Report October 2021 page 3.

Consideration of whether the registered chemical products can be varied in such a way as to meet the safety criteria

SunRice broadly supports the APVMA's reasons for varying the operator exposure, application method and the removal of the previously noted highest rate.

The proposed approval will require an updated label that displays these key recommendations:

- Use closed mixing and loading only;
- A single operator MUST NOT be involved in BOTH mixing/loading AND application in the same day;
- A single operator involved in mixing/loading of the product MUST NOT handle more than 1,400 L neat product per day;
- A single operator (pilot) MUST NOT apply the product spray to an area exceeding 280 hectares per day;
- Apply only by SCWIIRT (Soluble Chemical Water Injection In Rice Technique); and
- Maximum application rate 3.75L in minimum 10L/ha water.

After reviewing the Molinate Technical Report the RGA sought feedback on the proposed label changes from a range of aerial contractors servicing the rice industry in the Riverina. Two of the larger operators suggested that daily limit for a single pilot was around half of

the area per day that one pilot currently applied during the treatment period in October-November. As the need for a higher daily rate would be for only one to two weeks they suggested it if it was possible to increase the daily rate for a shorter defined period or basing compliance on an average of 280ha/day rate over the crop protection period would better suit their operations.

Based on the aerial operator feedback SunRice proposes that the APVMA reviews the suggested daily area a single pilot can treat and considers increasing it provided there is no increased exposure risk to the pilot.

1.3 Conclusion

SunRice supports the APVMA's proposed approval of Molinate as a herbicide for use in Australian rice crops. SunRice provides in-principle support to the proposed label application rate and operator exposure limits. SunRice suggests that the APVMA considers increasing the 280ha/day single pilot limit is provided there is no increased exposure risk to the pilot.

Thank you for the opportunity to participate in this review and provide a submission. If you require clarification about any of the matters raised in this submission, please do not hesitate to contact the RGA team.

1.4 Contacts

SunRice would be pleased to provide further information in relation to this submission.

If the NSW Government would like further information, please contact SunRice's Manager Grower Services and Agronomic Development, Mr Chris Quirk. Mr Quirk may be contacted on 0427 291 022 or at cquirk@sunrice.com.au.

Ricegrowers Limited
14 January 2022

SUBMISSION TO PROPOSED REGULATORY DECISION FOR THE APPROVAL OF MOLINATE IN AUSTRALIAN RICE PRODUCTION

January 2022

Rice Crop Protection Working Group (RCPWG)

Introduction

We welcome the opportunity to provide comment to the APVMA on the preliminary review decision for molinate.

Barnyard grass is the most competitive grass weed in Riverina rice crops. If it is not controlled, the weed competition will result in significant yield reduction and in a worse cases crop failure.

Molinate has been the linchpin of reliable barnyard grass control in water-seeded rice production for over forty years. There are alternate chemicals for the control of grass weeds in rice however they all have their limitations. These range from the potential for crop damage, weed resistance development or their effectiveness when water or weather conditions are not ideal. This means that the availability of molinate is critical to ensure long term protection of rice from grass weeds.

THE RCPWG Position

The RCPWG supports the Australian Pesticides and Veterinary Medicines Authority's (APVMA) proposed regulatory decision to approve the continued registration of molinate for the control grass weeds in Australian rice crops.

In 2013 the APVMA started a review into the safe use of molinate and the potential removal of its registration for use in Australian rice crops. In response the RGA began discussions with the APVMA highlighting that the currently available operator exposure data was out of date and not based on current best practice. It was agreed that a research project be established to identify the operator exposure risk during closed system loading and using the Soluble Chemical Water Injection in Rice Technique (SCWIIRT or Bickley boom application).

This research related to:

- The safety of people exposed to it during its handling;
- the likelihood of it being harmful to human beings; and
- the likelihood of an unintended effect that is harmful to animals, plants or things or to the environment.

The research was used to support three submissions to the APVMA for consideration.

