Re-evaluation Decision RVD2022-15

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

Final Decision

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Re-evaluation decision for sodium omadine and associated end-use products, used as a preservative in paints, coatings and related uses

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA), on behalf of the Minister of Health, to ensure that they continue to have acceptable risk to human health and the environment, and have acceptable value. The re-evaluation considers available data and information[1] from pesticide registrants, published scientific reports, existing assessments, other governments, and international regulatory authorities, as well as comments received during public consultations. Health Canada applies internationally accepted current risk assessment methods as well as risk management approaches and policies. More details, on the legislative framework, risk assessment and risk management approach, are provided under the section of Evaluation Approach of this document.

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. In the absence of scenario-specific data, paint studies/data were used as surrogates for the assessment of building materials and adhesives.

Sodium omadine is used as an "in-can" preservative of latex emulsions used in adhesives, caulks, patching compounds, sealants, paints and grouts against bacterial 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*). Currently registered products for use as a material preservative containing sodium omadine can be found in the Pesticide Product Information Database and in Appendix I.

The Proposed Re-evaluation Decision PRVD2020-03, *Sodium Omadine and Its Associated End-use Products, Used as a Preservative in Paints, Coatings and Related Uses*[2] containing the evaluation of the material preservative uses of sodium omadine and proposed decision, was published on 9 July 2020 for a 90-day consultation period. An additional 60 days for consultation was provided in response to requests from stakeholders to accommodate time constraints

[1] Canada. Health Canada. *Information Note – Determining Study Acceptability for use in Pesticide Risk Assessments*. Ottawa, 2019. (Internet: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/determining-study-acceptability-pesticide-risk-assessments.html; cited October 2022.)

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

imposed by pandemic measures; the 150-day consultation period ended on 6 December 2020. PRVD2020-03 proposed continued registration with mitigation measures for primary handlers (that is, closed transfer systems) and secondary handlers (that is, rate reductions for all uses).

Health Canada received comments and information relating to the health and value assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. Commenters are listed in Appendix II. These comments are summarized in Appendix III along with the responses by Health Canada. The information resulted in a revision to the value assessment (see Science Evaluation Update), and resulted in a change to the proposed re-evaluation decision as described in PRVD2020-03.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2020-03; and additional efficacy information used in the re-evaluation decision is listed in Appendix V of this document. Therefore, the complete reference list of all information used in this final re-evaluation decision includes both the information set out in PRVD2020-03 and the information set out in Appendix V herein.

This document presents the final re-evaluation decision[3] for the material preservative uses of sodium omadine, including the required amendments (risk mitigation measures) to protect human health, as well as label amendments required to bring labels to current standards. Environmental exposure from the material preservative use of sodium omadine is expected to be minimal. All products containing sodium omadine for use as a material preservative that are registered in Canada are subject to this re-evaluation decision.

Re-evaluation decision for sodium omadine as a preservative in paints, coatings and related uses

Health Canada has completed the re-evaluation of the material preservative uses of sodium omadine. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of all products containing sodium omadine is acceptable with mitigation measures. An evaluation of available scientific information found that the material preservative use of sodium omadine meets current standards for protection of human health and has acceptable value when used according to revised conditions of registration, which includes new mitigation measures. Label amendments, as summarized below and listed in Appendix IV, are required.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required amendments, including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of the material preservative use of sodium omadine, are summarized below. Refer to Appendix IV for details.

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

Human health – Risk Mitigation

The following risk-reduction measures are required for continued registration of sodium omadine in Canada:

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):

- 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.

To align efficacy claims on registered end-use product labels with supporting data:

- Remove any reference to the duration of antibacterial efficacy for preservation of paints and other building materials from the end-use product labels.

Next steps

Pest control products requiring label amendments

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry. Health Canada has determined that the identified risks from the use of sodium omadine as a material preservative under the current conditions of use were from longer-term exposure durations and therefore, the potential risks to human health are considered acceptable during the 24-month time period required to implement the required mitigation measures.

Sodium omadine-treated articles

Information Note – Treated Articles[4] (September 2022) provides regulatory requirements for articles that have been treated with pesticides.

The import and sale of products treated with sodium omadine at the unamended label rate or with any antibacterial efficacy claims is permitted during the 24-month implementation period. However, after 24 months, the import and sale of products treated at the unamended label rate and/or with any efficacy claims will be prohibited; all products sold after 24 months must be treated at the new label rate and without any claims to the duration of antibacterial efficacy.

