Proposed Re-evaluation Decision PRVD2020-03

Sodium Omadine and Its Associated End-use Products, Used as a Preservative in Paints, Coatings and Related Uses

Consultation Document

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Proposed Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

This document forms part of a re-evaluation assessment of several active ingredients used as preservatives in paints, coatings and related uses. As per Re-evaluation Note REV2018-02, *Approach for the Re-Evaluation of Pesticides Used as Preservatives in Paints, Coatings and Related Uses*, the paint-related uses of sodium omadine, chlorothalonil, dazomet, folpet and ziram were evaluated separately from other uses and relied on data provided by the registrants and the Antimicrobial Exposure Assessment Task Force II (AEATF II). This approach was adopted in order to obtain and review paint-related studies, have risk assessments more reflective of current and realistic exposure scenarios and to allow for a consistent approach to the risk assessment and risk management for these uses.

This document presents the proposed regulatory decision for the re-evaluation of sodium omadine, used as a preservative in paints, coatings and related uses, including the proposed risk mitigation measures to further protect human health, as well as the science evaluation on which the proposed decision was based. All products registered in Canada containing sodium omadine for use as a preservative in paints, coatings and related uses are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public, including the pesticide manufacturers and stakeholders, may submit written comments and additional information to Health Canada. The final re-evaluation decision will be published taking into consideration the comments and information received.

Sodium omadine is used as an "in-can" preservative of latex emulsions used in adhesives, caulks, patching compounds, sealants, paints and grouts against bacterial and fungal contamination and spoilage. All other registered uses of sodium omadine (that is, the preservation of aqueous based metalworking, cutting, cooling and lubrication fluids and fluid concentrates; and gypsum wallboards) were evaluated separately (Re-evaluation Decision RVD2018-06, *Sodium Omadine and Its Associated End-use Product*).

Outcome of Science Evaluation

With respect to human health, risks of concern were identified for primary handlers (industrial manufacturers) handling sodium omadine as a material preservative and for secondary handlers (professional and residential) using sodium omadine treated products. Therefore, mitigation measures for primary handlers (that is, closed transfer system) and secondary handlers (that is, rate reductions for all uses) are proposed.

Proposed Regulatory Decision for Sodium Omadine

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing sodium omadine used as a material preservative are acceptable for continued registration in Canada, provided that the proposed risk mitigation measures are in place.

Human Health

To mitigate risks to primary handlers (mixers/loaders) manufacturing latex paints and building materials (caulks, sealants, grouts, patching compounds and adhesives):

- Closed transfer systems are required for the commercial-class liquid product.

To mitigate risks to secondary handlers (professional and residential) applying latex paints using a brush and roller or an airless sprayer:

- Reduce the registered label rate to 0.058 g a.i./kg.

To mitigate risks to secondary handlers (professional and residential) applying building materials (caulks, sealants, grouts, patching compounds and adhesives) using a brush and roller:

- Reduce the registered label rate to 0.224 g a.i./kg for caulks and sealants; and
- Reduce the registered label rate to 0.196 g a.i./kg for all other building materials.

Rate reductions for all paint-related uses have been proposed in order to mitigate risks. The current label rate calls for a dosage of up to 1600 ppm of product to inhibit bacterial growth in latex emulsions; equivalent to up to 0.648 g a.i./kg latex emulsion. Value[1] information is required to confirm the acceptability of the proposed rate reductions for sodium omadine in paint (0.058 g a.i./kg) and building materials (0.224 g a.i./kg for caulks and sealants; 0.196 g a.i./kg for all other building materials). If value information is not received or if information does not demonstrate value, all paint and paint-related uses will be cancelled.

International Context

Sodium omadine is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the United States and Mexico. No decision by an OECD-member country to prohibit all uses of sodium omadine for health or environmental reasons has been identified.

[1] As defined in the *Pest Control Products Act*, value, in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.

Next Steps

The public, including the registrants and stakeholders, are encouraged to submit additional information that could be used to refine risk assessments during the 90-day public consultation period[2] upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,[3] which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Additional Scientific Information

Risks were not shown to be acceptable for sodium omadine used as a material preservative in paint and paint-related products (that is, building materials) at the current label rate; therefore, a rate reduction is proposed for all paint and paint-related uses. Value information is required for the proposed rate reductions for all paint and paint-related uses in order to maintain registration of sodium omadine products; failure to provide information or to demonstrate value of the proposed rate reductions will result in cancellation of sodium omadine products used as material preservatives in paint and paint-related products.

