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Proposed Registration Decision

PRD2025-12

# 3-Chloro-4- methylaniline hydrochloride and DRC-1339

*(publié aussi en français)*

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# Overview

## Proposed registration decision for 3-chloro-4-methylaniline hydrochloride

Health Canada's Pest Management Regulatory Agency (PMRA), pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of DRC-1339 Technical and DRC-1339, containing the active ingredient 3-chloro-4-methylaniline hydrochloride, for control of corvids in relation to greater sage-grouse recovery.

3-Chloro-4-methylaniline hydrochloride is currently registered for the control of corvids to protect greater sage-grouse populations in Alberta on an emergency basis.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of 3-chloro-4-methylaniline hydrochloride and DRC-1339.

## What does Health Canada consider when making a registration decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to individuals and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>1</sup> if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value<sup>2</sup> when used according to the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

To reach their decisions, Health Canada's PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children). They also consider the unique characteristics of organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how Health Canada's PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and pest management portion of [Canada.ca](http://Canada.ca).

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<sup>1</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>2</sup> "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "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."

Before making a final registration decision on 3-chloro-4-methylaniline hydrochloride and DRC-1339, Health Canada's PMRA will consider any written comments received from the public directly related to the proposed decision in this consultation document.<sup>3</sup> Health Canada will then publish a Registration Decision<sup>4</sup> on 3-chloro-4-methylaniline hydrochloride and DRC-1339, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

## **What is 3-chloro-4-methylaniline hydrochloride?**

3-Chloro-4-methylaniline hydrochloride is an avian nephrotoxin. It is the active ingredient in DRC-1339, a product used to manage corvid populations in greater sage-grouse habitat in order to protect greater sage-grouse nests from predation by corvids (for example, ravens, crows, and magpies).

## **Health considerations**

### **Can approved uses of 3-chloro-4-methylaniline hydrochloride affect human health?**

**DRC-1339, containing 3-chloro-4-methylaniline hydrochloride, is unlikely to affect your health when used according to proposed label directions.**

Potential exposure to 3-chloro-4-methylaniline hydrochloride may occur when handling and applying the end-use product and handling baited eggs. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are selected to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose level at which no effects are observed.

In laboratory animals, the technical grade active ingredient, DRC-1339 Technical, was of low acute toxicity via the dermal route of exposure, of high acute toxicity via the oral route of exposure, and expected to be of high acute toxicity via the inhalation route of exposure. It was corrosive to the eyes and skin, and caused an allergic skin reaction.

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<sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The acute toxicity profile of the end-use product DRC-1339, containing 3-chloro-4-methylaniline hydrochloride, is equivalent to that of the technical grade active ingredient. Consequently, the signal word “DANGER” and hazard statements “POISON”, “CORROSIVE TO EYES AND SKIN” and “POTENTIAL SKIN SENSITIZER” are required on the labels for both the technical grade active ingredient and the end-use product.

In addition to acute toxicity studies, registrant-supplied long-term (lifetime) oral toxicity tests and genotoxicity testing, as well as information from the published scientific literature, were assessed. Following repeated oral dosing in mice and rats, administration of surrogate test material 3-chloro-4-methylaniline resulted in decreased body weight in mice and rats and effects in the spleen and liver of rats. Results from testing indicate that 3-chloro-4-methylaniline hydrochloride is not mutagenic.

The toxicology database for 3-chloro-4-methylaniline hydrochloride did not contain the full array of studies normally required for pesticide registration. Rationales to waive additional toxicity testing were accepted based on the restricted-class designation, limited use and stringent use conditions of the associated end-use product, as well as the elaborate and significant risk mitigation measures for handlers and applicators included on the end-use product label. Although there were limited toxicity data available, the supporting toxicological database was considered to be adequate for the current assessment.

### **Occupational risks from handling DRC-1339**

#### **Occupational risks are not of health concern when DRC-1339 is used according to the proposed label directions, which include protective measures.**

Workers mixing, loading and injecting DRC-1339 into chicken, turkey or duck eggs, and workers handling baited eggs can be exposed to residues of 3-chloro-4-methylaniline hydrochloride through direct skin contact or through inhalation. Therefore, the label specifies that anyone mixing, loading and injecting DRC-1339 into the eggs must wear coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear, protective eyewear (goggles or face shield) and respirator. Workers handling the baited eggs must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. Taking into consideration the restricted marketing-class designation of the end-use product, the required personal protective equipment, restrictions on the location where DRC-1339 can be handled, and the product being confined inside an egg, the risks to these individuals from exposure to 3-chloro-4-methylaniline hydrochloride are not of health concern when the end-use product is used according to the proposed label directions.

### **Health risks in residential and other non-occupational environments**

#### **Risks in residential and other non-occupational environments are not of health concern when DRC-1339 is used according to the proposed label directions.**

DRC-1339 is a restricted-class end-use product, for use only in areas where corvid populations are to be controlled in relation to greater sage-grouse recovery. Furthermore, the general public is not permitted to enter baited sites. As such, residential exposure is not expected.

## Health risks to bystanders

**Bystander risks are not of health concern when DRC-1339 is used according to the proposed label directions.**

DRC-1339 is injected into hard-boiled eggs. Bystander exposure when workers are injecting or handling the eggs is not expected due to restrictions on the location where DRC-1339 can be handled.

## Environmental considerations

**What happens when 3-chloro-4-methylaniline hydrochloride is introduced into the environment?**

**When used according to label directions, the environmental risks associated with the use of 3-chloro-4-methylaniline hydrochloride and its associated end-use product, DRC-1339, to control corvids in greater sage-grouse habitat are acceptable.**

3-Chloro-4-methylaniline hydrochloride will enter the environment when DRC-1339 is used in egg baits to control corvids (for example, ravens, crows, and magpies) preying on greater sage-grouse (*Centrocercus urophasianus*) nests in Alberta. The greater sage-grouse is an endangered species in Canada, with fewer than 100 individuals left in Alberta. Corvids have been identified as a significant predator of greater sage-grouse eggs and chicks.

In order to control corvids, 3-chloro-4-methylaniline hydrochloride is injected into hard-boiled eggs which are then placed in dummy nests for a short period of time in the spring during the greater sage-grouse nesting season. A maximum of 18 eggs per site is permitted. Limited environmental exposure is expected from the proposed use.

3-Chloro-4-methylaniline hydrochloride is toxic to aquatic organisms; however, exposure to the aquatic environment is not expected from the proposed use. 3-Chloro-4-methylaniline hydrochloride is also toxic to non-target birds and mammals if they consume high enough quantities. Since corvids have been identified as a significant source of predation on greater sage-grouse eggs, they are expected to be the main species exposed to 3-chloro-4-methylaniline hydrochloride. Population-level effects in non-target species are not expected due to limited use of 3-chloro-4-methylaniline hydrochloride in terms of area, duration and amount used.

After a scientific review of the available information, Health Canada has concluded that the environmental risks from the proposed use of 3-chloro-4-methylaniline hydrochloride are acceptable when used according to the label directions.

## Value considerations

### What is the value of DRC-1339?

**DRC-1339 has value as a management tool to reduce corvid predation on critically endangered greater sage-grouse (*Centrocercus urophasianus*) and protect this species from extirpation in Canada.**

Greater sage-grouse was listed as endangered in Alberta in June 2000, and an Emergency Protection Order for greater sage-grouse has been in effect since 2014. Corvid predation of nests is a key risk factor in greater sage-grouse survival, with over 63% of monitored greater sage-grouse nests depredated by corvids in 2010-2013. DRC-1339 provides an essential tool as there are no alternative corvid control products registered in Canada. Without avian predator control, it is expected that greater sage-grouse would be extirpated from Alberta within 3 to 5 years.

## Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of DRC-1339 Technical and DRC-1339 to address the potential risks identified in this assessment are as follows.

