



**BIOPESTICIDES REGISTRATION ACTION DOCUMENT**

*Typhula phacorrhiza*  
Strain 94671

**PC Code: 036604**

**U.S. Environmental Protection Agency  
Office of Chemical Safety and Pollution Prevention  
Biopesticides and Pollution Prevention Division**

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## **I. BACKGROUND**

*Typhula phacorrhiza* is a fungus widely reported from northern temperate zones, thriving in cold temperatures and living on dead organic matter. While it is related to other *Typhula* species that are known plant pathogens, it has been shown to be a distinct species. *Typhula phacorrhiza* is often found in corn (*Zea mays* L.) residues and other organic debris following at least 80 days of snow cover, but has also been collected from dead leaves of other plants. *Typhula phacorrhiza* strain 94671 was originally isolated from overwintered corn husks and stubble in a field near Acton, Ontario (Canada). Cold weather and abundant moisture create optimum conditions for growth and reproduction, and *Typhula phacorrhiza* strain 94671 grows optimally at 4°C. The *Typhula phacorrhiza* strain 94671 end-use product is for non-food use. As a pesticide active ingredient, it is a competitor intended to prevent development of grey and pink snow molds of golf course turf grasses caused by *Typhula incarnata* or *Typhula ishikariensis*, and *Microdochium (Fusarium) nivale*, respectively. The product is to be applied to golf course turf in the fall, before snowfall, in regions where continuous snow cover persists for 90 days or more. *Typhula phacorrhiza* requires the same environmental cues of high moisture and near-freezing temperatures as do the plant pathogenic *Typhula incarnata* and *Typhula ishikariensis*, but is a superior competitor for resources and tolerates a wider range of conditions. *Microdochium nivale* frequently occurs with plant pathogenic *Typhula* species and while it doesn't require snow cover and has a higher optimum growth temperature, under the application conditions for the microbial pest control agent, *Typhula phacorrhiza* would be expected to out-compete it, as well.

On October 1, 2009, the Environmental Protection Agency (EPA or the Agency) announced a new policy to provide a more meaningful opportunity for the public to participate in major registration decisions before they occur. According to this new policy, the Agency intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food uses; first outdoor uses; first residential uses; and any registration decisions for which the Agency believes there may be substantial public interest.

Consistent with the new policy of making registration actions more transparent, *Typhula phacorrhiza* strain 94671 was the subject of a 30-day comment period as a "new active ingredient" whose registration would result in a "first outdoor use." While a final decision on registration was contingent upon review and consideration of public comments, no comments were received. The Agency believes that, based upon its assessment of the data and information submitted in support of registration of *Typhula phacorrhiza* strain 94671, it is in the best interest of the public and the environment to issue the registration for *Typhula phacorrhiza* strain 94671. The basis for this preliminary decision can be found in the risk assessment for *Typhula phacorrhiza* strain 94671, which is characterized throughout this Biopesticides Registration Action Document (BRAD) and the associated reference documents written by Agency scientists.

## II. ACTIVE INGREDIENT OVERVIEW

**Biological Name:** *Typhula phacorrhiza* strain 94671

**Culture Deposit:** University of Alberta Microfungus Collection and Herbarium  
(Accession Number UAMH 10959)

**Trade & Other Names:** Nivalis Technical

**OPP Chemical Code:** 036604

**Type of Pesticide:** Microbial Pesticide/Biofungicide

## III. REGULATORY BACKGROUND

### A. Applications for Pesticide Registration

On March 10, 2010, EPA published a Notice of Receipt in the Federal Register ([75 FR 11175](#)), announcing that Technology Sciences Group Incorporated, 712 Fifth Street, Suite A, Davis, CA 95616 (on behalf of the applicant, Agrium Advanced Technologies RP Incorporated) submitted applications to register two pesticide products (a technical product and one end-use product) containing a new active ingredient not included in any currently registered pesticide products. No comments were received following this publication.