Additionally, during the consultation period, the registrants and other stakeholders may consider submitting the following information that may address uncertainties in the available information database of sodium omadine and support refined risk assessment. In addition, stakeholders may consider providing information on risk management options for sodium omadine (for example, additional PPE, engineering controls).

The evaluation of any additional data would be based on the scientific merit and relevance to the risk assessment. While additional data may reduce uncertainty in the risk assessment, continued registration of any uses would be based on the acceptability of risk assessed using a science-based approach.

Additional detailed use description information that may allow further refinement of the risk assessment:

- Refined daily amounts of paint manufactured and treated with preservatives in Canada
- Actual daily amounts of paint-related uses/building materials treated with preservatives and handled by professional secondary handlers

[2] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[3] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Sodium omadine is used as an "in-can" preservative of latex emulsions used in adhesives, caulks, patching compounds, sealants, paints and grouts. All other registered uses of sodium omadine (that is, the preservation of aqueous based metalworking, cutting, cooling and lubrication fluids and fluid concentrates; and gypsum wallboards) were evaluated separately (Proposed Re-evaluation Decision PRVD2016-12, *Sodium Omadine*; Re-evaluation Decision RVD2018-06, *Sodium Omadine and Its Associated End-use Product*). Only human health (exposure) and value assessments related to the use of sodium omadine as a material preservative are presented herein; these assessments replace those previously presented in PRVD2016-12 for this specific use. Environmental exposure from this use is expected to be minimal.

Appendix I lists all sodium omadine products that are registered for use as material preservatives under the authority of the *Pest Control Products Act*.

2.0 Human Health Assessment

2.1 Toxicology Summary

See PRVD2016-12 and RVD2018-06.

2.2 Dietary Exposure and Risk Assessment

There are no food uses associated with the preservative uses of sodium omadine; therefore, no dietary exposure is anticipated.

2.3 Exposure from Drinking Water

Residues of sodium omadine in potential drinking water sources are not anticipated as a result of the preservative uses.

2.4 Residential and Occupational Exposure and Risk Assessment

Residential and occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

2.4.1 Toxicology Reference Values for Occupational and Residential Risk Assessment

See PRVD2016-12.

Dermal Absorption

As the dermal toxicological reference value is based on a dermal developmental toxicity study, the dermal absorption value is not required.

2.4.2 Residential Exposure and Risk Assessment

Residential risk assessment involves estimating risks to the general population, including youth and children, during or after pesticide application.

A residential applicator assessment for the sodium omadine preservative itself was not required since there are no registered domestic-class pesticide products for paint-related material preservatives. Residential handling of paint-related material preserved with sodium omadine is considered a postapplication scenario.

The following postapplication scenarios were assessed:

- Individuals applying paints and building materials (caulks, sealants, grouts, patching compounds, latex emulsions and adhesives) preserved with sodium omadine; and
- Individuals who contact surfaces treated with paints and surfaces to which building materials preserved with sodium omadine have been applied.

2.4.2.1 Residential Postapplication Exposure and Risk Assessment

Residential postapplication exposure occurs when an individual is exposed through dermal, inhalation and/or incidental oral (non-dietary ingestion) routes as a result of handling a product that has been treated with a pesticide, or being in a residential environment that has been previously treated with a pesticide.

There is potential for short-term exposure for residential handlers (≥16 years old) applying products preserved with sodium omadine. The following scenarios were assessed:

- Applying paints with paint brush and roller;
- Applying paints with an airless sprayer;
- Applying building materials; and
- Dermal contact with painted surfaces and surfaces to which building materials were applied.

Paint Uses

Chemical-specific exposure data were not available for sodium omadine for the painting scenarios. However, a brush and roller study (PMRA# 2849401) and an airless sprayer study (PMRA# 3003682) were submitted by the Antimicrobial Exposure Assessment Task Force II (AEATF II).

The brush and roller study was designed to quantify dermal and inhalation exposures to both occupational and residential painters while applying paint, containing an antimicrobial, using a brush or roller. The study monitored 18 test subjects using a brush and/or roller in six identical rooms in a warehouse space. The surrogate non-volatile active ingredient used in this study was 1,2-benzisothiazolin-3-one (BIT). The total amount of paint handled (8.520 to 9.940 kg), the time spent while painting (48 to 172 min), and the surface area painted (25 to 82.5 m^2), were all measured. Dermal exposures were measured using inner and outer cotton whole body dosimeters, painter's hat, hand washes (all subjects did not wear gloves) and face and neck wipes. Inhalation exposures were measured using air sampling tubes. Separate dermal unit exposure values were generated for residential painters wearing a short-sleeved shirt and shorts and for occupational workers wearing a long-sleeved shirt, long pants and no gloves. The inhalation unit exposure values for both occupational and residential handlers were generated for each individual performing light activities. The total dermal and inhalation unit exposure values were presented as geometric means based on the arithmetic mean (AMu) of all test subjects.