### Key risk-reduction measures

#### Human health

To reduce the potential exposure of workers to 3-chloro-4-methylaniline hydrochloride through direct skin contact or inhalation, workers mixing, loading and injecting DRC-1339 into poultry eggs must wear coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear, protective eyewear (goggles or face shield) and respirator. Workers handling the baited eggs must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. The label also restricts the general public from entering baited sites.

#### Environment

- A “toxic to aquatic organisms” label statement based on the inherent toxicity of 3-chloro-4-methylaniline hydrochloride.
- A “toxic to birds and small wild mammals” label statement.

## Next steps

Before making a final registration decision on 3-chloro-4-methylaniline hydrochloride and DRC-1339, Health Canada’s PMRA will consider any written comments received from the public that are directly related to this proposed decision, such as comments directed to the science evaluation, in response to this consultation document up to 30 days from the date of publication

(17 October 2025) of this document. If more time is required to provide comments, a request for an extension of up to 15 days can be made before the end of the original 30-day consultation period. Please forward all comments to PMRA Publications, through the Public Engagement Portal (Public Engagement Forms – Consultation Comment). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada’s response to these comments.

### **Other information**

When Health Canada’s PMRA makes its registration decision, a Registration Decision on 3-chloro-4-methylaniline hydrochloride and DRC-1339 (based on the Science Evaluation Section of this consultation document) will be published. In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA’s Reading Room. For more information or if you have questions, please contact the PMRA’s Pest Management Information Service.

## Science evaluation

### 3-Chloro-4-methylaniline hydrochloride and DRC-1339

#### 1.0 The active ingredient, its properties and uses

##### 1.1 Identity of the active ingredient

**Active substance** 3-chloro-4-methylaniline hydrochloride

**Function** Avicide

##### Chemical name

**1. International Union of Pure and Applied Chemistry (IUPAC)** 3-Chloro-4-methylaniline hydrochloride

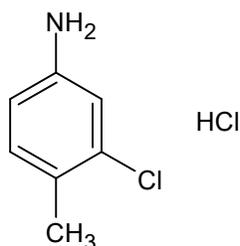
**2. Chemical Abstracts Service (CAS)** 3-chloro-4-methylbenzenamine hydrochloride (1:1)

**CAS number** 7745-89-3

**Molecular formula** C<sub>7</sub>H<sub>9</sub>Cl<sub>2</sub>N

**Molecular weight** 178.06

**Structural formula**



**Purity of the active ingredient** 98.8%

##### 1.2 Physical and chemical properties of the active ingredient and end-use product

##### Technical Product—DRC-1339 Technical

Property	Result
Colour and physical state	Grey solid (wetable powder)
Odour	Mothball-like odour
Melting range	N/A – Product is solid at room temperature
Boiling point or range	220–230°C (sublimation)

Property	Result										
Density	0.44 g/mL at 24°C (bulk density)										
Vapour pressure at 25°C	14.08 mPa										
Ultraviolet (UV)-visible spectrum	No absorption at > 300 nm										
Solubility in water at 20°C	91.6 g/L										
Solubility in organic solvents at 20°C	<table border="1"> <thead> <tr> <th>Solvent</th> <th>Solubility (g/L)</th> </tr> </thead> <tbody> <tr> <td><i>n</i>-octanol</td> <td>5.00</td> </tr> <tr> <td>acetonitrile</td> <td>0.129</td> </tr> <tr> <td>ethanol</td> <td>42800 (estimated)</td> </tr> <tr> <td>acetone</td> <td>1000 (estimated)</td> </tr> </tbody> </table>	Solvent	Solubility (g/L)	<i>n</i> -octanol	5.00	acetonitrile	0.129	ethanol	42800 (estimated)	acetone	1000 (estimated)
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acetonitrile	0.129										
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acetone	1000 (estimated)										
<i>n</i> -Octanol-water partition coefficient ( $K_{ow}$ )	<table border="1"> <thead> <tr> <th>Concentration (g/L)</th> <th><math>\log K_{ow}</math></th> </tr> </thead> <tbody> <tr> <td><math>8.47 \times 10^{-4}</math></td> <td>0.67</td> </tr> <tr> <td><math>8.47 \times 10^{-5}</math></td> <td>1.32</td> </tr> <tr> <td><math>8.47 \times 10^{-6}</math></td> <td>1.39</td> </tr> </tbody> </table>	Concentration (g/L)	$\log K_{ow}$	$8.47 \times 10^{-4}$	0.67	$8.47 \times 10^{-5}$	1.32	$8.47 \times 10^{-6}$	1.39		
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$8.47 \times 10^{-4}$	0.67										
$8.47 \times 10^{-5}$	1.32										
$8.47 \times 10^{-6}$	1.39										
Dissociation constant ( $pK_a$ )	3.7										
Stability (temperature, metal)	Exhibits thermal instability and sensitivity to sunlight; stable when stored in LDPE-lined fibre drums at ambient temperature for 1 year										

#### End-Use Product—DRC-1339

Property	Result
Colour	Grey
Odour	Mothball-like odour
Physical state	Solid (wetable powder)
Formulation type	Wetable powder (WP)
Label concentration	3-chloro-4-methylaniline hydrochloride ... 98.8%
Container material and description	Glass container, 0.5–25 g
Density	0.44 g/mL at 24°C (bulk density)
pH of 1% dispersion in water	2.67
Oxidizing or reducing action	Does not contain oxidizing or reducing components
Storage stability	Stable when stored in LDPE-lined fibre drums at ambient temperature for 1 year – extrapolation of results from plastic to glass (proposed commercial container) is acceptable for this solid product
Corrosion characteristics	Not corrosive to packaging material
Explosibility	Not explosive

### **1.3 Directions for use**

DRC-1339 is a restricted-use product for use as a management tool to reduce nest predation by corvids on critically endangered greater sage-grouse (*Centrocercus urophasianus*). DRC-1339 is injected into hard-boiled chicken, turkey, or duck eggs as either 1 mL of a 2% solution or 0.5 mL of a 4% solution, resulting in a dosage of 20 mg DRC-1339 per egg. Treated eggs are then marked with a skull and crossbones and the word POISON. Treated egg baits are placed in sets of 1–10 eggs within 7.6 m of the center of a baited site. No more than 18 eggs are to be used per baited site. Bait sets must be made in “dummy” nests created by making small depressions in the ground whenever practical, or eggs must be placed on elevated wooden platforms. Eggs are placed in a basket mounted to the platform to prevent them from falling off the platform or being removed by birds.

### **1.4 Mode of action**

The active ingredient 3-chloro-4-methylaniline hydrochloride is an avian nephrotoxin, which results in renal failure and death following consumption by the target bird.

## **2.0 Methods of analysis**

### **2.1 Methods for analysis of the active ingredient**

The methods provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable.

### **2.2 Method for formulation analysis**

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

### **2.3 Methods for residue analysis**

No methods are required to quantify residues of 3-chloro-4-methylaniline hydrochloride because there are no proposed food uses.

## **3.0 Impact on human and animal health**

### **3.1 Hazard assessment**

#### **3.1.1 Toxicology summary**

3-Chloro-4-methylaniline hydrochloride is an avicide. Following consumption, 3-chloro-4-methylaniline hydrochloride acts as an avian nephrotoxin, resulting in renal failure.

A review of the toxicology database for 3-chloro-4-methylaniline hydrochloride was conducted in support of the technical grade active ingredient, DRC-1339 Technical, and the end-use product, DRC-1339, which is a re-pack of the technical grade active ingredient. Some studies

were conducted with the surrogate compound 3-chloro-4-methylaniline, also known as 3-chloro-*p*-toluidine, which only differs in structure from the active ingredient in that it lacks the hydrochloride moiety that is present in 3-chloro-4-methylaniline hydrochloride, and is considered to be toxicologically equivalent to 3-chloro-4-methylaniline hydrochloride. Although the data package for 3-chloro-4-methylaniline hydrochloride is considered limited, the supporting toxicological database is considered to be adequate for the current assessment.