Submitted by	Contents	Review comments
Ricegrowers' Association of Australia October 2014	<i>Mixer and Loader Exposure Study with Molinate</i> . Preliminary trial with 3 operators (3 replicates) to assess the extent of dermal exposure when wearing specified personal protective equipment (PPE) during mixing and loading (Agrisearch 2014).	Preliminary indication that aerial application of molinate could be supported with appropriate restrictions. Further replicates required to confirm preliminary outcomes.
Ricegrowers' Association of Australia April 2016	Submission of collated water monitoring data for 2010–11 to 2014–15 growing seasons (RGA 2016).	Detections of molinate declined with one detection in the 2013–14 season and zero detections above the environmental guideline in the 2014–15 season.
Crop Care Australasia Pty Ltd/Nufarm Australia February 2017	<i>Mixer/Loader and Applicator Exposure Study with molinate – Final Study</i> . Worker exposure study for mixing/loading and application by aircraft (Bickley Boom*; Agrisearch 2016).	Continued use of molinate is supported with restrictions to the amount of molinate that can be mixed and applied per day.

Molinate Technical Report October 2021 states that; “The additional information received has been considered and based on the evaluation of this information, the APVMA is currently satisfied that the instructions for use for agricultural molinate products can be varied to satisfy the requirements for continued registration.” *Molinate Technical Report October 2021 page 3*.

Consideration of whether the registered chemical products can be varied in such a way as to meet the safety criteria

The RCPWG broadly supports the APVMA’s reasons for varying the operator exposure, application method and the removal of the previously noted highest rate.

The proposed approval will require an updated label that displays these key recommendations:

- Use closed mixing and loading only.
- A single operator MUST NOT be involved in BOTH mixing/loading AND application in the same day.
- A single operator involved in mixing/loading of the product MUST NOT handle more than 1,400 L net product per day.
- A single operator (pilot) MUST NOT apply the product spray to an area exceeding 280 hectares per day.
- Apply only by SCWIIRT (Soluble Chemical Water Injection In Rice Technique).
- Maximum application rate 3.75L in minimum 10L/ha water.

The rice industry sort feedback on the proposed label changes from a range of aerial contractors servicing the rice industry in the Riverina. Two of the larger operators suggested that daily limit for a single pilot was around half of the area per day that one pilot currently applied during the treatment period in October-November. As the need for a higher daily rate would be for only one to two weeks they suggested it if it was possible to increase the daily rate for a shorter defined period or basing

compliance on an average of 280ha/day rate over the crop protection period it would better suit their operations.

Based on the aerial operator feedback RCPWG proposes that the APVMA considers increasing the daily area a single pilot can treat provided there is no increased exposure risk to the pilot.

CONCLUSION

The RCPWG supports the APVMA'S proposed approval of molinate as a weedicide for use in Australian rice crops. SunRice provides in principle support to the proposed label application rate and operator exposure limits. SunRice suggests that the APVMA considers increasing the 280ha/day single pilot limit is provided there is no increased exposure risk to the pilot.

Thank you for the opportunity to participate in this review and provide a submission

CONTACTS

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RICEGROWERS' ASSOCIATION
OF AUSTRALIA INC
SERVING OUR MEMBERS
FOR 90 YEARS

SUBMISSION TO PROPOSED REGULATORY DECISION FOR THE APPROVAL OF MOLINATE IN AUSTRALIAN RICE PRODUCTION.

January 2022

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1. INTRODUCTION

The Ricegrowers' Association of Australia (RGA) welcomes the opportunity to provide comment to the APVMA on the preliminary review decision for molinate.

Barnyard grass is the most competitive weed in Riverina rice crops. If it is not controlled, the weed competition will result in significant yield reduction, even crop failure.

Molinate has been the linchpin of reliable barnyard grass control in water-seeded rice production for over forty years. There are alternate chemicals for the control of grass weeds in rice, however they all have their limitations. These range from the potential for crop damage, weed resistance development or their effectiveness when water or weather conditions are not ideal. This means that the availability of molinate is critical to ensure long term protection of rice from grass weeds.

2. THE RGA'S POSITION

The Ricegrowers' Association of Australia supports the Australian Pesticides and Veterinary Medicines Authority's (APVMA) proposed regulatory decision to approve the continued registration of molinate for the control grass weeds in Australian rice crops.

2.1.1. THE APVMA molinate review and the RGA response

In 2013 the APVMA started a review into the safe use of molinate and the potential removal of its registration for use in Australian rice crops. In response the RGA began discussions with the APVMA highlighting that the currently available operator exposure data was out of date and not based on current best practice. It was agreed that a research project be established to identify the operator exposure risk during closed system loading and using the Soluble Chemical Water Injection in Rice Technique (SCWIIRT or Bickley boom application). The RGA then secured RIRDC funding to research operator exposure of molinate when using current best practice.