Refer to Appendix I for details on specific products affected by this decision.

Other information

Any person may file a notice of objection[5] regarding this decision on *Sodium Omadine and Its Associated End-use Products, Used as a Preservative in Paints, Coatings and Related Uses* within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact Health Canada's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2020-03 and Appendix V of this document) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact Health Canada's Pest Management Information Service.

4 Canada. Health Canada. *Information Note – Treated Articles*. Ottawa, 2022. (Internet: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/treated-articles.html; cited October 2022.)

5 As per subsection 35(1) of the *Pest Control Products Act*

Evaluation Approach

Legislative framework

The Minister of Health's primary objective under the *Pest Control Products Act* (or the Act) subsection 4(1) is to prevent unacceptable risks to individuals and the environment from the use of pest control products.

As noted in the preamble of the Act, it is in the national interest that the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses risks to human health, the environment and value both before and after registration and applies to the regulation of pest control products throughout Canada; and that pest control products with acceptable risk and value be registered for use only if it is shown that their use would be efficacious and if conditions of registration can be established to prevent unacceptable risks to human health and the environment.

For the purposes of the Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions of registration as per subsection 2(2) of the *Pest Control Products Act*.

Risk for the human health and environment, and value are defined under the Act subsection 2(1) as follows:

> **health risk**, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **environmental risk**, in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration
>
> **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.

When evaluating the health and environmental risks of a pesticide and determining whether those risks are acceptable, subsection 19(2) of the *Pest Control Products Act* requires Health Canada to apply a scientifically-based approach. The science-based approach to assessing pesticides considers both the toxicity and the level of exposure of a pesticide in order to fully characterize risk.

Risk and value assessment framework

Health Canada uses a comprehensive body of modern scientific methods and evidence to determine the nature as well as the magnitude of potential risks posed by pesticides. This approach allows for the protection of human health and the environment through the application of appropriate and effective risk management strategies, consistent with the purpose described in the preambular text set out above.

Health Canada's approach to risk and value assessment is outlined in A Framework for Risk Assessment and Risk Management of Pest Control Products.[6] A high-level overview is provided below.

i) Assessing Potential Health Risks

With respect to the evaluation and management of potential health risks, Health Canada's risk assessments follow a structured, predictable process that is consistent with international approaches and the Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks.[7]

The evaluation of potential health risks begins with a consideration of the toxicological profile of a pesticide to establish reference doses at which no adverse effect is expected and against which the expected exposure is assessed. This includes, where appropriate, the use of uncertainty (protection) factors to provide additional protection that accounts for the variation in sensitivity among members of human population and the uncertainty in extrapolating animal test data to humans. Under certain conditions, the *Pest Control Products Act* requires the use of another factor to provide additional protection to pregnant women, infants, and children. Other uncertainty factors, such as a database deficiency factor, are considered in specific cases. More details related to the application of the uncertainty factors are provided in SPN2008-01[8].

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6 Canada. Health Canada. *PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products, 2021* (Internet: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/risk-management-pest-control-products.html, cited October 2022).

7 Canada. *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks,* 2000 (Internet: https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html, cited October 2022)

8 Canada. Health Canada. Science Policy Note: *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*, 2008 (Internet: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2008/application-uncertainty-factors-pest-control-products-act-factor-human-health-risk-assessment-pesticides-spn2008-01.html, cited October 2022).

Assessments estimate potential health risks to defined populations[9] under specific exposure conditions. They are conducted in the context of the registered conditions of use, such as the use of a pesticide on a particular field crop using specified application rates, methods and equipment. Potential exposure scenarios consider exposures during and after application of the pesticide in occupational or residential settings, food and drinking water exposure, or exposure when interacting with treated pets. Also considered are the anticipated durations (short-, intermediate- or long-term) and routes of exposure (oral, inhalation, or skin contact). In addition, an assessment of health risks must consider available information on aggregate exposure and cumulative effects.

ii) Assessing risks to the environment

With respect to the evaluation of environmental risks, Health Canada's environmental risk assessments follow a structured, tiered approach to determine the likelihood that exposure to a pesticide can cause adverse effects on individual organisms, populations, or ecological systems. This involves screening assessments starting with simple methods, conservative exposure scenarios and sensitive toxicity effects metrics, then moving on, where required, to more refined assessments that can include exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods.