The submitted toxicology database consisted of acute toxicity (via the oral and dermal routes), eye and skin irritation, and dermal sensitization studies, as well as a 78-week non-guideline oral oncogenicity study in mice and rats and a battery of genotoxicity studies (including in vitro bacterial reverse mutation, in vitro gene mutation and chromosomal aberration studies) conducted with the technical grade active ingredient. Additionally, waiver rationales were submitted to address requirements for studies assessing toxicokinetics, acute inhalation toxicity, short-term oral and dermal toxicity, reproductive and prenatal developmental toxicity, and in vivo mutagenicity of the technical grade active ingredient.

The technical grade active ingredient, DRC-1339 Technical, was of high acute toxicity by the oral route in rats and of low acute toxicity via the dermal route in rabbits. It was corrosive to the eyes and skin of rabbits and was positive for skin sensitization when tested in guinea pigs using the Buehler method. Based on the high acute oral toxicity and corrosive properties to the skin, the requirement for an acute inhalation toxicity study was waived and 3-chloro-4-methylaniline hydrochloride was considered to be of high acute toxicity via the inhalation route of exposure.

The acute toxicity of the end-use product, DRC-1339, containing 3-chloro-4-methylaniline hydrochloride, is equivalent to the acute toxicity profile of DRC-1339 Technical.

In a 78-week non-guideline oral oncogenicity study in mice and rats, administration of the surrogate test material 3-chloro-4-methylaniline resulted in decreased body weight in both sexes and species. An increased incidence of non-neoplastic lesions in the spleen (fibrosis) and liver (fatty metamorphosis) was observed in both sexes of rats at the high dose. Additionally, high dose female rats exhibited an increased incidence of endometrial stromal polyps that exceeded the incidence in historical controls. Uterine stromal polyps are benign tumours that are not uncommon in aging rats and it was noted that there was an unusually low incidence of these polyps in the control group. Overall, there is a low level of concern for this lesion particularly since the study authors reported a decrease in body weight that is indicative of a dose approaching the maximum tolerated dose, and additionally the potential for exposure is quite limited for the proposed uses. 3-Chloro-4-methylaniline hydrochloride was not mutagenic in a bacterial reverse mutation assay, nor in an in vitro mammalian cell gene mutation assay, but was found to induce structural chromosome aberrations in the presence of metabolic activation in mammalian cells when tested in vitro. Overall, it was concluded based on the weight of evidence that 3-chloro-4-methylaniline hydrochloride demonstrated equivocal evidence of tumourigenicity and did not damage genetic material.

Supporting documentation and a search of the public literature indicate that 3-chloro-4-methylaniline has the potential to cause methemoglobinemia in rats and mice following intraperitoneal administration of acute lethal doses, and additionally in rabbits following gavage dosing and in dogs following intravenous dosing.

Based on the restricted-class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, rationales to waive the metabolism, short-term oral and dermal toxicity, reproductive and prenatal developmental toxicity, and in vivo mutagenicity testing were accepted.

In the future, if new uses, use patterns or exposure scenarios are proposed or identified, the acceptability of the existing toxicology database and the requirement for additional studies will be reconsidered.

Results of the toxicology studies conducted on laboratory animals with 3-chloro-4-methylaniline hydrochloride and 3-chloro-4-methylaniline are summarized in Table 1 of Appendix I.

### **3.1.2 *Pest Control Products Act* hazard characterization**

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.<sup>5</sup>

Given that there are no dietary uses of the product and 3-chloro-4-methylaniline hydrochloride will not be used in or around homes or schools, characterization of the *Pest Control Products Act* factor (PCPA factor) was not required.

## **3.2 Toxicology reference values**

### **3.2.1 Route and duration of exposure**

Exposure to DRC-1339 is characterized as short-term in duration and is predominantly by the dermal and inhalation routes for those mixing/loading and injecting DRC-1339 into the eggs and by the dermal route for those handling the baited eggs.

### **3.2.2 Occupational toxicology reference values**

Toxicology reference values are not required as it was determined that a qualitative approach to the human health risk assessment would be appropriate for 3-chloro-4-methylaniline hydrochloride for the current assessment.

### **3.2.3 Acute reference dose (ARfD)**

Establishment of an acute reference dose is not required as no exposure via the diet or drinking water is expected.

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<sup>5</sup> SPN2008-01, *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*.

### **3.2.4 Acceptable daily intake (ADI)**

Establishment of an acceptable daily intake is not required as no exposure via the diet or drinking water is expected.

### **3.2.5 Cancer assessment**

Considering that exposure is quite limited and the equivocal evidence of tumourigenicity, a cancer risk assessment is not necessary.

### **3.2.6 Aggregate toxicology reference values**

There is no residential or dietary exposure to 3-chloro-4-methylaniline hydrochloride. Therefore, an aggregate assessment is not necessary.

### **3.3 Dermal absorption**

Dermal absorption data were not required as a quantitative risk assessment was not conducted.

### **3.4 Occupational and residential risk assessment**

#### **3.4.1 Acute hazards of the end-use product DRC-1339 and mitigation measures**

The acute hazard assessment indicated that DRC-1339 is of high acute toxicity via the oral route of exposure and of low acute toxicity via the dermal route of exposure. It is corrosive to the eyes and skin and is a potential dermal sensitizer according to the Buehler method. The requirement for an acute inhalation toxicity study was waived due to the high acute oral hazard and the corrosive nature of the product. Therefore, DRC-1339 is considered to be of high acute toxicity via the inhalation route of exposure.

Based on these acute hazards, coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear, protective eyewear (goggles or face shield) and respirator are required for workers during mixing, loading, injection, and clean-up. Workers handling the baited eggs must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes.

#### **3.4.2 Occupational exposure and risk assessment**

##### **3.4.2.1 Mixer, loader and applicator exposure and risk assessment**

Individuals have potential for exposure to 3-chloro-4-methylaniline hydrochloride during mixing, loading, injection and clean-up. Therefore, the label specifies that anyone mixing, loading and injecting DRC-1339 into the eggs or during clean-up must wear coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear, protective eyewear (goggles or face shield) and respirator.

However, based on the limited amount of product handled, the requirement for the end-use product to be mixed under a fume hood or in an outdoor location and the high level of dermal, ocular and respiratory personal protective equipment (PPE), exposure to the active ingredient is expected to be limited. As such, a quantitative risk assessment was not required.

#### **3.4.2.2 Postapplication exposure and risk assessment**

After the eggs are injected with DRC-1339, a worker marks the eggs with the word 'POISON' and an image of a skull and crossbones prior to placing them in the nests in the field. After a certain time, any eggs not consumed by corvids will be removed and disposed of. Anyone handling the baited eggs during these processes must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. As DRC-1339 is confined within the egg, exposure to any worker is expected to be negligible. Therefore, a quantitative risk assessment was not required.

#### **3.4.3 Residential exposure and risk assessment**

The product is not proposed for use in residential areas. The proposed label indicates that the general public is not allowed to access areas which contains treated eggs. As such, residential exposure is not expected.

#### **3.4.4 Bystander exposure and risk assessment**

Based on the use pattern of the end-use product, where it is injected into the eggs and is entirely contained inside a hard-boiled egg, bystander exposure is not expected.

### **3.5 Cumulative assessment**

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mammalian mechanism of toxicity for non-occupational (dietary and residential) sources of exposure.

Given that there are no dietary or residential uses for 3-chloro-4-methylaniline hydrochloride, a cumulative health risk assessment is not necessary at this time.

### **3.6 Health incident reports**

As of 6 May 2025, no human or domestic animal incidents involving 3-chloro-4-methylaniline hydrochloride have been submitted to the PMRA.