This research relating to:

- The safety of people exposed to it during its handling;
- the likelihood of it being harmful to human beings; and
- the likelihood of an unintended effect that is harmful to animals, plants or things or to the environment.

The work was completed by Crop Care Australasia Pty Ltd/ Nufarm Australia, Eurofins Pty Ltd and Agropraisils Pty Ltd with in-kind support from Field Air Pty Limited.

The collaborative research was used to support three submissions to the APVMA for consideration.

Submitted by	Contents	Review comments
Ricegrowers' Association of Australia October 2014	<i>Mixer and Loader Exposure Study with Molinate</i> . Preliminary trial with 3 operators (3 replicates) to assess the extent of dermal exposure when wearing specified personal protective equipment (PPE) during mixing and loading (Agriseach 2014).	Preliminary indication that aerial application of molinate could be supported with appropriate restrictions. Further replicates required to confirm preliminary outcomes.
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2.1.2. Consideration of whether the registered chemical products can be varied in such a way as to meet the safety criteria

The RGA largely supports the APVMA’s reasons for varying the operator exposure, application method and reduction the removal of the previous highest rate.

The proposed approval will require an updated label that displays these key recommendations:

- Use closed mixing and loading only.
- A single operator MUST NOT be involved in BOTH mixing/loading AND application in the same day.
- A single operator involved in mixing/loading of the product MUST NOT handle more than 1,400 L neat product per day.
- A single operator (pilot) MUST NOT apply the product spray to an area exceeding 280 hectares per day.
- Apply only by SCWIIRT (Soluble Chemical Water Injection In Rice Technique).
- Maximum application rate 3.75L in minimum 10L/ha water.

After reviewing the Molinate Technical Report, the RGA sort feedback on the proposed label changes from a range of aerial contractors servicing the rice industry in the Riverina. Two of the larger operators suggested that the daily limit for a single pilot was around half of the area per day that one pilot treated currently during the treatment period of October and November. As the need for a higher daily rate would be for only one to two weeks, they suggested the RGA investigate if the APVMA could consider raising the daily rate for a shorter defined period, or basing compliance on an average of 280ha/day rate over the crop protection period.

Based on the aerial operator feedback the RGA proposes that the APVMA reviews the suggested daily area a single pilot can treat and considers increasing it provided there is no increased exposure risk to the pilot.

3. CONCLUSION

The RGA supports the APVMA'S proposed approval of molinate active constituents in weedicides for the control of grass weeds in Australian rice crops. The RGA provides in principle support to the proposed label application rate and operator exposure limits. The RGA proposes that the APVMA considers increasing the 280ha/day single pilot limit there is no increased exposure risk to the pilot.

Thank you for the opportunity to participate in this review and provide a submission. If you require clarification about any of the matters raised in this submission, please do not hesitate to contact the RGA team.

4. CONTACTS

For further information please contact:

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23 Dec 2021

APVMA Chemical Review
GPO Box 3262
Sydney, NSW, 2001, Australia

Dear Chemical Review

Submission on molinate review consultation

Thank you for the opportunity to comment on the preliminary review decision for molinate. Nufarm have reviewed the proposal and concur with the APVMA's risk assessment with one exception. When determining applicator (pilot) exposure, APVMA used dosimeter recovery data from the preliminary study (which provided no results for pilot exposure) to adjust the results of the final study. We do not believe that this is an appropriate methodology and have proposed alternative approaches in this submission.

Review of recovery data

Dosimeter recoveries were collected at two different spike rates (0.005 mg and 1 mg) and two different intervals (immediate collection and after being placed in situ for 2 hours). Based on the magnitude of the recovery results, the most appropriate spike rate is 0.005 mg which is analysed in both the preliminary and final study in a box and whisker chart shown in Figure 1.