The environmental assessment considers both the exposure (environmental fate, chemistry, and behaviour, along with the application rates and methods) and hazard (toxic effects on organisms) of a pesticide. The exposure assessment examines the movement of the pesticide in soil, water, sediments and air, as well as the potential for uptake by plants or animals and transfer through the food web. The possibility for the pesticide to move into sensitive environmental compartments such as groundwater or lakes and rivers, as well as the potential for atmospheric transport, is also examined. The hazard assessment examines effects on a large number of internationally recognized indicator species of plants and animals (terrestrial organisms include invertebrates such as bees, beneficial arthropods, and earthworms, birds, mammals, plants; aquatic organisms include invertebrates, amphibians, fish, plants and algae), and includes considering effects on biodiversity and the food chain. Acute and chronic effects endpoints are derived from laboratory and field studies that characterize the toxic response and the dose–effect relationship of the pesticide.

The characterization of environmental risk requires the integration of information on environmental exposure and effects to identify which, if any, organisms or environmental compartments may be at risk, as well as any uncertainties in characterizing the risk.

[9] Consideration of Sex and Gender in Pesticide Risk Assessment, 2020 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/consideration-sex-gender-pesticide-risk-assessment-infographic.html, cited October 2022).

iii) Value assessment

Value assessments consist of two components: an assessment of the performance of a pest control product and its benefits.

During re-evaluation, value is examined under current conditions and in light of alternative pest control methods (both chemical and nonchemical) that may have been developed since the pesticide was first registered. An assessment of the benefits associated with the pesticide may also be conducted to demonstrate its value in the current context, and to identify potential alternatives.

Risk management

The outcomes of the assessments of risks to human health and the environment, and the assessment of value, form the basis for identifying risk management strategies. These include appropriate risk mitigation measures and are a key part of decision-making on whether health and environmental risks are acceptable. The development of risk management strategies take place within the context of the pesticide's conditions of registration. Conditions can relate to, among other things, the specific use (for example, application rates, timing, frequency and method of application), personal protective equipment, pre-harvest intervals, restricted entry intervals, buffer zones, spray drift and runoff mitigation measures, handling, manufacture, storage or distribution of a pesticide. If feasible conditions of use that have acceptable risk and value cannot be identified, the pesticide use will not be eligible for registration.

The selected risk management strategy is then implemented as part of the re-evaluation decision. The pesticide registration conditions include legally-binding use directions on the label. Any use in contravention of the label or other specified conditions is illegal under the *Pest Control Products Act*. Implementation of post-market decisions follow the framework articulated in the *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*.[10]

Following a decision, continuous oversight activities such as post-market review, monitoring and surveillance, including incident reporting, all play an essential role to help ensure the continued acceptability of risks and value of registered pesticides.

[10] Canada. Health Canada. PMRA Regulatory Directive DIR2018-*01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review*, 2018 (Internet: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2018/dir2018-01-policy-cancellations-amendments.html, cited October 2022).

Science evaluation update

Additional data were received for the re-evaluation of the material preservative use of sodium omadine. A human in vitro dermal absorption study was received but did not result in changes to the human health risk assessments (refer to Appendix III for details). Efficacy data were received from both registrants in response to PRVD2020-03; the value assessment was updated to reflect the new data. Refer to Appendix III for a summary of the comments received and Health Canada's responses.

Revised value assessment

As part of the re-evaluation of sodium omadine, 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, rate reductions were proposed for all paint and paint-related uses in PRVD2020-03. Proposed rate reductions were as follows:

- 58 ppm of active ingredient in latex paints
- 224 ppm of active ingredient in caulks and sealants
- 196 ppm of active ingredient in other building materials such as patching compounds and grouts

Value information was required for the proposed rate reductions for all paint and paint-related uses in order to maintain registration of sodium omadine products. In response to the PRVD, two efficacy studies were submitted, one from each of two registrants.

One study demonstrated the antibacterial efficacy of sodium omadine as an in-can preservative in latex paint at concentrations of 50 ppm a.i. and greater. From this study it can be concluded that all the reduced rates proposed in PRVD2020-03 have acceptable value.