### B. North American Free Trade Agreement Joint Review

*Typhula phacorrhiza* strain 94671 was the subject of a North American Free Trade Agreement joint registration review conducted by the Environmental Protection Agency Office of Pesticide Programs and the Health Canada Pest Management Regulatory Agency (PMRA). The PMRA consultation document recommending full registration of *Typhula phacorrhiza* strain 94671 was made available on September 10, 2010, for public comment for a period of 45-days; the consultation period for that announcement is now closed. For the PMRA Proposed Registration Decision, see <http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/prd2010-23/prd2010-23-eng.php>.

### C. Food Clearances/Tolerances

No tolerance or exemption from the requirement of a tolerance is associated with or required for this regulatory action as only non-food uses are currently proposed for *Typhula phacorrhiza* strain 94671. Accordingly, this action is outside the scope of the Food Quality Protection Act (FQPA). There are no CODEX maximum residue levels established for *Typhula phacorrhiza* strain 94671.

#### **IV. RISK ASSESSMENT**

On October 26, 2007, the Agency issued a Final Rule in the Federal Register on the data requirements to support registration of microbial pesticides and updated the definition for microbial pesticides ([72 FR 61002](#)). The rule became effective on December 26, 2007. The data and information evaluated for this BRAD were considered in light of these requirements.

The classifications that are found for each data submission are assigned by Agency science reviewers and are an indication of the usefulness of the information contained in the documents for risk assessment. A rating of “ACCEPTABLE” indicates the study is scientifically sound and is useful for risk assessment. A “SUPPLEMENTAL” rating indicates the data provide some information that can be useful for risk assessment. The studies may have certain aspects determined not to be scientifically acceptable (“SUPPLEMENTAL: UPGRADABLE”). If a study is rated as “SUPPLEMENTAL: UPGRADABLE,” the Agency always provides an indication of what is lacking or what can be provided to change the rating to “ACCEPTABLE.” If there is simply a “SUPPLEMENTAL” rating, the reviewer will often state that the study is not required by the current 40 Code of Federal Regulations (CFR) part 158. Both “ACCEPTABLE” and “SUPPLEMENTAL” studies may be used in the risk assessment process, as appropriate. An “UNACCEPTABLE” rating indicates that new data need to be submitted.

For the acute toxicity data requirements, toxicity categories are assigned based on the hazard(s) identified from studies and/or other information submitted to the Agency in support of a pesticide registration. The active ingredient or particular product is classified into Toxicity Category I, II, III, or IV, where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity.

##### **A. Active Ingredient Characterization**

Nivalis Technical is a manufacturing-use product to be incorporated into an end-use product. The active ingredient is 4.00% weight/weight *Typhula phacorrhiza* strain 94671 (minimum of 181,600 cfu/lb).

All product analysis data requirements for registration of *Typhula phacorrhiza* strain 94671 have been **satisfied**.

Refer to Table 1 in Appendix A for a brief summary of these data requirements.

Additionally, the comprehensive Agency risk assessments that evaluate these data are available as “Supporting & Related Materials” within Docket Number EPA-HQ-OPP-2010-0090 at <http://www.regulations.gov> (U.S. EPA 2010a and U.S. EPA 2010c).

## **B. Human Health Assessment**

### **1. Toxicity**

All toxicology data requirements for *Typhula phacorrhiza* strain 94671 have been **satisfied**.

Acceptable Tier I mammalian toxicology data/information support the registration of *Typhula phacorrhiza* strain 94671. The infectivity/pathogenicity endpoint was not addressed by a study following the suggested guidelines, but rather with a pilot study and data indicating the inability of the fungal active ingredient to grow at mammalian body temperatures. Furthermore, Tier II and Tier III studies were not required for *Typhula phacorrhiza* strain 94671 based on the lack of acute toxicity/pathogenicity in the Tier I studies.

Refer to Table 2 in Appendix A for a brief summary of these data requirements.

Additionally, the comprehensive Agency risk assessments that evaluate these data are available as “Supporting & Related Materials” within Docket Number EPA-HQ-OPP-2010-0090 at <http://www.regulations.gov> (U.S. EPA 2010a.).

### **2. Effects on the Endocrine System**

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and nine inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

*Typhula phacorrhiza* strain 94671 is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for all pesticide active ingredients.