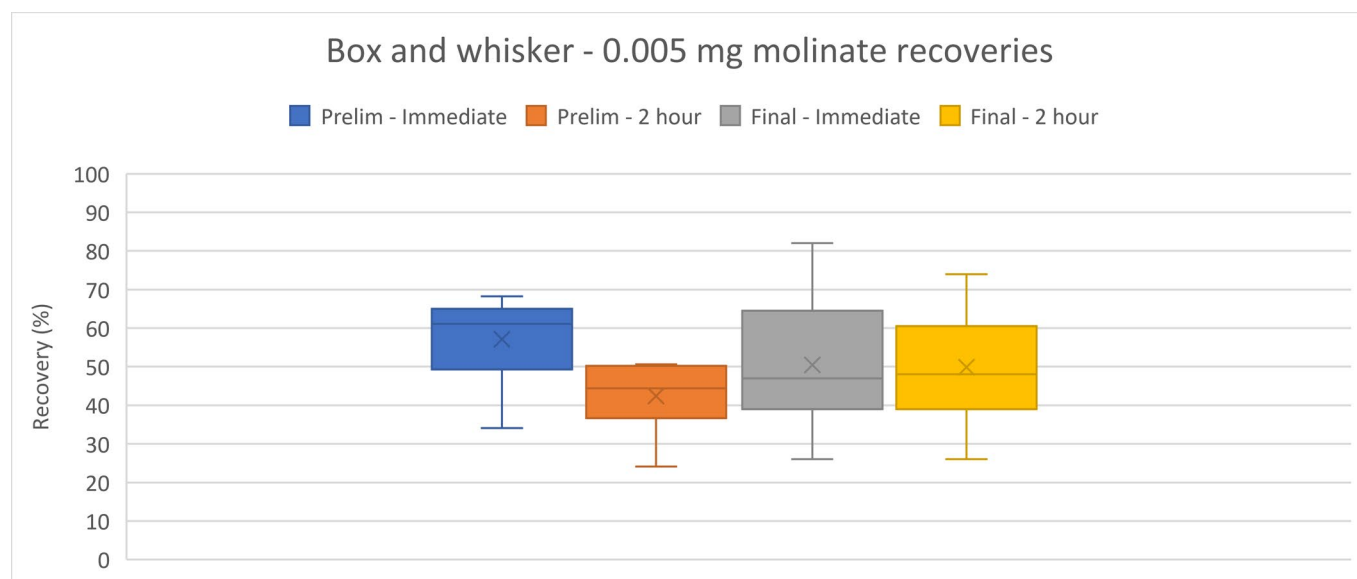


Figure 1: Molinate recovery analysis

In a well conducted study, the recoveries would be consistent between sampling intervals as this reflects the robustness of the protocol whilst the study is being conducted. In the preliminary study, there was a significant difference between the immediate and 2-hour sampling intervals with the 75th percentile and maximum results from the 2-hour data being approximately equal to the 25th percentile of the immediate sample and the mean and medians differing by 10-15 percentage points. In contrast in the final study, the mean, median, 25th percentile and minimum results are almost identical in the preliminary and final study. As a result, Nufarm propose that the preliminary data be disregarded for the pilot exposure assessment given pilot exposure was not assessed in that study and the data quality is poor compared to the final study.

Outliers in final study recoveries

Before data can be used for risk assessment purposes, the dataset should be examined for outliers if there is enough statistical significance in the data. Two methods were used by Nufarm to identify outliers in the final study recovery (0.005 mg spike, 2 hour sampling interval):

- Firstly, the same method proposed by APVMA in their review (MEAN \pm 3 x Standard Error of Mean (SEM)) was used to identify results below 39 and above 60.8 were outliers.
- Secondly, the 25th and 75th percentiles were calculated to identify results below 39 and above 60.5 were outliers.

The results of this analysis are tabulated in Table 1 and illustrated in Figure 2. This again demonstrates the quality of this study as both methods identify the same outliers.

Table 1: Summary descriptors for final study recoveries (0.005 mg spike, 2 hour sampling interval)

Descriptor	Calculated value
Median	48.0
Mean	49.9
Std Dev	13.6
25th Percentile	39.0
75th Percentile	60.5
Standard Error of Mean (SEM)	3.6
Mean - 3*SEM	39.0
Mean + 3*SEM	60.8