## **4.0 Impact on the environment**

### **4.1 Fate and behaviour in the environment**

3-Chloro-4-methylaniline hydrochloride is a light-sensitive chemical that is expected to degrade in the sun. It does not undergo hydrolysis but is quickly broken down by microorganisms in the environment to form up to four major transformation products (3-chloro-4-methyl-acetanilide

and three unidentified compounds) and carbon dioxide. 3-Chloro-4-methylaniline hydrochloride and its transformation products dissipate rapidly to form high levels of unextracted residues which are irreversibly bound to soil. The environmental fate parameters for 3-chloro-4-methylaniline hydrochloride are provided in Appendix I, Table 2.

## **4.2 Environmental risk characterization**

### **4.2.1 Risks to terrestrial organisms**

The end-use product, DRC-1339, is to be injected into the yolks of hard-boiled egg baits and placed in the nesting grounds of greater sage-grouse. No more than 18 eggs per baited site are to be used. The timing of the application will coincide with the spring nesting period of greater sage-grouse. Bait sets must be made in ‘dummy’ nests created by making small indentations in the ground, or on elevated wooden platforms. If platforms are used, the eggs must be placed in a basket mounted to the platform to prevent them from falling off the platform or being removed by birds. The province of Alberta has had an emergency registration for the proposed use of 3-chloro-4-methylaniline hydrochloride that has been renewed yearly since 2014 and have reportedly used less than 100 g of 3-chloro-4-methylaniline hydrochloride annually.

#### **Risks to invertebrates and terrestrial plants**

Significant exposure of terrestrial invertebrates (earthworms, bees and other beneficial arthropods) and terrestrial plants to 3-chloro-4-methylaniline hydrochloride is not expected given that it is to be injected into hard-boiled egg baits. As such, risks to these organisms are acceptable.

#### **Risk to birds**

As an avicide, 3-chloro-4-methylaniline hydrochloride is toxic to birds. The susceptibility of birds to 3-chloro-4-methylaniline hydrochloride varies by species, with LD<sub>50</sub> values ranging from 1.33 mg/kg bw for the American crow (a corvid) to 562 mg/kg bw for the Cooper’s hawk (Appendix I, Table 3). An American crow would be killed by consuming only one egg treated with 3-chloro-4-methylaniline hydrochloride. Based on the available information, 3-chloro-4-methylaniline hydrochloride is most toxic to corvids, icterids (blackbirds), the northern bobwhite, mourning dove, barn owl and herring gull. Non-target birds (for example, barn owl or herring gulls) that consume eggs treated with 3-chloro-4-methylaniline hydrochloride may be poisoned. Other species such as northern bobwhite or mourning doves are not expected to eat eggs as part of their main diet, and are therefore likely not at risk of exposure. As corvids have been identified as a significant source of predation on greater sage-grouse eggs, they are considered most likely to be preying on the nests. This assumption is supported by a previous report by Alberta Environment and Protected Areas that wildlife cameras deployed at bait sites did not record non-target animals feeding on egg baits.

3-Chloro-4-methylaniline hydrochloride is slow-acting and takes between 3 and 80 hours to kill the target bird after ingestion of a lethal dose, resulting in the chemical being partially or mostly metabolized before death (PMRA# 3558693). The United States Department of Agriculture (USDA, 2019; PMRA# 3558693) reports that approximately 90% or more of 3-chloro-4-

methylaniline hydrochloride is metabolized and excreted in animals within 2 hours after ingestion. As such, secondary poisoning of non-target birds consuming the carcasses of animals that have died from 3-chloro-4-methylaniline hydrochloride poisoning is not expected to be a concern.

The use of 3-chloro-4-methylaniline hydrochloride to control corvids preying on greater sage-grouse nests is not expected to result in population-level effects in non-target birds given its limited use, in terms of area, duration and amount used (less than 100 g/year). Risks to non-target birds are acceptable when the product is used according to label directions in the context of a species at risk recovery program.

### **Risks to mammals**

3-Chloro-4-methylaniline hydrochloride is slightly to moderately toxic to mammals, with LD<sub>50</sub> values ranging from 302 mg/kg bw for the brown rat to 1800 mg/kg bw for the North American deer mouse (Appendix I, Table 3). Non-target mammalian predators and scavengers (for example, raccoons, foxes, and skunks) would be exposed to 3-chloro-4-methylaniline hydrochloride if they feed on the treated egg baits.

A maximum of 18 egg baits, each containing 20 mg of 3-chloro-4-methylaniline hydrochloride, is permitted per baited site. In order to assess risk to non-target mammals, the number of eggs treated with 3-chloro-4-methylaniline hydrochloride that animals commonly found in Alberta would have to consume to reach a lethal dose was estimated (Appendix I, Table 4). The lethal dose was estimated based on the most sensitive endpoint available for mammals (LD<sub>50</sub> of 302 mg a.i./kg bw for the brown rat) divided by an uncertainty factor of 10 to account for potential differences in species sensitivity. It is feasible that mammals under 12 kg, such as raccoons, skunks, bobcats and coyotes, could consume enough eggs treated with 3-chloro-4-methylaniline hydrochloride to reach a lethal dose; however, there would not be enough treated eggs present on an individual site to poison larger animals. While it may be feasible for a 12-kg animal to consume 18 eggs at once, this may not be likely as it represents 100%, or more, of the animal's daily food ingestion rate.

The Albertan range of the swift fox (*Vulpes velox*), which is also an endangered species in Canada, overlaps with that of the greater sage-grouse. The majority of the swift fox's diet is meat; however, it is an omnivorous animal and may consume eggs, if found. Based on the conservative LD<sub>50</sub> endpoint of the rat, adjusted with an uncertainty factor of 10, a swift fox (based on its size and diet) consuming three to four eggs treated with 3-chloro-4-methylaniline hydrochloride could receive a lethal dose. Three to four eggs are a reasonable number of eggs for a swift fox to consume upon finding a nest. As such, a swift fox finding a bait set could be poisoned by consuming the eggs.

The use of 3-chloro-4-methylaniline hydrochloride to control corvids preying on greater sage-grouse nests may result in the death of non-target mammals if they consume the treated eggs; however, population-level effects in common mammals are not expected given the limited use of 3-chloro-4-methylaniline hydrochloride, in terms of area and amount (less than 100 g/year), as well as duration of use (spring nesting season). As noted above for birds, secondary poisoning is not expected to be a concern. While enough eggs treated with 3-chloro-4-methylaniline

hydrochloride would be present at each bait site to cause toxic effects in the endangered swift fox, 3-chloro-4-methylaniline hydrochloride is for use only by designated employees of Alberta Environment and Protected Areas, who are also responsible for the recovery of the swift fox. Alberta Environment and Protected Areas has previously reported that wildlife cameras deployed at bait sites did not record non-target animals feeding on egg baits. This does not rule out the possibility that non-target animals have fed on egg baits in locations where cameras were not present; however, risks are considered to be acceptable when 3-chloro-4-methylaniline hydrochloride is used according to label directions in the context of a species at risk recovery program.

#### **4.2.2 Risks to aquatic organisms**

3-Chloro-4-methylaniline hydrochloride is not permitted to be used in water. It is to be injected into egg baits and placed in the nesting grounds of greater sage-grouse. Exposure of aquatic organisms to 3-chloro-4-methylaniline hydrochloride is not expected. 3-Chloro-4-methylaniline hydrochloride is slightly to very highly toxic to freshwater organisms, and the label statement “toxic to aquatic organisms” is required to inform users of its inherent toxicity (Appendix I, Table 3). Risks to aquatic organisms are acceptable when 3-chloro-4-methylaniline hydrochloride is used according to label directions.

#### **4.2.3 Environmental incident reports**

As of 6 May 2025, no environmental incident reports involving 3-chloro-4-methylaniline hydrochloride have been submitted to the PMRA.

### **5.0 Value**

Submitted value information included demonstrated efficacy in Canada during the Emergency Registration of DRC-1339 in Alberta since 2014 and various field reports on successful use of DRC-1339 in the United States (U.S.). DRC-1339 has been registered in the U.S. since 1967 to control birds, including ravens, starlings, crows, pigeons, cowbirds, grackles, magpies, and certain gull species by application to various baits such as meat, grains, eggs, and French fries, placed in bait boxes or broadcast in target areas. Submitted scientific studies included numerous efficacy trials and field reports with different uses and/or application rates than those intended for use in Canada. These trials were used as supplemental supporting information. One trial was submitted which tested egg baits against corvids with the same use pattern intended for use in Canada.