The second study demonstrated the antibacterial efficacy of sodium omadine as an in-can preservative in latex paint at concentrations of 200 ppm a.i. and greater. From this study it can be concluded that the reduced rates of 0.224 g a.i./kg for caulks and sealants and 0.196 g a.i./kg for all other building materials proposed in PRVD2020-03 have acceptable value.

Overall, there is sufficient evidence to conclude that the reduced application rates proposed in PRVD2020-03 have acceptable value.

Currently the claims on registered end use product labels indicate that bacterial growth is inhibited "for a period of up to 1 year". This duration of protection is not supported based on the two studies above. Therefore, any reference to the duration of antibacterial efficacy for preservation of paints and other building materials will be removed from the product labels.

List of abbreviations

AEATF II	Antimicrobial Exposure Assessment Task Force II
CPCA	Canadian Paint and Coatings Association
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
REV	Re-evaluation Note
RVD	Re-evaluation Decision
USEPA	United States Environmental Protection Agency

Appendix I Registered material preservative products containing sodium omadine in Canada as of 7 September 2022

Table 1 Sodium omadine products used as preservatives in paints coatings and related uses that do not require label amendments

Registrant	Registration number	Product name	Marketing class
Arch Chemicals, Inc.	29714	Sodium Omadine 40% Technical	T
Troy Chemical Corporation	32939	Pyrithione 40 MUP	T

T = technical grade active ingredient

Table 2 Sodium omadine products used as preservatives in paints coatings and related uses that require label amendments

Registrant	Registration number	Product name	Marketing class
Arch Chemicals, Inc.	24098	Sodium Omadine 40% Aqueous Solution Industrial Fungicide & Bactericide	C
Troy Chemical Corporation	33676	Troyshield FSP40	C

C = commercial

Note: Discontinued products and products with submissions for discontinuation not included.

Appendix II List of commenters to PRVD2020-03

List of commenters' affiliations for comments submitted in response to PRVD2020-03

Category	Commenter
Industry association	Canadian Paint and Coatings Association (CPCA)
Registrant	Troy Chemical Corporation
Registrant	Arch Chemicals, Inc.

Appendix III Comments and responses

Health Canada received comments during the public consultation for the sodium omadine proposed re-evaluation decision. Commenters' affiliations are listed in Appendix II. These comments were considered during the final decision phase of this re-evaluation. Summarized comments and Health Canada's responses to them are provided below.

1.0 Comments related to Health Canada processes and policies

1.1 Comments related to harmonization of Health Canada and United States Environmental Protection Agency (USEPA) timelines and decisions:

Comments were submitted by the Canadian Paint and Coatings Association (CPCA) expressing the importance of a more aligned North American review process for biocides to maintain fair trade and access to a sufficient number of biocides in both countries for all paint manufacturers.

Health Canada response

As outlined in the sodium omadine proposed re-evaluation decision document (PRVD2020-03), Health Canada relied on data provided by the registrant and the Antimicrobial Exposure Assessment Task Force II (AEATF II) to conduct the risk assessments for each of the active ingredients in the paint cluster. Health Canada has engaged with the AEATF II and the USEPA on science matters prior to and following the submission of this data.

Health Canada continues to communicate with its USEPA counterparts on science-related topics. Health Canada has also shared the outcome of its paint preservative assessments and proposed decisions with the USEPA and other regulatory authorities.

1.2 Comments related to the re-evaluation process and paint-related antimicrobials

Comments were submitted regarding the re-evaluation process with respect to antimicrobials for use as paint preservatives in general. These comments included topics such as socio-economic cost impact, transparency, research and development, and the method of assessment for antimicrobials.

Health Canada response

Health Canada considered a science-based risk assessment and risk management approach for this re-evaluation; risk mitigation measures were implemented to address potential risks related to human health. Comments regarding Health Canada's re-evaluation process and protocols in general are beyond the scope of the re-evaluation of the material preservative uses of sodium omadine and cannot be adequately addressed in this document.

2.0 Comments related to the health risk assessment

2.1 Comments related to toxicology assessment

The registrants commented on various aspects of the toxicology assessment, in particular the determination of the *Pest Control Products Act* factor of threefold, the point of departure used as the basis for the dermal risk assessment, the selection of uncertainty factors, and the conclusion regarding evidence of neurotoxicity.