The airless sprayer study was designed to quantify exposure to painters using airless sprayers. The study monitored 18 test subjects divided into 3 groups based on volume of paint sprayed (37.9 L, 56.8 L and 114 L). The surrogate active ingredient used in this study was propiconazole (PON). Within each group, subjects were subdivided into groups based on dose concentration (0.12% PON or 1.2% PON). All test subjects were occupational painters who had experience painting and handling airless sprayer equipment. The study was conducted in a warehouse facility constructed into three separate modules representing two residential spaces and one commercial office space. All subjects were required to open paint buckets, strain and pour the paint into the equipment and apply paint to the walls, ceiling and other surfaces of the modules. Test subjects wore a long-sleeved shirt and long pants over a 100% cotton dosimeter, as well as a half-face respirator, goggles, shoes and a painter's hat over a dosimeter placed on their head. The test subjects did not wear gloves. Dermal deposition was corrected to account for skin protected by a half-face respirator and goggles. Separate dermal unit exposure values were generated for residential painters wearing a short-sleeved shirt and shorts and for occupational workers wearing a long-sleeved shirt, long pants and no gloves. The inhalation unit exposure values for both occupational and residential handlers were generated for each individual performing light activities. The total dermal and inhalation unit exposure values were presented as the AMu of all test subjects. There were a number of limitations with the study; however, these did not preclude the use of this study to establish unit exposure values for painting with airless sprayers.

The unit exposure values from the brush and roller, and airless sprayer studies, were combined with the default amounts of paint handled per day from the USEPA 2012 Residential SOP (PMRA# 2409268), where a residential painter may apply up to two 1-gallon cans (7.58 L total) daily when using a brush and roller and approximately three 5-gallon cans (56.7 L total) when using an airless sprayer.

The unit exposure values from these studies, assuming the clothing scenario of a residential handler to be shorts and a short-sleeved shirt, were combined with the default amounts handled. Calculated dermal MOEs did not meet the target MOEs when applying paint using a brush and roller or an airless sprayer; therefore, risks were not shown to be acceptable. To mitigate this risk, it is proposed that the registered rate of sodium omadine in paints be reduced to 0.058 g a.i./kg. See Appendix II, Table 1 for more information.

To determine the potential transfer of preservative residues from a painted surface, transferable residue studies (PMRA#s 2967976 and 2883917) were submitted by the AEATF II. The studies demonstrated that the transfer of residues onto the skin following contact with a painted surface is minimal. Hence exposure to sodium omadine is expected to be negligible. Based on the findings of these studies, a quantitative residential postapplication risk assessment for contact with a treated surface for sodium omadine used in paint was not required and is considered acceptable.

Building Materials

In the case of building materials, no use description information was provided. Therefore, the default amount of paint handled per day by a residential painter (7.58 L) was used as a surrogate for the amount of building materials handled. Likewise, in the absence of a scenario-specific exposure study, the total body unit exposure values from the brush and roller study were used as a surrogate for applying building materials (except caulks and sealants). For caulks and sealants, where the majority of the exposure is limited to the hands, in comparison to the exposure from applying other building materials (for example, adhesives, grouts), only the unit exposure values for the hands from the brush and roller study were considered in the risk assessment.

Using the appropriate unit exposure values from the brush and roller study, assuming the clothing scenario to be shorts and a short-sleeved shirt, together with the default amounts handled, calculated MOEs for residential handlers applying building materials met the target MOE when the registered rate of sodium omadine in caulks and sealants was reduced to 0.224 g a.i./kg and to 0.196 g a.i./kg for all other building materials. See Appendix II, Table 2 of more information.

The likelihood of sodium omadine to leach out of dried adhesives, caulks, grouts, sealants and patching compounds is expected to be very limited. This is further supported by the paint transferable residue studies, which demonstrated that the transfer of residues onto the skin following contact with a painted surface is minimal. Therefore transfer of, and dermal postapplication exposure to, sodium omadine residues is expected to be minimal.

Bystander Exposure

Bystander exposure is expected to be negligible for the preservative uses of sodium omadine.

2.4.3 Occupational Exposure and Risk Assessment

There is potential for exposure to sodium omadine in occupational scenarios when workers handle the pesticide during the mixing and loading process in industrial (manufacturing) settings, and for postapplication exposure to workers handling products treated with sodium omadine.