DRC-1339 has been successfully used for control of corvids in Alberta with treated egg baits under approved emergency registrations since 2014. The demonstrated efficacy of DRC-1339 over 10 years of use in Canada was sufficient to support the value of DRC-1339 and to demonstrate that an application rate of 20 mg DRC-1339 per egg bait was effective at controlling corvids. The submitted trials and field reports confirm this use history. Due to the acute toxicity to corvids and the targeted control provided by DRC-1339 egg baits, resistance to the mode of action of this product is not expected. DRC-1339 egg baits have a long history of successful use for control of corvids both in Canada since 2014 and in other jurisdictions since the 1960s. There are no registered alternative active ingredients for control of corvids.

Overall, the value information was sufficient to support DRC-1339 as a restricted-use product for the management of corvids in relation to greater sage-grouse recovery at an application rate of 20 mg of DRC-1339 injected into hard-boiled chicken, turkey, or duck eggs as either 1 mL of a 2% solution or 0.5 mL of a 4% solution.

## **6.0 Pest Control Product Policy considerations**

### **6.1 Toxic Substances Management Policy considerations**

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a pest control product.

During the review process, 3-chloro-4-methylaniline hydrochloride and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03<sup>6</sup> and evaluated against the Track 1 criteria. Health Canada has reached the conclusion that 3-chloro-4-methylaniline hydrochloride and its transformation products do not meet all of the TSMP Track 1 criteria.

Please refer to Appendix I, Table 5 for further information on the TSMP assessment.

### **6.2 Formulants and contaminants of health or environmental concern**

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use product are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.<sup>7</sup> The list is used as described in the PMRA Science Policy Note SPN2020-01<sup>8</sup> and is based on existing policies and regulations, including the *Toxic Substance Management Policy and Formulants Policy*,<sup>9</sup> and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999*, (substances designated under the *Montreal Protocol*).

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<sup>6</sup> DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

<sup>7</sup> SI/2005-114, last amended on September 25, 2024. See Justice Laws website, Consolidated Regulations, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.

<sup>8</sup> PMRA's Science Policy Note SPN2020-01, Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under paragraph 43(5)(b) of the Pest Control Products Act

<sup>9</sup> DIR2006-02, Formulants Policy and Implementation Guidance Document

Health Canada has reached the conclusion that DRC-1339 Technical and its end-use product, DRC-1339, do not contain any formulants or contaminants identified on Parts 1 or 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

## **7.0 Proposed regulatory decision**

Health Canada's PMRA, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of DRC-1339 Technical and DRC-1339, containing the active ingredient 3-chloro-4-methylaniline hydrochloride, to control corvids in relation to greater sage-grouse recovery.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

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## List of abbreviations

>	greater than
<	less than
%	percent
±	with or without
↓	decreased
♀	female
♂	male
µg	microgram
°C	degrees centigrade
a.i.	active ingredient
ADI	acceptable daily intake
AOPWIN	Atmospheric Oxidation Estimation Program for Windows
ARfD	acute reference dose
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
CEPA	<i>Canadian Environmental Protection Act</i>
CHO	Chinese hamster ovary
cm <sup>3</sup>	cubic centimetre
COSEWIC	Committee on the Status of Endangered Wildlife in Canada
DACO	data code
DIR	Directive
DT <sub>50</sub>	dissipation time 50% (the time required to observe a 50% decline in concentration)
EC <sub>50</sub>	effective concentration on 50% of the population
FIR	food ingestion rate
g	gram
h	hour
IORE	indeterminate order rate equation model
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
<i>K</i> <sub>ow</sub>	<i>n</i> -octanol-water partition coefficient
KOWWIN	log Octanol-water Partition Coefficient Estimation Program for Windows
L	litre
LC <sub>50</sub>	lethal concentration 50%
LD <sub>50</sub>	lethal dose 50%
LDPE	low-density polyethylene
LOAEL	lowest observed adverse effect level
m	metre
MAS	maximum average score
MIS	maximum irritation score
mg	milligram(s)
mL	millilitre
mPa	millipascal(s)

MRID	US Master Record Identification Number
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OH	hydroxyl radical
$pK_a$	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
RRT	relative retention time
SPN	Science Policy Note
TGAI	technical grade active ingredient
TP	transformation product
$t_r$	representative half-life
TSMP	Toxic Substances Management Policy
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency

## Appendix I Tables and figures

**Table 1 Toxicity Profile of Technical 3-chloro-4-methylaniline hydrochloride**

Effects observed in both sexes are presented first followed by sex-specific effects in males, then females, each separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to body weights unless otherwise noted. Unless otherwise indicated, studies were conducted with 3-chloro-4-methylaniline hydrochloride.

Study Type/Animal/PMRA #	Study Results
<b>Toxicokinetic Studies</b>	
Metabolism	Based on the proposed non-food use of the end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and restrictive statements included on the end-use product label, the requirement for metabolism and toxicokinetic data has been waived.
<b>Acute Toxicity Studies</b>	
Acute Oral Toxicity (Standard test)  Wistar albino rat  PMRA # 3427162	LD <sub>50</sub> = 350 mg/kg bw (♂) = 303 mg/kg bw (♀) = 330 mg/kg bw (combined)  Mortality occurred at all doses. Death was preceded by physical signs of lethargy, ataxia, flaccid muscle tone, negative righting reflex, chromodacryorrhea, ptosis, piloerection, tachypnea, chromorhinorrhea, coma, prostration, brown staining of body areas and wetness of the nose/mouth area in the majority of cases.  High acute oral toxicity
Acute Dermal Toxicity  New Zealand albino rabbit  PMRA # 3427163	>2000 mg/kg bw (♂/♀)  All animals survived to study termination. Clinical signs included diarrhea, few feces and soiling of the anogenital area.  Low acute dermal toxicity
Acute Inhalation Toxicity - Waiver Request  PMRA # 3470280	The proposed product meets criteria outlined in the PMRA's Guidance for Waiving or Bridging of Mammalian Acute Toxicity Tests for Pesticides (2013) as it demonstrates the highest toxicity category for acute oral toxicity and is corrosive to the skin.  Therefore, the requirement for an acute inhalation toxicity study has been waived and 3-chloro-4-methylaniline hydrochloride is considered to be of high acute toxicity via the inhalation route.  High acute inhalation toxicity

Study Type/Animal/PMRA #	Study Results
Eye Irritation New Zealand albino rabbit PMRA # 3427165	Corneal opacity, iritis and severed conjunctival irritation (redness, chemosis and discharge) were observed in all animals and persisted to Day 7. Study terminated on Day 7 due to severity of responses.  Corrosive to eyes
Dermal Irritation New Zealand albino rabbit PMRA # 3427166	MAS <sup>a</sup> = 3.3/8 MIS <sup>b</sup> = 4.3/8 at 1 hour  Eschar formation (2/6 animals), and black areas and areas of flaky skin (4/6 animals) indicate injuries penetrating deep within the layers of skin. The test material is therefore considered to be corrosive.  Corrosive to skin
Dermal Sensitization (Buehler method) Hartley albino guinea pig PMRA # 3427167	Positive  Potential dermal sensitizer
<b>Short-term Toxicity Studies</b>	
90-day Oral Toxicity – Waiver request PMRA # 3427164	Based on the restricted class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, the requirement for a repeat-dose oral toxicity study has been waived.
21-Day Dermal Toxicity – Waiver request PMRA # 3427164	Based on the restricted class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, the requirement for a repeat-dose dermal toxicity study has been waived.
90-Day Inhalation Toxicity – Waiver assessment	This study is conditionally required based on the likelihood of significant repeated inhalation exposure to the product as a gas, vapour or aerosol. The active ingredient has a vapour pressure of 14.08 mPa at 25°C. Handling of the test material and preparation of the bait eggs requires the use of a respirator and is performed under a fume hood or in a secure outdoor location. Therefore, the potential for repeated inhalation exposure is quite limited and the requirement for a repeat-dose inhalation toxicity study has been waived.
<b>Chronic Toxicity/Oncogenicity Studies</b>	
78-Week Oral Toxicity (diet)	Acceptable with limitations.  Study author NOAEL = 300 ppm (45 mg/kg bw/day, estimated) (♀) Study author LOAEL = 600 ppm (90 mg/kg bw/day, estimated) (♂)

