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Special Review Decision

SRD2019-01

# Special Review Decision: Hexazinone and Its Associated End-use Products

*Final Decision Document*

*(publié aussi en français)*

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## Special Review Decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of all registered pest control products containing hexazinone, based on the 1998 Norway regulatory decision to prohibit all uses of hexazinone in Norway due to environmental concerns. The PMRA evaluated the aspects of concern that prompted the special review in accordance with the subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2017-11, *Special Review of Hexazinone: Proposed Decision for Consultation* (Canada, 2017). Appendix I summarizes the comments received during the consultation period and provides the PMRA's response to these comments. Currently registered products containing hexazinone are listed in Appendix II.

Comments received during the consultation process were taken into consideration in making this special review decision, and they did not result in changes to the proposed regulatory decision as described in REV2017-11. Therefore, the PMRA, under the authority of the *Pest Control Products Act*, is confirming the current registration of pest control products containing hexazinone in Canada with the label amendments outlined in Appendix III.

Please refer to the Regulatory Directive DIR2014-01, *Approach to Special Reviews*, for details of the PMRA's special review approach.

## Other Information

Any person may file a notice of objection<sup>1</sup> regarding this decision on hexazinone within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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<sup>1</sup> As per subsection 35(1) of the *Pest Control Products Act*.

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## Appendix I Comments and Responses

The PMRA received comments from stakeholders in response to Re-evaluation Note REV2017-11, *Special Review of Hexazinone: Proposed Decision for Consultation*. The PMRA consolidated and summarized the comments related to the aspects of concern of this special review and provides responses below.

### 1.1 Increased Use of Hexazinone in Canada

The use of hexazinone in Canada has increased in the past years (2012-2014). Over the same period, farm area cultivated for blueberry production, one of the main uses of hexazinone, also increased. Water monitoring data used in the risk assessment were mostly predating 2012. The data does not reflect the current use pattern. If more recent monitoring data is not available, the PMRA should note this data gap and avoid relying on monitoring data that does not reflect current use pattern.

#### PMRA Response

Following the initiation of the special review of hexazinone, the PMRA requested information related to the aspects of concern from provinces and other relevant federal departments and agencies in accordance with subsection 18(2) of the *Pest Control Products Act*, including water monitoring information. The available Canadian water monitoring data was considered in the special review.

As noted in the proposed special review decision, hexazinone is registered to control weeds in blueberry, alfalfa grown for seeds and forage, woodland management areas and Christmas tree plantations. Monitoring information considered in the assessment includes contribution from use of hexazinone not only on blueberries alone, but also on other uses. It is noted that most of the available Canadian surface water monitoring information were from samples collected before 2012. However, the monitoring database contained a relatively large Canadian data set (nearly 1300 ground water samples and 2000 surface water samples) from sites across the country with infrequent detections. As outlined in the REV2017-11, the estimated levels of hexazinone considered in the drinking water assessment far exceed the actual levels detected in Canadian water monitoring information (maximum groundwater 8.9 µg/L; maximum surface water 11.78 ug/L). Thus, the drinking water assessment is considered conservative and protective. In addition, only very few instances (only two samples) of the measured concentrations exceeded the toxicity endpoint for algae. The toxicity endpoint selected for the risk assessment is known to be protective of other algal species, and the effects realized at the algal community level are expected to be infrequent and short lived, with recovery and re-colonization expected in natural waters.

### 1.2 Risks to Aquatic Ecosystems

While the PMRA's modelling of estimated environmental concentrations from spray drift identified potential risk, based on the monitoring data considered, the PMRA concluded that the levels of hexazinone found in Canadian waters are not expected to pose a risk of concern to aquatic non-vascular plants and a disagreement with this conclusion was expressed in the comment. Environment Canada's National Water Quality Surveillance Program (2003-2005) indicated detections in British Columbia and Prince Edward Island, and that the four detections

in Prince Edward Island exceeded the threshold value of 70 ng/L. This contradicts the PMRA's finding that concentrations of hexazinone exceeded levels of concern in only two samples out of 2000 monitoring samples. The estimated environmental concentrations considered in the special review modelled only spray drift and exposure from runoff should also be considered. In addition, the comment indicated that the monitoring data may underestimate exposures for two reasons. First, sampling generally does not capture peak concentrations. Second, the use of hexazinone has increased in recent years and the monitoring data considered in the special review may not be representative of environmental concentrations of the current use pattern.

### **PMRA Response**

The PMRA follows a risk-based scientific approach to determine risks to non-target organisms. This approach takes into consideration both the exposure and the toxicity of the pesticide. For characterization of exposure, the PMRA considered modelling and available water monitoring information. Consequently, environmental risk characterization was done using monitoring and modelling information. The PMRA recognizes that water monitoring sampling may not capture peak concentrations and this is certainly a consideration when using monitoring data to refine a risk assessment.