2.4.3.1 Mixer, Loader and Applicator Exposure and Risk Assessment

There is potential for exposure to sodium omadine in occupational scenarios in industrial settings when workers handle the commercial-class sodium omadine product during the mixing and loading process to manufacture paints and building materials (adhesives, caulks, patching compounds, sealants and grouts).

Exposure to sodium omadine from its use in manufacturing facilities is expected to be long-term in duration (that is, >180 days), via the dermal and inhalation routes.

The commercial class product registered for use in the manufacturing of paints and building materials is formulated as a liquid/solution. Therefore, the following scenario was assessed:

- Mixing/transfer of liquids, open pour

Chemical-specific exposure data were not available for sodium omadine for this scenario. However, a liquid pour exposure study (PMRA#s 2296582 and 2296584) was submitted by the AEATF II.

This liquid pour study was designed to determine the dermal and inhalation exposures to occupational workers during manual open pouring of a non-volatile liquid containing an antimicrobial product.

Three different liquid pouring scenarios were considered in the study: use of conventional containers with no design modifications, reduced-splash or “no-glug” containers, and pouring into a trigger spray bottle. The trigger spray bottle scenario was not considered relevant to paint-related manufacturing. Two non-volatile active ingredients, formulated as soluble concentrates, didecyl dimethyl ammonium chloride (DDAC) and C^{14}-alkyl dimethyl benzyl ammonium chloride (C^{14}-ADBAC) were used. The conventional and reduced-splash container scenarios included pouring a range of various amounts of active ingredient handled at different heights using various sized pouring and receiving containers. In this study, 18 subjects that performed 36 monitoring events (MEs) using the two surrogate active ingredients were monitored for dermal and inhalation exposures. Eighteen MEs poured DDAC, and eighteen MEs poured C^{14}-ADBAC. Each subject performed two MEs, one for pouring from a conventional container and the second from a reduced-splash container.

Container sizes were based on the typical product containers currently in the market. To account for different pouring heights, the receiving containers were placed randomly either on a table or on the floor. The receiving container sizes were variable and ranged from 3.785 or 7.571 L buckets to 189 L low-walled plastic troughs.

Subjects wore inner and outer cotton dosimeters. An air sampling pump was attached to the belt of the subject, and an OVS air sampling tube was placed in the subject’s breathing zone. The face and the neck were wiped with gauze and exposure to the rest of the head was extrapolated based on the ratio of the surface area of the face/neck to that of the rest of the head (all subjects were provided with safety glasses). Hand washes were conducted following the removal of the gloves;

residues on the chemical-resistant gloves were not quantified. Total dermal exposure was calculated by summing the residues on the inner and outer dosimeters (based on the clothing scenario), face/neck wipes and hand wash samples for each monitoring event (ME). Inhalation unit exposure values were generated for workers performing light activity, not wearing respiratory protection.

To assess occupational exposure for scenarios where individuals handled conventional and reduced-splash containers, dermal unit exposure values were generated based on a single layer (long-sleeved shirt and long pants) plus chemical-resistant gloves. However, unit exposure values could not be generated for different levels of personal protective equipment, as exposure to the body was already minimal and below the level of quantification for most MEs. Therefore, adding additional protective equipment is not expected to significantly change exposure. The total dermal and inhalation unit exposure values for pouring from conventional containers and reduced-splash containers were presented as the AMu.

The unit exposure values from the liquid open pour study were combined with the default amounts of paint (also used as surrogate for building materials) treated per day by workers in manufacturing facilities to estimate exposures. The amounts of paint treated per day were based on the USEPA Antimicrobial Division Draft Summary of Amounts Handled or Treated for Occupational Handler Scenarios[4], where it was assumed that facilities may treat up to 7571 L (9388 kg based on paint density of 1.24 kg/L) of paint per day.

Calculated dermal MOEs for mixing/transfer of a liquid did not reach the target MOE and, therefore, risks were not shown to be acceptable. To mitigate this risk, it is proposed that a closed transfer system be used for handling the commercial-class liquid product. Appendix III, Table 1 summarizes the calculated MOEs for mixers/loaders.

2.4.3.2 Postapplication Worker Exposure and Risk Assessment

Downstream postapplication workers in industrial settings are expected to be wearing PPE as required by law under occupational health and safety, which would limit potential exposure. Furthermore, the use of sodium omadine as an in-can preservative of latex emulsions used in paints and building materials is limited to mixing, which is largely automated. Therefore, a quantitative risk assessment for downstream workers in industrial facilities involved with the manufacturing of paints and building materials (adhesives, caulks, patching compounds and sealants) was not conducted.