Health Canada response

The complete toxicology re-evaluation review of sodium omadine was summarized previously in the Proposed Re-evaluation Decision PRVD2016-12, *Sodium Omadine*, which underwent public consultation. Comments received on PRVD2016-12 were reviewed and addressed in Re-evaluation Decision RVD2018-06, *Sodium Omadine and Its Associated End-use Product*. No new toxicology data were provided in response to PRVD2020-03; therefore, the previously conducted toxicology assessment for sodium omadine is not being revisited at this time. For more information on the toxicology assessment, please refer PRVD2016-12 and RVD2018-06.

2.2 Comments related to occupational/residential exposure

2.2.1 Comment related to Health Canada's assessment of the exposure studies

A comment was received from the CPCA expressing concern about the major limitations identified by Health Canada following the review of the AEATF II study reports, even though the protocols/studies were approved beforehand by Health Canada and the USEPA. Moreover, the comment stated that these limitations led Health Canada to apply safety factors in the calculation of unit exposure values, noting that additional safety factors should only be applied following appropriate risk evaluations that are linked to actual related incidents and applied in a transparent manner.

Health Canada response

While limitations have been identified within the individual exposure studies (for example, brush and roller and airless sprayer studies), the unit exposure values derived from each study align closely between Health Canada and the USEPA and no additional safety factors were applied to the risk assessments to account for these limitations. In turn, Health Canada has considered this information in the risk assessments, along with the other information, based on a weight-of-evidence approach. This approach is in alignment with Health Canada's standard policy for evaluating risks.

2.2.2 Comment related to the amount of paint applied per day and use of airless sprayer by residential users

One comment referred to the new information from an American Coatings Association (ACA) survey which indicates the maximum amount of paint applied per year is 10 gallons and the fact that airless spray is not used by residential users.

Health Canada response

The referenced survey, indicating that the maximum amount of paint applied per year is 10 gallons (38 L), was not provided to Health Canada, and no data were submitted supporting the statement that airless sprayers are not used by residential users. Considering that airless sprayers can be purchased online or at various retail stores, potential risks associated with their use cannot be disregarded. New information can be submitted to Health Canada for consideration via a pre-market submission.

2.2.3 Comment related to the dermal absorption value

Comments were received asking the PMRA to consider the matrix effect, as the paint matrix is expected to reduce exposure as compared to a vehicle that is used in animal experiments.

Health Canada response

Following the publication of PRVD2020-03, a human in vitro dermal absorption study was submitted to compare the dermal bioavailability of sodium omadine formulated at a typical concentration in a water-based paint formulation to that of sodium omadine formulated in a skin cream (Aquaphor®). The latter vehicle is representative of a vehicle used in dermal toxicity studies on sodium omadine. An additional objective was to assess the human in vitro dermal absorption of sodium omadine formulated in the representative paint.

Dermal absorption of [^{3}H]-sodium omadine in Aquaphor and paint formulations was evaluated in vitro using automated flow-through diffusion cells and human skin samples. The skin samples were determined to have adequate barrier integrity. A nominal dose of approximately 10 µL/cm^2 of 0.648 mg ai/g product was applied to eight flow through diffusion cells per test formulation. [^{3}H]-sodium omadine was analyzed in the receptor cell at regular time intervals over 24 hours. Skin was washed at 24 hours. After the last receptor fluid sample was collected, the skin membrane surface and the diffusion cell were thoroughly rinsed and skin washes were analyzed for radioactivity. Each skin membrane was tape stripped to remove the stratum corneum. Recovery of the applied dose was deemed acceptable and average recovery ranged from 98–99%.

The majority of the administered dose was recovered from the skin wash (33–36%) and receptor fluid (33–42%). A range of 17–26% of the applied dose was retained in the skin. Estimates of dermal absorption (total absorbed dose) were based on the sum of residues retained in the skin (exposed, unexposed) + receptor fluid (including compartment wash and rinse) and tape strips. The dermal absorption of sodium omadine was estimated to be 63% in Aquaphor and 60–65% in paint.

The results of the study suggest that the bioavailability of sodium omadine in paint and skin cream (Aquaphor) formulations is similar. Although there are uncertainties when interpreting the results, such as the use of radiolabelled hydrogen, there were no major limitations identified in the study. The dermal risk estimates were not adjusted, as the study was not able to demonstrate a matrix effect of dermal absorption of sodium omadine in paint versus the skin cream formulation used in the dermal toxicology study.