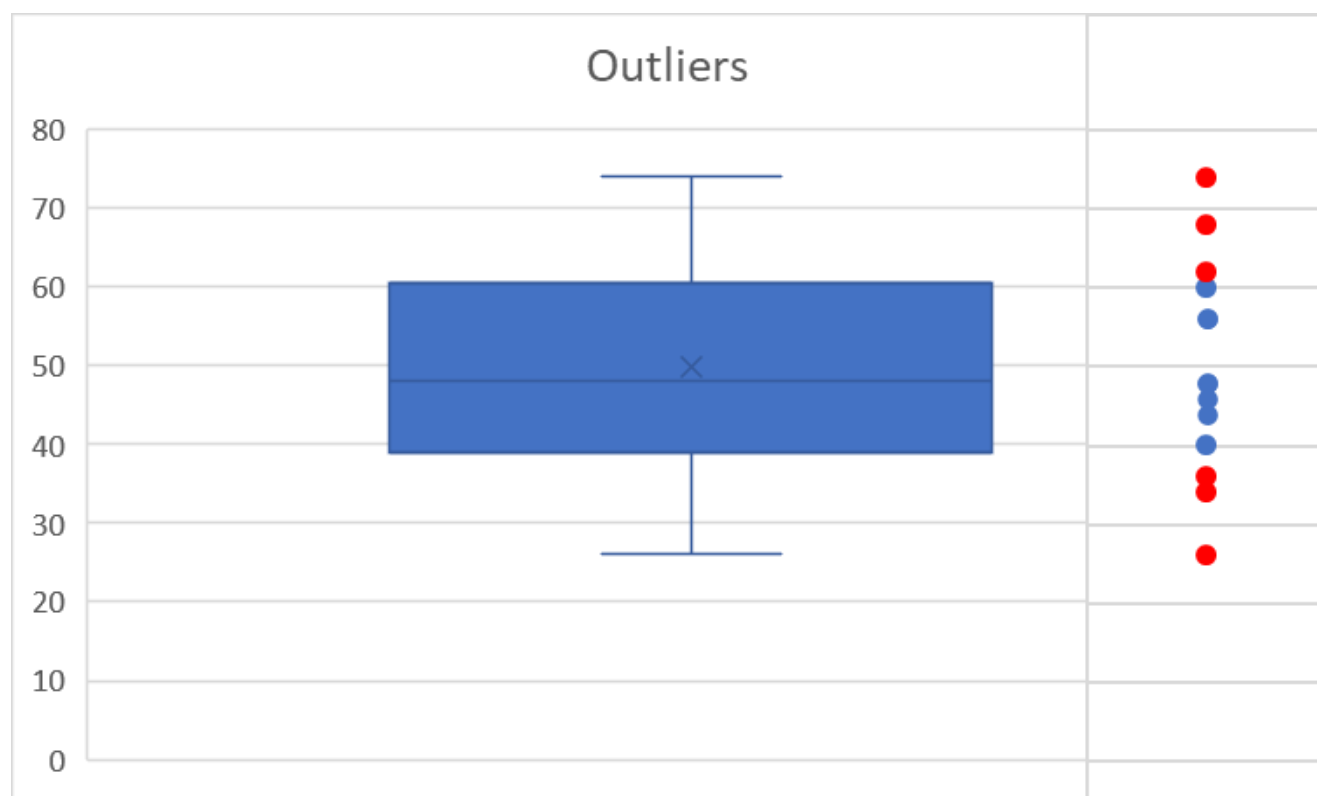


Figure 2: Summary chart for final study recoveries (0.005 mg spike, 2 hour sampling interval – outliers are coloured red)

Revised risk assessment

Following removal of the outliers, the most suitable statistically relevant result from the remaining data can then be used to revise the risk assessment. The following values were used for this purpose:

- 25th percentile which also equals the mean minus three SEMs (39%)
- Lowest recorded value (40%)
- Median (48%)
- Mean (49%)
- 75th percentile (60.5)
- Mean plus three SEMs (60.8)

The results of this revised risk assessment (using the same methodology as the APVMA review and assuming the application rate is always 3.75 L/ha of Ordram) are shown in Table 2

Table 2: Revised risk assessment for applicator (pilot) exposure

Exposure (mg per applied kg) - Median	Recovery Assumption (fraction)	Exposure (mg per applied kg), adjusted	Dermal Exposure (mg/kg bw/d)	MOE (LOAEL 1.8 mg/kg bw/day)	Acceptable quantity per day (kg)	Acceptable quantity per day (L)	Acceptable daily work rate (ha/day)
0.0171	0.39	0.043846154	0.000250549	7,184	1,703	1,774	473
0.0171	0.4	0.04275	0.000244286	7,368	1,746	1,819	485
0.0171	0.48	0.035625	0.000203571	8,842	2,096	2,183	582
0.0171	0.49	0.034897959	0.000199417	9,026	2,139	2,228	594
0.0171	0.605	0.028264463	0.000161511	11,145	2,641	2,751	734