Study Type/Animal/PMRA #	Study Results
<p>Conducted with 3-chloro-4-methylaniline (also identified as 3-chloro-<i>p</i>-toluidine)</p> <p>Mouse (B6C3F1)</p> <p>PMRA # 3448885</p>	<p>≥600 ppm (90 mg/kg bw/day, estimated): ↓ bw (♂/♀)</p> <p>No evidence of tumourigenicity.</p> <p>Limitations: Purity of the test material was not reported, only two doses were administered, control and dose groups did not contain the same number of animals (20 in control vs. 50 in dose groups), animals in the treated groups received the untreated control diet for a 12 week observation period that followed the 78-week dosing period, food consumption was not measured, body weight results were only provided in graph format, hematological and clinical chemistry parameters were not measured, not all tissues/organs were examined histopathologically, organs were not weighed, no individual animal data were provided for any observation (i.e., summary data only provided for neoplastic and non-neoplastic lesions).</p>
<p>78-Week Oral Carcinogenicity (diet)</p> <p>Conducted with 3-chloro-4-methylaniline (also identified as 3-chloro-<i>p</i>-toluidine)</p> <p>Rat (Fischer 344)</p> <p>PMRA # 3448885</p>	<p>Acceptable with limitations.</p> <p>Study author NOAEL = 1635 ppm (114 mg/kg bw/day, estimated) (♂/♀)</p> <p>3269 ppm (229 mg/kg bw/day, estimated): ↓ bw, fibrosis of the splenic capsule, hepatic fatty metamorphosis (♂/♀); equivocal evidence of endometrial stromal polyp (♀).</p> <p>Equivocal evidence of tumourigenicity.</p> <p>Limitations: Purity of test material was not reported, only two doses were administered, control and dose groups did not contain the same number of animals (20 in control vs. 50 in dose groups), food consumption was not measured, body weight results were only reported in graph format, hematological and clinical chemistry parameters were not measured, not all tissues/organs were examined histopathologically, organs were not weighed, no individual animal data were provided for any observation (i.e., summary data only provided for neoplastic and non-neoplastic lesions). Additionally, after test material administration for 7 weeks, doses were reduced from 6000 ppm and 3000 ppm to 3000 ppm and 1500 ppm, for the high and low doses, respectively, for the remaining 71 weeks of administration for an unspecified reason. This was followed by an observation period of 24 or 25 weeks during which the treated animals received the untreated control diet. Resulting dietary concentrations were reported as a time-weighted average.</p>

Study Type/Animal/PMRA #	Study Results
<b>Developmental/Reproductive Toxicity Studies</b>	
Reproductive Toxicity - Waiver request  PMRA # 3427164, 3448886	Based on the restricted class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, the requirement for a multi-generation reproductive toxicity study has been waived.
Developmental Toxicity - Waiver request  PMRA # 3427164, 3448886	Based on the restricted class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, the requirements for a prenatal developmental toxicity study in both rodents and non-rodents have been waived.
<b>Genotoxicity Studies</b>	
Bacterial Reverse Mutation Assay  <i>Salmonella typhimurium</i> TA1535, TA1537, TA1538, TA98, TA100  PMRA # 3448887	Negative ± metabolic activation  Tested up to cytotoxic concentrations.
In vitro Forward Gene Mutation Assay  CHO Cells  PMRA # 3448890	Negative ± metabolic activation  Tested up to precipitating and/or cytotoxic concentrations.
In vitro Chromosome Aberration Assay  CHO Cells  PMRA # 3448888	Negative in the absence of metabolic activation. Positive in the presence of metabolic activation at non-cytotoxic concentrations.
In vivo Cytogenetics – Waiver request  PMRA # 3718028	Overall, the available mutagenicity studies indicate that DRC-1339 Technical is not mutagenic and the oncogenicity/carcinogenicity study conducted in mice and rats did not provide any indication of tumourigenicity in mice and only equivocal evidence of tumourigenicity in rats. Additionally, due to the restricted class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, exposure to DRC-1339 is expected to be quite

Study Type/Animal/PMRA #	Study Results
	limited. Therefore, based on the information above, the requirement for an in vivo cytogenetics study has been waived.
<b>Neurotoxicity Studies</b>	
Acute Neurotoxicity – Waiver request PMRA # 3427164	This study is conditionally required based on the neurotoxic potential of the test material. Based on the restricted class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, the requirement for an acute neurotoxicity study has been waived.
Short-term Neurotoxicity – Waiver request PMRA # 3427164	This study is conditionally required based on the neurotoxic potential of the test material. Based on the restricted class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, the requirement for a short-term neurotoxicity study has been waived.
<b>Other Studies</b>	
Immunotoxicity – Waiver request PMRA # 3427164	This study is conditionally required based on the potential of the test material to affect the immune system. Based on the restricted class designation and proposed use pattern of the associated end-use product, the minimal amount of DRC-1339 permitted to be handled in a single year, the significant personal protective equipment and additional exposure mitigation measures included on the end-use product label, the requirement for an immunotoxicity study has been waived.

<sup>a</sup> MAS = Maximum Average Score for 24, 48, and 72 hours

<sup>b</sup> MIS = Maximum Irritation Score

**Table 2 Fate and Behaviour in the Environment**

Property	Test substance	Medium	Value	Kinetic model	Major transformation products <sup>(1)</sup>	Comments	PMRA #
<b>Abiotic transformation</b>							
Hydrolysis	DRC-1339	pH 5, 7 and 9 buffers				Hydrolysis is a negligible process	3427169
Phototransformation in soil	Data not required based on the proposed use (use site category 32 - various outdoor sites) and were not submitted by the applicant.						

Property	Test substance	Medium	Value	Kinetic model	Major transformation products <sup>(1)</sup>	Comments	PMRA #
Phototransformation in water							
Phototransformation in air							
<b>Biotransformation</b>							
Biotransformation in aerobic soil <sup>(2)</sup>	DRC-1339	Menlo Park (loam)	$t_R/DT_{50} = 1.1$ days	Pseudo first order	3-chloro-4-methyl-acetanilide Unextracted residues CO <sub>2</sub>	DRC-1339 is non-persistent in the tested soils.  The TPs were non-persistent to slightly persistent (DT <sub>50</sub> values 1.1 to 24 days)	3427170
		Iowa (silt loam)	$t_R = 0.04$ days DT <sub>50</sub> = 0.00 days	IORE	Three unidentified compounds with relative retention times (RRT) of 0.2, 0.86 and 1.18. Unextracted residues CO <sub>2</sub>		3545303
		Massachusetts (clay)	$t_R = 12.0$ days DT <sub>50</sub> = 2.19 days	IORE	Unextracted residues		
		North Dakota (clay loam)	$t_R = 0.68$ days DT <sub>50</sub> = 0.07 days	IORE	3-chloro-4-methyl-acetanilide Unextracted residues CO <sub>2</sub>		
		Texas (loam)	$t_R/DT_{50} = 6.1$ days	SFO	Unidentified (RRT 1.18) Unextracted residues		
Biotransformation in anaerobic soil	Data not required based on the proposed use (use site category 32 - various outdoor sites) and were not submitted by the applicant.						