2.2.4 Comment related to the exposure assessment of handling building materials

A comment was received regarding the PMRA's use of the AEATF II brush and roller exposure data to represent caulks and sealants.

The comment also noted that the use of sodium omadine in building products is limited to its use in gypsum board, and this use is controlled by manufacturing conditions whereby application to the slurry occurs and the slurry is applied to a paper matrix and baked to form wallboard. A coating is applied to the finished wallboard surface to ensure leaching from the sodium omadine core does not occur.

Health Canada response

As noted in the PRVD2020-03, no use description information was provided for building materials, including caulks and sealants. Therefore, the default amount of paint handled per day by a professional painter (18.7 L) was used as a surrogate for the amount handled for caulks and sealants. Likewise, in the absence of a scenario-specific exposure study, the unit exposure values for the hands only, from the brush and roller study, were considered for the dermal risk assessment for caulks and sealants. This was based on the assumption that 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).

With regards to the use of sodium omadine in the preservation of gypsum wallboard, this use was granted registration in 2013 and, therefore, was not considered in either of the sodium omadine re-evaluations under PRVD2016-12 or PRVD2020-03.

2.3 Comment related to the lack of incident reports

A comment was received from the CPCA stating that no incident reports were noted in any of the assessment monographs, which normally justify the decision to impose drastic reductions of use levels and/or cancellations of use.

Health Canada response

A low number or a lack of incidents cannot be used to imply an absence of risks of concern. Secondary (professional and residential) handlers applying or using adhesives, caulks, patching compounds, sealants, paints and grouts are likely unaware that these products have been treated with a material preservative. Therefore, the true burden of any observed adverse effect from exposure to the preservative, resulting from the application/use of final products, is unknown.

Underreporting of incidents and barriers to reporting have been documented in many areas including pesticides (Prado et al., 2017[11]; Bell et al., 2005[12]). Health Canada therefore considers all available data and scientific information to ensure that registered pesticides continue to meet current health and environmental safety standards and continue to have value.

3.0 Comment related to the value assessment

3.1 Comment related to limited or no alternatives to material preservative active ingredients

Stakeholders emphasized that there are limited or no alternatives to some active ingredients used as material preservatives and indicated challenges with the registered alternatives (for example, higher cost, lower effectiveness, undesirable effects such as yellowing of paints).

Health Canada response

Health Canada acknowledges that there are limitations to alternative active ingredients registered for certain material preservative uses. Health Canada considers the value of currently registered uses of sodium omadine to be acceptable, however, information related to the value of registered alternatives cannot be used to negate required risk mitigation measures.

[11] Prado J.B., Mulay P.R., Kasner E.J., Bojes H.K. and Calvert, G.M. (2017). Acute pesticide-related illness among farmworkers: Barriers to reporting to Public Health Authorities. Journal of Agromedicine, 22(4): 395-405.

[12] Bell, E.M., Sandler, D.P., and Alavanja, M.C. (2006). High Pesticide exposure events among farmers and spouses enrolled in the Agricultural Health Study. Journal of Agricultural Safety and Health, 12(2):101-116.

Appendix IV Label amendments for material preservative products containing sodium omadine

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

Label amendments for commercial class end-use products containing sodium omadine

Label must indicate:

- Product is only for use in a closed transfer system. A closed transfer system is defined as a procedure for removing a pesticide from its original container, rinsing the emptied container and transferring the pesticide and rinse solution through connecting hoses pipes, and coupling that are sufficiently tight to prevent exposure of any person to the pesticide or rinse solution. Furthermore, the closed transfer system must be equipped with a dry coupling system that is designed to drip less than 2 mL per coupling.
- Maximum permissible rates; the rates of sodium omadine below are to be converted into the corresponding product rate by the registrant for each product label:
    - 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

Remove any reference to the duration of antibacterial efficacy for preservation of paints and other building materials from the product labels.

Appendix V References considered following publication of PRVD2020-03

A. Information considered in the updated value assessment

List of studies/information submitted by registrant

PMRA document number	Title
3227608	2021. Efficacy Study for Sodium Omadine™ 40% Aqueous Solution Industrial Fungicide & Bactericide. Arch Chemicals Inc.
3248362	2020. Performance Evaluation of Troyshield® FSP40 in Paint and Polymer Emulsion. Troy Corporation