Algae can be exposed to hexazinone as a result of spray drift and/or runoff from treated agricultural fields entering surface water. In the PMRA assessment, a conservative screening level risk assessment using direct overspray of hexazinone on a water body identified potential risks to algae. Additional characterization of the risk resulted in buffer zones to mitigate the risk from spray drift. Water monitoring data was used to further refine the risk assessment. Water monitoring data reflect the contribution of both runoff and spray drift into receiving water bodies. As outlined in the previous response (see Section 1.1), the PMRA considered a total of 2052 Canadian surface water monitoring samples. An analysis of the water monitoring data determined that hexazinone is detected in Canadian surface water occasionally, but very rarely at concentrations that may pose a risk to algae.

The algal toxicity endpoint used in the PMRA risk assessment was conservative and it was 7 µg/L (5 day-EC<sub>50</sub> for a freshwater green algae). This toxicity value was taken from a recent review conducted by the United States Environmental Protection Agency (2015) and was the most sensitive of 4 nonvascular aquatic plant endpoints. Information published by United States Department of Agriculture (USDA 2005) indicates that there are differences in sensitivity to hexazinone among algal species, with EC<sub>50</sub> values ranging from 7 µg/L to 16 µg/L. The most sensitive value identified by the United States is 7 µg/L (USDA 2005; USEPA 2015). This value of 7 µg/L was subsequently used in the PMRA risk assessment. Even though evidence shows that an EC<sub>50</sub> of 7 µg/L is protective of other species, the PMRA applied an additional uncertainty factor and used an endpoint of 3.5 µg/L for risk assessment purposes. Based on the available surface water monitoring information, only two samples from the 2052 samples available (< 0.1%) exceeded this endpoint. Using the maximum concentration measured in Canadian waters (11.78 µg/L), the maximum risk quotient determined from the available water monitoring data was low (3.4).

The publicly available Environment Canada report (2011) on the Presence and Levels of Priority Pesticides in Selected Canadian Aquatic Ecosystem cited in the comment identifies a water quality benchmark for hexazinone of 70 ng/L (0.07 µg/L). This value is much lower than the

3.5 µg/L determined by the PMRA. The origins of this benchmark are however not well documented in the report. The report points out that the Canadian Water Quality Guidelines for the Protection of Aquatic Life do not include a benchmark for hexazinone. In the absence of a benchmark, Environment Canada derived a benchmark value for hexazinone, and indicated that the benchmark values are not meant to be used for regulatory purposes. The PMRA is not able to determine how the 0.07 µg/L benchmark was derived and does not consider it for regulatory purposes.

The Environment Canada report cited by the commenter indicates that hexazinone was detected in surface water samples collected in Prince Edward Island during 2003 at concentrations of 0.08, 0.12, 0.16 and 0.24 µg/L. These data were among the 2052 samples considered in the PMRA water monitoring analysis. These detections are well below the toxicity endpoint for algae, 3.5 µg/L. In addition, these detections are much lower than the maximum detection of 11.78 µg/L considered in the PMRA risk assessment. In addition to the Canadian water monitoring information, the PMRA considered the surface water monitoring data from the United States, which shows that hexazinone was detected in 13% of 44 436 samples. Despite the extensive sampling done in the United States, the maximum concentration detected (2.27 µg/L) is well below the 3.5 µg/L algal toxicity endpoint considered in the special review.

The algal toxicity endpoint used in the PMRA assessment is based on a measurement of the density of algal cells. Based on available water monitoring data showing < 0.1% of detects were above the level of concern, effects, such as a reduction in cell count or growth inhibition as a result of exposure to hexazinone residues in water would not be expected to cause impacts at the community level. Any impacts at the population level would be expected to be short lived and result in recovery or re-colonization of the algal population. In addition, the endpoint being used in the risk assessment is a 5 day-EC<sub>50</sub>. As a result, algae would need to be exposed to concentrations above this endpoint for an extended period of time before harmful effects would be expected. Exposure at levels that could cause harm is not supported by the available water monitoring data.

### **1.3 Inadequacy of Proposed Risk Reduction Measures**

The proposed precautionary label statements and additional directions for use offer inadequate protection for aquatic ecosystems. Precautionary label statements cannot be relied on to protect against environmental risks. A recommendation was made to launch an initiative to evaluate the effectiveness of precautionary statements for use in reducing risks from pesticides. The proposed decision requires buffer zones to reduce runoff to freshwater habitats, but for field spray applications the proposed buffer zones are very narrow. The PMRA provides no evidence that such narrow buffer zones will be effective in meaningfully reducing spray drift and again fails to account for agricultural runoff.

## **PMRA Response**

Precautionary label statements are included on pesticide labels to inform users of best management practices to reduce pesticide exposure. The directions for use provide specific instructions on product use. Following best management practices may reduce pesticide entering water from runoff. The risk assessment for hexazinone determined that potential risk to algae from runoff is acceptable under the current conditions of use.