Property	Test substance	Medium	Value	Kinetic model	Major transformation products <sup>(1)</sup>	Comments	PMRA #
Biotransformation in aerobic and anaerobic aquatic systems (total system)	Data not required based on the proposed use (use site category 32 - various outdoor sites) and were not submitted by the applicant.						
<b>Bioconcentration</b>							
Bioconcentration in fish ( <i>Lepomis macrochirus</i> )	Bioconcentration is not expected to be a concern based on the log K <sub>OW</sub> of 2.27. Furthermore, bioconcentration data are not required for use site category 32 (various outdoor sites), as significant exposure of the aquatic environment from the proposed use is not expected.						
<b>Mobility</b>							
Adsorption / desorption in soil	A definitive adsorption/desorption study was not conducted because degradation of the test item prevented the calculation of accurate adsorption parameters as equilibrium was not reached.						3427171
Soil leaching	The leaching behaviour of aged <sup>14</sup> C-DRC-1339 residues in Menlo Park loam soil was evaluated. The mobility of DRC-1339 was determined to be low, with less than 3% of the applied radioactivity removed in leachate.						3427172
Volatilization	A volatility study is conditionally required for use site category 32. DRC-1339 has intermediate to high vapour pressure but is not expected to be volatile from moist soil or a water surface based on its Henry's law constant. Given the very limited extent of the use of DRC-1339 (reportedly less than 100 g annually, injected into eggs), a volatility study was not required.						
<b>Field studies</b>							
Terrestrial field dissipation	Data not required based on the proposed use (use site category 32 - various outdoor sites) and were not submitted by the applicant.						

Table 3 Toxicity to Non-Target Species

Organism	Exposure	Test substance	Endpoint	Comments/ Degree of toxicity <sup>1</sup>	PMRA #
<b>Terrestrial organisms</b>					
Honey bees ( <i>Apis mellifera</i> )	48-h Acute oral	DRC-1339 (TGAI; 95.5%)	48-h LD <sub>50</sub> >100 µg/bee	Practically non-toxic	3427185

Organism	Exposure	Test substance	Endpoint	Comments/ Degree of toxicity <sup>1</sup>	PMRA #
<b>Birds</b>					
American crow ( <i>Corvus brachyrhynchos</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 1.33 mg/kg bw	Very highly toxic	3558693
Scrub jay ( <i>Aphelocamoma sp.</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 1.8 mg/kg bw	Very highly toxic	3558693
Red-winged blackbird ( <i>Agelaius phoeniceus</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 2.4 mg/kg bw	Very highly toxic	3558693
Northern bobwhite ( <i>Colinus viginianus</i> )	Acute oral	DRC-1339 (TGAI; 97.1%)	LD <sub>50</sub> = 2.60 mg/kg bw	Very highly toxic	3427183
Common raven ( <i>Corvus corax</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 2.9 mg/kg bw	Very highly toxic	3558693
Mourning dove ( <i>Zenaida macroura</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 3.2 mg/kg bw	Very highly toxic	3558693
European starling ( <i>Stumus vulgaris</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 3.2 mg/kg bw	Very highly toxic	3558693
Barn owl ( <i>Tyto alba</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 4.2 mg/kg bw	Very highly toxic	3558693
Herring gull ( <i>Larus argentatus</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 4.6 mg/kg bw	Very highly toxic	3558693
Ring-necked pheasant ( <i>Phasianus colchicus</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 10 mg/kg bw	Highly toxic	3558693
Domestic turkey ( <i>Meleagris gallopavo</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 10.26 mg/kg bw	Highly toxic	3558693
Rock dove ( <i>Columba livia</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 17.7 mg/kg bw	Highly toxic	3558693
Chachalaca ( <i>Ortalis vetula</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 42.1 mg/kg bw	Highly toxic	3558693
Mallard duck	Acute oral	DRC-1339 (TGAI; 97.1%)	LD <sub>50</sub> = 100 mg/kg bw	Moderately toxic	3427184

Organism	Exposure	Test substance	Endpoint	Comments/ Degree of toxicity <sup>1</sup>	PMRA #
<i>Anas platyrhynchos</i>	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 105 mg/kg bw	Moderately toxic	3558693
House sparrow ( <i>Passer domesticus</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 375 mg/kg bw	Moderately toxic	3558693
Cooper's hawk ( <i>Accipiter cooperii</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 562 mg/kg bw	Slightly toxic	3558693
<b>Mammals</b>					
Domestic dog ( <i>Canis familiaris</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> >100 mg/kg bw	No mortality up to the highest concentration tested (100 mg/kg bw); however, vomiting occurred at all treatment levels (10, 50 and 100 mg/kg bw).	3558693 3558694
Domestic sheep ( <i>Ovis aries</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 400 mg/kg bw	Moderately toxic. No mortality up to 200 mg/kg bw.	3558693 3558694
North American deer mouse ( <i>Peromyscus maniculatus</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 1800 mg/kg bw	Slightly toxic	3558693
Wistar albino rat ( <i>Rattus norvegicus domestica</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 330 mg/kg bw	Moderately toxic	3427162
Brown rat ( <i>Rattus norvegicus</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 302 mg/kg bw	Moderately toxic	3558693
	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 1170 - 1770 mg/kg bw	Slightly toxic	3558693
Wistar Albino rat ( <i>Rattus norvegicus</i> )	Acute oral	DRC-1339 (TGAI; purity not reported)	LD <sub>50</sub> = 303 mg/kg bw	Moderately toxic	3427162

Organism	Exposure	Test substance	Endpoint	Comments/ Degree of toxicity <sup>1</sup>	PMRA #
<b>Freshwater organisms</b>					
<i>Daphnia magna</i>	48-h Acute	DRC-1339 (TGAI; 96.3%)	48-h EC <sub>50</sub> = 0.079 mg/L 48-h NOEC = 0.032 mg/L	Very highly toxic	3427175
Bluegill sunfish ( <i>Lepomis macrochirus</i> )	96-h Acute	DRC-1339 (TGAI; purity not reported)	96-h LC <sub>50</sub> = 7 mg/L	Moderately toxic	3427177
		DRC-1339 (TGAI; 99.07%)	96-h LC <sub>50</sub> = 10 mg/L 96-h NOEC = 4.2 mg/L	Moderately toxic	3427179
		DRC-1339 (TGAI; 96.3%)	96-h LC <sub>50</sub> = 11 mg/L 96-h NOEC = 2.8 mg/L	Slightly toxic	3427182
Channel catfish ( <i>Ictalurus punctatus</i> )	96-h Acute	DRC-1339 (TGAI; purity not reported)	96-h LC <sub>50</sub> = 38 mg/L	Slightly toxic	3427177
Goldfish ( <i>Carassius auratus</i> )	96-h Acute		96-h LC <sub>50</sub> = 34 mg/L	Slightly toxic	
Rainbow trout ( <i>Oncorhynchus mykiss</i> )	96-h Acute		96-h LC <sub>50</sub> = 8 mg/L	Moderately toxic	
		DRC-1339 (TGAI; 96.3%)	96-h LC <sub>50</sub> = 9.7 mg/L NOEC = 1.2 mg/L	Moderately toxic	3427178

<sup>1</sup> USEPA classification, where applicable.