Exposure (professional secondary handlers) to sodium omadine-treated paints and building materials (adhesives, caulks, patching compounds and sealants) were the postapplication occupational scenarios assessed in this review.

[4] PMRA# 3084493. USEPA (2018). Summary of Amounts Handled or Treated for Occupational Handler Scenarios. EPA: Washington, DC.

Paint Uses

There is potential exposure for professional painters applying paint preserved with sodium omadine.

Exposure to sodium omadine in paint is expected to be long-term in duration (that is >180 days), via the dermal and inhalation routes.

Based on the use pattern, the following major scenarios were identified for professional painters:

- Applying paint using paint brush and roller; and
- Applying paint using an airless sprayer.

The unit exposure values from the above brush and roller and airless sprayer exposure studies were combined with the default amounts of paint applied per day: 18.7 L per day (equivalent to 23.19 kg, based on paint density of 1.24 kg/L) using a brush and roller (2001 PMRA survey) and 120 L per day (equivalent to 232.5 kg, based on paint density of 1.24 kg/L) using an airless sprayer (PMRA#2992785).

Calculated dermal MOEs did not meet the target MOEs when professional painters used a brush and roller or airless sprayer. To mitigate these risks, it is proposed to reduce the label rate for paints to 0.058 g a.i./kg. Appendix III, Table 2 summarizes the calculated MOEs for professional painters.

Based on the findings of the paint transferable residue study, a quantitative occupational postapplication risk assessment for professional secondary handlers contacting treated surfaces for sodium omadine used in paint was not required.

Building Materials

In the case of building materials, no use description information was provided. Therefore, the default amount of paint handled per day by a professional painter (18.7 L or 23.19 kg) was used as a surrogate for the amount of building materials handled. Likewise, in the absence of a scenario-specific exposure study, the total body unit exposure values from the brush and roller study were used as a surrogate for applying building materials (except caulks and sealants).

For caulks and sealants, where the majority of the exposure is limited to the hands, in comparison to the exposure from applying other building materials (for example, grouts and adhesives), only the unit exposure values for the hands from the brush and roller study were considered for the risk assessment.

Using the appropriate unit exposure values from the brush and roller study, assuming the clothing scenario to be a long-sleeved shirt and long pants, together with the default amount handled, calculated MOEs for workers applying all building materials did not meet the target MOEs. To mitigate these risks, it is proposed to reduce the label rates to 0.224 g a.i./kg for caulks and sealants and 0.196 g a.i./kg for all other building materials. See Appendix III, Table 3 for more information.

The likelihood of sodium omadine to leach out of dried adhesives, caulks, grouts, sealants and patching compounds is expected to be very limited. This is further supported by the paint transferable residue studies, which demonstrated that the transfer of residues onto the skin following contact with a painted surface is minimal. Therefore transfer of, and dermal postapplication exposure to, sodium omadine residues is minimal and considered to be acceptable.

2.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

There are no registered sodium omadine food uses, nor is it used in products designed for food packaging materials or in areas where food is stored, handled or processed. Therefore, an aggregate exposure and risk assessment is not required.

2.6 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative effects of pest control products that have a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify a common mechanism of toxicity for sodium omadine and other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

2.7 Incident Reports

As of 20 December 2019, no human or domestic animal incidents involving sodium omadine as a material preservative were submitted to the PMRA.

3.0 Value Assessment

Sodium omadine is registered as a material preservative in aqueous based products. It is incorporated into products during manufacturing, to provide protection from bacterial and fungal degradation.

This active ingredient is effective at controlling the various micro-organisms responsible for degrading paints, caulks, grouts, adhesives, latex emulsions, and other aqueous based products when used as currently directed on the registered product labels.

Protection of these products is important to industry as degradation of the products can lead to a failure of the product to perform its intended purpose, discoloration, odour formation or other complications arising from bacterial or fungal growth in the aqueous solutions.

4.0 Conclusion of Science Evaluation

4.1 Human Health

With respect to human health, the health risks associated with the use of sodium omadine and associated end-use product in the manufacturing (primary handlers) and use (secondary handlers) of paints and building materials are shown to be acceptable with the proposed mitigation measures for these uses, including the reduction of the registered application rate (see proposed revised label directions under Appendix IV).

4.2 Value

Sodium omadine is used to control bacterial and fungal degradation in a variety of aqueous based products, including latex based paints/emulsions and other building materials in order to prevent deleterious effects imposed on the product by the degrading organisms. Alternatives are available for industry to utilize.