The no-spray buffer zones included in the label are not designed to mitigate risks from run-off, but rather protect non-target organisms from potential risks from spray drift. As part of the special review, buffer zones were updated using buffer zone calculation models. Buffer zones were determined using spray drift deposition models based on data for field sprayer equipment, and AGDISP v.8.21 software for fixed- and rotary wing aircraft. Those models take into considerations of various factors such as physicochemical properties and environmental fate characteristics of hexazinone, toxicity to non-target aquatic organisms, product formulation and guarantee, product application rate, number of applications, method of application, spray quality, spray volume, and weather conditions. Additional information on spray drift mitigation and the PMRA's buffer zone calculator can be found on the [Drift Mitigation page](#) of the Pesticides section of Canada.ca.

The updated buffer zones are included in the Appendix III.

The PMRA routinely conducts active prevention and monitoring programs across the regulated community and follows up on situations of reported or suspected pesticides misuse, working in partnership with our federal and provincial colleagues.

## Appendix II Registered Products Containing Hexazinone as of 10 December 2018

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
19544	Technical	TESSENDERLO KERLEY, INC.	Hexazinone Technical Herbicide	SO	98.7%
27551	Manufacturing concentrate	TESSENDERLO KERLEY, INC.	Hexazinone 90SP MUP	SP	90.0%
29291	Manufacturing concentrate	TESSENDERLO KERLEY, INC.	Velpar L MUP Herbicide	SN	240 g/L
29613	Manufacturing concentrate	TESSENDERLO KERLEY, INC.	Velpar DF CU MUP	WG	75.0%
14163	Commercial	TESSENDERLO KERLEY, INC.	Velpar Weed Killer Herbicide	SP	90%
18197	Commercial	TESSENDERLO KERLEY, INC.	Velpar L CU Herbicide	SN	240 g/L
21390	Commercial	TESSENDERLO KERLEY, INC.	Pronone 10G Granular Herbicide	GR	10%
25225	Commercial	TESSENDERLO KERLEY, INC.	Velpar DF Herbicide Water Dispersible Granule	WG	750 g/kg
31766	Commercial	Bayer CropScience Inc.	Velpar DF VU Herbicide Water Dispersible Granule	WG	75.0%
31786	Commercial	Bayer CropScience Inc.	Velpar L VU Herbicide	SN	240 g/L

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## Appendix III Label Amendments for Products Containing Hexazinone

The label amendments presented below do not include all label requirements for individual products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on the labels of currently registered products should not be removed unless it contradicts the label statements below.

1. Technical and manufacturing concentrates:

1) Add the following to a section entitled **ENVIRONMENTAL HAZARDS**

“TOXIC to aquatic organisms”

2) Add the following to the section entitled **PRECAUTIONS**

“DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.”

2. End-use products for all formulations except granular

The labels of all end-use products (except granular) must be amended to include the following statements to further protect the environment.

2.1 *For all products registered for use on lowbush blueberry, highbush blueberry and alfalfa*

**Add to DIRECTIONS FOR USE:**

“Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Boom height must be 60 cm or less above the crop or ground.

**DO NOT** apply by air.”

2.2 *For all products registered uses on woodland management) and Christmas Tree plantations*

“Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.”

### Buffer zones:

“Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

### Buffer Zone Required

Method of Application	Crop		Buffer zones (metres) required for the protection of				Terrestrial habitat
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	woodland management (less than 500 ha)		3	1	2	1	NR
	lowbush blueberry		2	1	1	1	5
	established conifers		2	1	1	1	5
	highbush blueberry		1	1	1	1	5
	established seed and forage alfalfa		1	1	1	1	5
Aerial (SG formulation)	woodland management (less than 500 ha)	Fixed wing	350	175	250	125	NR
		Rotary wing	225	100	150	80	NR
Aerial (SN formulation)	woodland management (less than 500 ha)	Fixed wing	375	200	250	125	NR
		Rotary wing	225	125	150	80	NR

NR: Buffer zones for the protection of terrestrial habitats are not required for use in forestry and woodlot management.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for products containing hexazinone can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency website.”

3. End-use product for granular formulation (Reg. No. 21390)

Remove the following statements

“DO NOT apply by ground within 50 meters of water bodies.”

“DO NOT apply by ground within 50 meters or by air within 100 meters of water bodies.”

4. For all end-use products, in the section entitled “**ENVIRONMENTAL HAZARDS**”, replace the existing label statements related to groundwater leaching with the following

“This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.”

## Reference List

### Published Information

<b>PMRA Number</b>	<b>Reference</b>
2920317	USDA 2005, Hexazinone - Human Health and Ecological Risk Assessment – Final Report
2747312	Canada 2017, REV2017-11, Special Review of Hexazinone, Proposed Decision for Consultation
2525751	Environment Canada. 2011. Presence and levels of priority pesticides in selected Canadian aquatic ecosystems. Water Science and Technology Directorate, Environment Canada. ISBN 978-1-100-18386-2.