**Table 4 Estimation of Environmental Risks to Mammals**

Species	A		B <sup>1,2</sup>		C <sup>3, 4</sup>		D <sup>5</sup>		E <sup>6</sup>	
	Body weight range (kg)		FIR range (g/day)		Amount of a.i. consumed to reach LD <sub>50</sub> /10 (mg)		Number of eggs to reach LD <sub>50</sub> /10		% of daily FIR	
	Low end	High end	Low end	High end	Low end	High end	Low end	High end	Low end of FIR	High end of FIR
Swift fox ( <i>Vulpes velox</i> )	2.2	2.4	210	330	66	72	3	4	55	38
Skunk ( <i>Mephitis meohitis</i> )	3	8	170	380	91	242	5	12	94	111
Bobcat ( <i>Lynx rufus</i> )	4	18	215	739	121	544	6	27	98	129
Raccoon ( <i>Procyon lotor</i> )	5	12	258	530	151	362	8	18	102	120
Coyote ( <i>Canis latrans</i> )	6.8	21	332	839	205	634	10	32	108	132
Cougar ( <i>Puma concolor</i> )	41	71	1455	2285	1238	2144	62	107	149	164
Black bear ( <i>Ursus americanus</i> )	57	250	1907	6429	1721	7550	86	378	158	205
Generic animal <sup>7</sup>	10	12	456	530	302	362	15	18	116	120

a.i. = active ingredient

FIR = Food ingestion rate

LD<sub>50</sub> = lethal dose to 50% of the population

- FIR was estimated using the equation from Nagy (1987). For mammals, the “all mammals” equation was used:  

$$\text{FIR (g dry weight/day)} = 0.235 (\text{bw in g})^{0.822}$$
- For the swift fox, the daily food intake was taken from the COSEWIC (2021) Assessment and Status Report for the Swift Fox (PMRA # 3478748).
- The most sensitive toxicity endpoint available for mammals (LD<sub>50</sub> of 302 mg a.i./kg bw for the brown rat) was used to estimate risk for all species. An uncertainty factor of 10 was applied to the LD<sub>50</sub> to account for potential differences in species sensitivity.
- The amount of DRC-1339 needed to be consumed to reach the LD<sub>50</sub>/10 was calculated as the LD<sub>50</sub>/10 multiplied by body weight.
- Each egg treated with DRC-1339 contains 20 mg a.i.. To calculate the number of eggs to reach the LD<sub>50</sub>/10, the values in column C were divided by 20.
- The % of the daily FIR represented by the number of eggs needing to be consumed to reach the LD<sub>50</sub>/10 was calculated by multiplying column D by 35 g (assumed weight of a chicken egg) divided by the FIR in column B, and then multiplying by 100.

7. A 'generic' animal, assumed to be 10-12 kg, was used to determine the size at which all of the eggs at a baited site would need to be consumed to meet the lethal threshold.

**Table 5 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria**

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
CEPA toxic or CEPA toxic equivalent <sup>1</sup>	Yes		Yes	Yes
Predominantly anthropogenic <sup>2</sup>	Yes		Yes	Yes
Persistence <sup>3</sup> :	Soil	Half-life $\geq 182$ days	No, aerobic DT <sub>50</sub> values: $\leq 6.1$ days	No, aerobic DT <sub>50</sub> values: 1.1 to 24 days
	Water	Half-life $\geq 182$ days	Data were not submitted as they are not required for use site category 32. These data would not change the outcome of the TSMP assessment given that the bioaccumulation criteria are not met.	
	Sediment	Half-life $\geq 365$ days		
	Air	Half-life $\geq 2$ days or evidence of long-range transport	No, the AOPWIN (v1.92)-predicted half-life in the gas phase in the atmosphere is 0.12 days based on the hydroxyl (OH) radical reaction ( $1.5 \times 10^6$ molecules OH/cm <sup>3</sup> ) during 12 hours of daylight.	No, the AOPWIN (v1.92)-predicted half-lives in the gas phase in the atmosphere based on the hydroxyl (OH) radical reaction ( $1.5 \times 10^6$ molecules OH/cm <sup>3</sup> ) during 12 hours of daylight are: <ul style="list-style-type: none"> <li>• 0.98 days for 3-chloro-4-methyl-acetanilide</li> <li>• 0.53 days for the unidentified TP of molecular weight of 158 g/mole, based on the proposed structure</li> </ul>
Bioaccumulation <sup>4</sup>	log $K_{ow} \geq 5$		No, log $K_{ow} = 2.27$	No, log $K_{ow}$ values estimated by KOWWIN (v1.68) are: <ul style="list-style-type: none"> <li>• 3-chloro-4-methyl-acetanilide: 2.29</li> <li>• Unidentified TP of molecular weight of 158 g/mole: 2.22</li> </ul>
	BCF $\geq 5000$		Data not required based on log $K_{ow}$ value	
	BAF $\geq 5000$		Data not required based on log $K_{ow}$ value	
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	No, TPs do not meet TSMP Track 1 criteria.

<sup>1</sup> All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria

are met).

- 2 The policy considers a substance “predominantly anthropogenic” if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
- 3 If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
- 4 Bioaccumulation describes the process by which a substance accumulates in a living organism - either from the surrounding medium or through food containing the substance. A substance’s potential to bioaccumulate can be expressed by the bioaccumulation factor (BAF), the bioconcentration factor (BCF), or the octanol-water partition coefficient ( $\log K_{ow}$ ). The BAF and the BCF measure the concentration of a substance in a living organism relative to its concentration in the surrounding medium. The BAF accounts for substance intake from both food and the surrounding medium, while the BCF accounts for intake from the surrounding medium only. The  $\log K_{ow}$  estimates a substance’s tendency to partition from water to organic media, such as lipids present in living organisms. In the absence of BAF or BCF data, the  $\log K_{ow}$  may be used

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## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Chemistry

##### PMRA document number

##### Reference

3427141	2018, Product Chemistry of DRC-1339 Technical: Description of Formulation Process, MRID 50693204, DACO: 2.11,2.11.1 CBI
3427142	2019, Product Chemistry of DRC-1339 Technical: Description of Formulation Process, MRID 50877404, DACO: 2.11,2.11.1 CBI
3427143	2018, Product Chemistry of DRC-1339 Technical: Descriptions of the Materials Used to Produce the Product, MRID 50693202, DACO: 2.11.2 CBI
3427144	2019, Product Chemistry of DRC-1339 Technical: Descriptions of the Materials Used to Produce the Product, MRID 50877402, DACO: 2.11.2 CBI
3427145	2018, Product Chemistry of DRC-1339 Technical: Description of Production Process, MRID 50693203, DACO: 2.11.3 CBI
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3516259	2023, 2.13.3 Waiver request for new Batch data, DACO: 2.13.3
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3555337	2024, 2.13.1 Rationale_excel diagrams, DACO: 2.13.1
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3555339	2024, Impurities [PRIVACY INFO Removed] (NWRC Sample S170928-03), DACO: 2.13.3 CBI
3555341	2024, Impurities [PRIVACY INFO Removed] (NWRC Sample S170928-04), DACO: 2.13.3 CBI
3555342	2024, Impurities [PRIVACY INFO Removed] (NWRC Sample S170928-02), DACO: 2.13.3 CBI
3555343	2024, Impurities [PRIVACY INFO Removed] (NWRC Sample S170928-01), DACO: 2.13.3 CBI
3555344	2024, Impurities [PRIVACY INFO Removed] (NWRC Sample S170724-05), DACO: 2.13.3 CBI
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3555346	2024, Impurities [PRIVACY INFO Removed] (NWRC Sample S170724-03), DACO: 2.13.3 CBI
3555347	2024, Impurities [PRIVACY INFO Removed] (NWRC Sample S170724-01), DACO: 2.13.3 CBI
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3580999	2024, 2.11.4 MRID-52270903_Discussion of formation of Impurities, DACO: 2.11.4 CBI
3581000	2024, 2.11.3 MRID-52270904 Detailed Manu Process, DACO: 2.11.3 CBI
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3709658	2025, DACO_2.13.3_23-024 230620 Day 1 Chromatograms, DACO: 2.13.3 CBI
3709659	2025, DACO_2.13.3_23-025 230710 CPTH Impurities QuantReport, DACO: 2.13.3 CBI
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## 2.0 Human and Animal Health

### PMRA document number

### Reference

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3427167	1992, Delayed Contact Dermal Sensitization Test - Buehler Method, DACO: 4.2.6,4.6.6
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### 3.0 Environment

#### PMRA document number

#### Reference

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3427190	2023, 12.5.8, 12.5.9 EPA-HQ-OPP-2011-0696-0015_content, DACO: 12.5.8,12.5.9

#### 4.0 Value

##### PMRA document number

	Reference
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## B. Additional Information Considered

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