List of Abbreviations

µg	microgram
% w/w	percent weight per weight, concentration of solute in solution
ADBAC	alkyl dimethyl benzyl ammonium chloride
AEATF II	Antimicrobial Exposure Assessment Task Force II
a.i.	active ingredient
AMu	geometric mean based on the arithmetic mean
BIT	1,2-benzisothiazolin-3-one
bw	body weight
DDAC	didecyl dimethyl ammonium chloride
g	gram(s)
kg	kilogram(s)
L	litre(s)
m	metre(s)
m^2	square metres
ME	monitoring event
mg	milligram(s)
min	minute(s)
mL	millilitre(s)
MOE	margin of exposure
NOAEL	no observed adverse effect level
OVS	OSHA Versatile Sampler
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
Resp	respirator
REV	Re-evaluation Note
RVD	Re-evaluation Decision
USEPA	United States Environmental Protection Agency

Appendix I Products Used as Preservatives in Paints, Coatings and Related Uses

Table 1 Sodium Omadine Products Used as Preservatives in Paints, Coatings and Related Uses, as of 7 January 2020.

Registrant	Registration Number	Product Name	Marketing Class
Arch Chemicals, Inc	29714	SODIUM OMADINE 40% TECHNICAL	T
	24098	SODIUM OMADINE 40% AQUEOUS SOLUTION INDUSTRIAL FUNGICIDE & BACTERICIDE	C
Troy Chemical Corporation	32939	PYRITHIONE 40 MUP	T

T = technical grade active ingredient; C = commercial;
Note: Discontinued products and products with submissions for discontinuation not included.

Appendix II Non-Occupational (Residential) Risk Assessment

Table 1 Residential Painting Exposure and Risk Assessment (Short-Term)

Scenario	Application rate (g a.i./kg paint)[a]	Amount handled per day (g a.i./day)[b]	Unit exposure value[c] (µg/kg a.i.)		Daily exposure[d] (mg/kg bw/day)		Margin of exposure (MOE)[e]	
			Dermal	Inhalation	Dermal	Inhalation	Dermal[f]	Inhalation[g]
Shorts, short-sleeved shirt, no gloves								
Brush and roller	0.648	6.09	237445	17.3	0.018	0.000001	166	213346
	0.058	0.54	237445	17.3	0.0016	0.0000001	1857	2387087
Airless sprayer	0.648	45.56	196244	2169	0.157	0.001	19	227
	0.058	4.07	196244	2169	0.0010	0.00011	300	2545

Shaded cells indicate where the MOE is less than the target MOE (dermal: 300; inhalation: 100)

[a] Application rate = Product application rate (0.16% [registered] and 0.0143% [max rate at which MOEs are shown to be acceptable] w/w for paint) × a.i. guarantee × CF (1000 g/kg)

[b] Amount handled per day for each type of painting equipment = Application rate × amount of paint applied/day (7.58 L using brush and roller and 56.7 L using airless sprayer) × paint density (1.24 kg/L)

[c] Unit exposure values from AEATF II brush and roller and airless sprayer studies

[d] Daily exposure = [Maximum amount handled per day × Unit exposure value × CF (1 mg/1000 µg) × CF (1 kg/1000 g) × Absorption]/80 kg bw. Absorption not required for dermal exposure; 100% absorption for inhalation exposure.

[e] MOE = NOAEL/Dermal or Inhalation daily exposure

[f] Dermal NOAEL of 3 mg/kg bw/day from a rat dermal toxicology study and target MOE of 300.

[g] Inhalation NOAEL of 0.281 mg/kg bw/day from a rat inhalation study and target MOE of 100.

Table 2 Residential Exposure and Risk Assessment from Handling Building Materials (Short-Term)

Scenario	Product Type	Application rate (g a.i./kg product)[a]	Amount handled per day (g a.i./day)[b]	Unit exposure value[c] (µg/kg a.i.)		Daily exposure[d] (mg/kg bw/day)		Margin of exposure (MOE)[e]	
				Dermal	Inhalation	Dermal	Inhalation	Dermal[f]	Inhalation[g]
Shorts, short-sleeved shirt, no gloves									
Brush and roller	Caulks and sealants	0.648	6.09	154209	17.30	0.0117	0.000001	256	213346
		0.224	2.11	154209	17.30	0.0041	0.0000005	739	617276
	Other building materials	0.648	6.09	237445	17.3	0.0181	0.000001	166	213346
		0.196	1.85	237445	17.30	0.0055	0.0000004	547	703822