To test which of these values is the most appropriate, a Monte Carlo simulation was run with the following conditions:

- Forecast values:
 - Exposure (mg per applied kg) – random uniform distribution model with outlier identified by APVMA removed (range 0.059 to 0.083)
 - Recovery (fraction) - random uniform distribution model with outliers identified by APVMA removed (range 0.4 to 0.6)
- Number of simulations:
 - 10,000

The purpose of the Monte Carlo simulation is to provide a probability-based measure of risk instead of assuming the worst-case scenario occurs for every application all the time. It is not appropriate to use outliers in these simulations as the reason they have been excluded from the analysis is suspected experimental area (e.g., it is not expected that they were correct measurements). Therefore, this simulation provides an assessment across the range of low, moderate, and high exposures expected during real world application which is illustrated in Figure 3 and is described in the percentiles shown in Table 3.

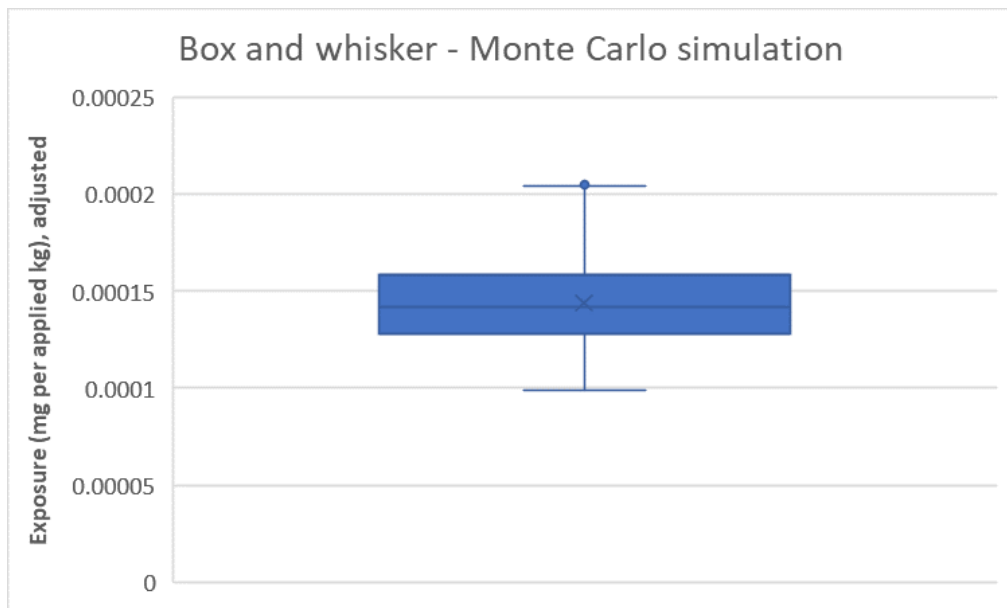


Figure 3: Box and whisker chart of the Monte Carlo simulation

Table 3: Monte Carlo simulation (probability assessment)

Percentile (fraction)	Exposure (mg per applied kg), adjusted	Quantity applied (kg)	Exposure (mg)	Dermal Exposure (mg/kg bw/d)	MOE (LOAEL 1.8 mg/kg bw/day)	Acceptable quantity per day (kg)	Acceptable quantity per day (L)	Acceptable daily work rate (ha/day)
1	0.000207	237	0.0490	0.000280	6,426	1,523	1,586	423
0.99	0.000196	237	0.0465	0.000266	6,775	1,606	1,673	446
0.95	0.000184	237	0.0435	0.000249	7,242	1,716	1,788	477
0.9	0.000174	237	0.0413	0.000236	7,622	1,806	1,882	502
0.75	0.000159	237	0.0376	0.000215	8,380	1,986	2,069	552
0.5	0.000142	237	0.0336	0.000192	9,366	2,220	2,312	617