Shaded cells indicate where the MOE is less than the target MOE (dermal: 300; inhalation: 100)

[a] Application rate = Product application rate (0.16% w/w [registered] for all building materials; 0.0553% w/w for caulks and sealants or 0.0485% w/w for other building materials [max rates at which MOEs are shown to be acceptable]) × a.i. guarantee × CF (1000 g/kg)

[b] Amount handled per day for each type of building material = Application rate × amount of building materials applied/day (7.58 L using brush and roller) × paint density (1.24 kg/L; surrogate for building materials)

[c] Unit exposure values from AEATF II brush and roller study

[d] Daily exposure = [Amount handled per day × Unit exposure values × Absorption × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw. Absorption not required for dermal exposure; 100% absorption for inhalation exposure.

[e] MOE = NOAEL/Dermal or Inhalation daily exposure

[f] Dermal NOAEL of 3 mg/kg bw/day from a rat dermal toxicology study and target MOE of 300.

[g] Inhalation NOAEL of 0.281 mg/kg bw/day from a rat inhalation study and target MOE of 100.

Appendix III Occupational Risk Assessment

Table 1 Occupational Long-Term Industrial Exposure and Risk Assessment for Use of Sodium Omadine in Manufacturing Facilities Using Liquid, Open Pour Scenario

Use	Application rate (g a.i./kg product)[a]	Amount handled per day (g a.i./day)[b]	Unit exposure values[c] (µg/kg a.i.)		Daily exposures[d] (mg/kg bw/day)		Margin of Exposure (MOE)[e]	
			Dermal	Inhalation	Dermal	Inhalation	Dermal[f]	Inhalation[g]
Chemical-resistant coveralls over single layer, chemical-resistant gloves								
All uses	0.648	6083	1922	5.08	0.146	0.0004	21	727
Paint	0.058	544	1922	5.08	0.013	0.00003	230	8134
Caulks and sealants	0.224	2102	1922	5.08	0.051	0.0001	60	2103
Other building materials	0.196	1844	1922	5.08	0.044	0.0001	68	2398

Shaded cells indicate where the MOE is less than the target MOE (dermal: 300; inhalation: 100)

[a] Application rate = Product application rate (0.16% w/w [registered] for all uses; 0.0143% w/w for paint, 0.0553% w/w for caulks and sealants, and 0.0485% w/w for other building materials [max rates at which MOEs are shown to be acceptable]) × a.i. guarantee × CF (1000 g/kg)

[b] Amount handled per day for each use = Application rate × amount of paint or building materials treated/day (7571 L) × paint density (1.24 kg/L; surrogate for building materials)

[c] Unit exposure values from AEATF II liquid, open pour study

[d] Daily exposure = [Amount handled per day × Unit exposure value × Absorption × CF (1 mg/1000 µg) × CF (1 kg/1000 g)] /80 kg bw. Absorption not required for dermal exposure; 100% absorption for inhalation exposure.

[e] MOE = NOAEL/Dermal or Inhalation daily exposure

[f] Dermal NOAEL of 3 mg/kg bw/day from a rat dermal toxicology study and target MOE of 300.

[g] Inhalation NOAEL of 0.281 mg/kg bw/day from a rat inhalation study and target MOE of 100.

Table 2 Professional Painter Long-Term Exposure and Risk Assessment

Scenario	Application rate (g a.i./kg product)[a]	Amount handled per day (g a.i./day)[b]	Unit exposure value[c] (µg/kg a.i.)		Daily exposure[d] (mg/kg bw/day)		Margin of Exposure (MOE)[e]	
			Dermal	Inhalation	Dermal	Inhalation	Dermal[f]	Inhalation[g]
Single layer, no gloves								
Brush and roller	0.648	15.0	175871	17.3	0.033	0.00003	91	86479
	0.058	1.34	175871	17.3	0.003	0.0000003	1016	967600
Airless sprayer	0.648	96.4	65937	2169	0.080	0.0026	38	107
	0.058	8.62	65937	2169	0.0071	0.00023	422	1203

Shaded cells indicate where the MOE is less than the target MOE (dermal: 300; inhalation: 100)

[a] Application rate = Product application rate (0.16% w/w [registered] and 0.0143% w/w [max rate at which MOEs are shown to be acceptable]) × a.i. guarantee × CF (1000 g/kg)

[b] Amount handled per day for each type of painting equipment = Application rate × maximum amount of paint applied/day (7.58 L using brush and roller and 120 L for airless sprayer) × paint density (1.24 kg/L)

[c] Unit exposure values from AEATF II brush and roller and airless sprayer studies

[d] Daily exposure = [Amount handled per day × Unit exposure values × Absorption × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw. Absorption not required for dermal exposure; 100% absorption for inhalation exposure.

[e] MOE = NOAEL/Dermal or Inhalation daily exposure

[f] Dermal NOAEL of 3 mg/kg bw/day from a rat dermal toxicology study and target MOE of 300.

[g] Inhalation NOAEL of 0.281 mg/kg bw/day from a rat inhalation study and target MOE of 100.

Table 3 Professional Worker Long-Term Exposure and Risk Assessment from Handling Building Materials

Scenario	Product Type	Application rate (g a.i./kg product)[a]	Amount handled per day (g a.i./day)[b]	Unit exposure value[c] (µg/kg a.i.)		Daily exposure[d] (mg/kg bw/day)		Margin of exposure (MOE)[e]	
				Dermal	Inhalation	Dermal	Inhalation	Dermal[f]	Inhalation[g]
Single layer, no gloves									
Brush and roller	Caulks and sealants	0.648	15.03	154209	17.3	0.0290	0.000003	104	86479
		0.224	5.19	154209	17.3	0.0100	0.000001	300	25021
	Other building materials	0.648	15.03	175871	17.3	0.0330	0.000003	91	86479
		0.196	4.55	175871	17.3	0.0100	0.000001	300	285292

Shaded cells indicate where the MOE is less than the target MOE (dermal: 300; inhalation: 100)

[a] Application rate = Product application rate (0.16% w/w [registered] for all building materials; 0.0553% w/w for caulks and sealants or 0.0485% w/w for other building materials [max rates at which MOEs are not of concern]) × a.i. guarantee × CF (1000 g/kg)

[b] Amount handled per day for each type of building material = Application rate × amount of building materials applied/day (18.7 L using brush and roller) × paint density (1.24 kg/L; surrogate for building materials)

[c] Unit exposure values from AEATF II brush and roller study

[d] Daily exposure = [Amount handled per day × Unit exposure values × Absorption × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw. Absorption not required for dermal exposure; 100% absorption for inhalation exposure.

[e] MOE = NOAEL/Dermal or Inhalation daily exposure

[f] Dermal NOAEL of 3 mg/kg bw/day from a rat dermal toxicology study and target MOE of 300.

[g] Inhalation NOAEL of 0.281 mg/kg bw/day from a rat inhalation study and target MOE of 100.

Appendix IV Proposed Label Amendments for End-Use Products Containing Sodium Omadine

Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

1. Proposed Label Amendments for Commercial Class End-use Products Containing Sodium Omadine

Label must indicate:

- Product is only for use in a closed transfer system.
- Maximum permissible rates:
  - Paint: 0.058 g a.i./kg
  - Caulks and sealants: 0.224 g a.i./kg
  - All other building materials (for example, patching compounds, adhesives, grouts): 0.196 g a.i./kg

References

A. Information Considered for the Occupational and Residential Assessment

Published Information

PMRA Document Number	Reference
2409268	USEPA (2012a). Standard Operating Procedures for Residential Pesticide Exposure Assessment. EPA: Washington, DC. Revised October 2012. Section 10.

AEATF II Studies:

PMRA Document Number	Reference
2296582	A Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of a Liquid Containing an Antimicrobial. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA05.
2849401	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting. Antimicrobial Exposure Assessment Task Force II (AEATF II), Washington, DC. January 31, 2018. (AEATF II) Project ID: AEA09.
3003682	A Study for Measurement of Potential Dermal and Inhalation Exposure During the Application of Paint Containing an Antimicrobial using an Airless Sprayer. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA10.
2967976	Analysis of Propiconazole Used as an In-Can Paint Preservative in Wall Wipe Samples Collected from Dried Paint During An Airless Paint Monitoring Study. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II (AEATF II). (AEATF II) Project ID: AEA10.
2883917	Analysis of 1,2-Benzisothiazolin-3-one (BIT) in Background Wall Wipe Samples from Indoor Wall Surfaces Painted with Latex Paint Using a Brush and Roller (Non-GLP). Antimicrobial Exposure Assessment Taskforce II (AEATF II), Washington, DC. (AEATF II) Project ID: AEA19.
2296584	A Study for Measurement of Potential Dermal and Inhalation Exposure During Manual Pouring of a Liquid Containing an Antimicrobial. Supplemental Report – Supplement 1, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA05.
2992785	2017, Study Design: A Study for Measurement of Potential Dermal and Inhalation Exposure During the Application of Paint Containing an Antimicrobial using an Airless Sprayer. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA10.