This simulation demonstrates that if a pilot applied 423 hectares of Molinate at 3.75 L/ha every day over 10,000 days (the equivalent of 250 years assuming 40 days of spraying annually) at the worst-case exposure levels (with both measured exposure and recoveries considered) then the risk would be deemed acceptable. However, given this is not a realistic situation, it is appropriate to use an alternative percentile. In this case, the 95th percentile was chosen as it is the inverse of the most common probabilistic risk assessment currently conducted by APVMA (the species sensitivity distribution). This analysis demonstrates the Ordram could be safely applied at a 95% confidence level when the label instructions are followed at the maximum application rate of 3.75 L/ha whilst treating 477 hectares per day (which is conservative as it is extremely unlikely any pilot will apply the maximum amount in consecutive days each season). This closely aligns with the revised risk assessment using 40% as the worst-case recovery value (485 hectares), so Nufarm propose that this value of a maximum 485 hectares per day be adopted by the APVMA.

Proposed label statement

Whilst 3.75 L/ha is the maximum application rate proposed by the APVMA, there is also a 2.5 L/ha rate. This lower rate is currently rarely used, but with recent new herbicide registrations it may provide greater flexibility in tank mixes to allow it to be considered in the label restriction. Therefore, in consideration of the revised risk assessment and the application rate range, Nufarm propose the following change to the APVMA label published in the preliminary review decision:

Remove:

~~A single operator (pilot) MUST NOT apply the product spray to an area exceeding 280 hectares per day~~

Add:

A single operator (pilot) MUST NOT apply more than 1,820 litres of Ordram per day (equivalent to spraying an area of no more than 485 hectares at the maximum rate of 3.75 L/ha or no more than 730 hectares at the minimum rate of 2.5 L/ha).

Other minor comments:

- Given the requirement for the closed mixing and loading system, Nufarm propose that the disposal instructions be limited to refillable containers only instead of the current recyclable wording:

Remove:

~~STORAGE AND DISPOSAL~~

~~For general containers:~~

~~Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight. Store in a locked room away from children, animals, food, feedstuffs, seed and fertilisers.~~

~~Triple-rinse containers before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. 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, bury the empty packaging 500 mm below the surface in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.~~

~~For containers carrying the drumMUSTER logo:~~

~~Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight. Store in a locked room away from children, animals, food, feedstuffs, seed and fertilisers. This container can be recycled if it is clean, dry, free of visible residues and has the drumMUSTER logo visible. Triple-rinse container for disposal. Dispose of rinsate by adding it to the spray tank. Do not dispose of undiluted chemical on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any drumMUSTER collection or similar container management program site. The cap should not be replaced, but may be taken separately.~~

Add:

STORAGE AND DISPOSAL

Store in the closed, original container in a cool, well-ventilated area. DO NOT store for prolonged periods in direct sunlight. Store in a locked room away from children, animals, food, feedstuffs, seed and fertilisers.

Empty contents fully into application equipment. Close all valves and return to point of supply for refill or storage.

- Note that the Group J Herbicide statement will need to be changed to Group 15 Herbicide throughout to align with the upcoming changes to herbicide resistance classification in Australia.
- Molinate is not an approved active constituent in New Zealand so the reference to the New Zealand poison information centre should be removed to avoid confusion and delays in the event of an emergency.

Conclusion

Other than the minor comments above and the proposed alternate risk assessment proposal to better represent the risk of the product and not unnecessarily restrict users, Nufarm welcomes the conclusion of the APVMA review of molinate.

Nufarm would also like to take this opportunity to re-iterate the vital importance of the APVMA publishing full and complete risk assessment reports with preliminary review findings (with CCI redacted as appropriate). In this instance the human health report was provided after the initial publication following a request from Nufarm. Without this it would not have been possible to identify the potential for an alternative risk assessment which emphasises how critical it is for these documents to be published to ensure chemical reviews are conducted in a transparent manner where potential errors can be identified and rectified under the review. This was also significant failing of the recent 2,4-D review which uncovered errors related to the run-off and spray drift risk assessments on model labels, so we look forward to this issue being resolved prior to the next preliminary review finding being released.

Please do not hesitate to contact me should the APVMA have any queries in relation to this submission.

Yours sincerely



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David Rumbold
ANZ Lead - Regulatory
Nufarm Australia Limited