For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: <http://www.epa.gov/endo/>.

### **3. Risk Characterization**

The Agency considered human exposure to *Typhula phacorrhiza* strain 94671 in light of the relevant safety factors in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of *Typhula phacorrhiza* strain 94671 when label instructions are followed.

## **C. ENVIRONMENTAL ASSESSMENT**

### **1. Nontarget Organism Toxicology**

All nontarget toxicology data requirements for *Typhula phacorrhiza* strain 94671 have been **satisfied**.

Adequate Tier I nontarget organism data/information are available to support registration of *Typhula phacorrhiza* strain 94671.

Refer to Table 3 in Appendix A for a brief summary of these data requirements.

Additionally, the comprehensive Agency risk assessments that evaluate these data are available as “Supporting & Related Materials” within Docket Number EPA-HQ-OPP-2010-0090 at <http://www.regulations.gov> (U.S. EPA 2010b).

### **2. Environmental Fate and Ground Water Data**

As the information provided is sufficient to both satisfy the Tier I nontarget organism data requirements and for nontarget organism risk assessment for *Typhula phacorrhiza* strain 94671, further testing at higher tier levels (i.e., Tiers II, III, and IV) is not required.

### **3. Ecological Exposure and Risk Characterization**

The Agency has performed an environmental risk assessment based on the data, literature citations, and data waiver rationale provided by the registrant, and has determined that the proposed use of *Typhula phacorrhiza* strain 94671 does not pose risk to nontarget organisms. *Typhula phacorrhiza* is a saprotrophic snow mold that is an obligate psychrophile (i.e., it requires low temperatures for growth and reproduction and lives on dead organic matter). It is abundant within its range and is widely distributed in areas with persistent snow cover. *Typhula phacorrhiza* is recognized as a species distinct from the target *Typhula* species that are recognized plant pathogens. It is not known to produce toxins or other chemicals as a means of competing with other fungi. Exposure of nontarget organisms to actively growing *Typhula phacorrhiza* strain 94671 is also expected to be limited due to the conditions it requires for growth.

The registrant has submitted data waiver rationale to satisfy data requirements for nontarget organism risk assessment with the active ingredient (TGAI). Review of the rationale and data submitted to support the registration of *Typhula phacorrhiza* strain 94671 was completed jointly with Health Canada's PMRA. Submitted data, data waiver rationale, and a search by EPA of several literature databases provides sufficient information to determine that toxicity/pathogenicity to wild mammals, avian wildlife, freshwater and marine/estuarine vertebrates and invertebrates, honey bees, nontarget insects, and terrestrial and aquatic plants is not expected from the proposed label uses. As a result, a "No Effect" determination is also made for direct and indirect effects to listed species and their designated critical habitats resulting from the proposed use of *Typhula phacorrhiza* strain 94671, as labeled.

The information provided is sufficient to both satisfy the Tier I nontarget organism data requirements and for nontarget organism risk assessment for the active ingredient. Further testing at higher tier levels is not required.

#### **4. Threatened and Endangered Species Assessment**

EPA has determined that adverse effects will not occur to nontarget organisms as a result of the proposed labeled applications of *Typhula phacorrhiza* strain 94671. Additionally, *Typhula phacorrhiza* is a saprotrophic fungus that competes specifically with other snow mold fungi, and reduction or loss of these fungi will not affect habitat or other resources required by threatened and endangered species.

Since the Agency has determined that no effects are anticipated for any nontarget species exposed to *Typhula phacorrhiza* strain 94671 as a result of the proposed labeled applications, effects to federally-listed threatened and endangered species and their designated critical habitats are also not expected. Therefore, a "No Effect" determination is made for direct and indirect effects to listed species and their designated critical habitats resulting from the registered uses of *Typhula phacorrhiza* strain 94671, as labeled.

#### **D. PRODUCT PERFORMANCE DATA (EFFICACY)**

Submission of product performance data (OPPTS 810.3000) is listed as a requirement for all pesticide products. The Agency retains the right to require submission of efficacy data to support an application for registration of a pesticide, but customarily only requires the data in connection with the registration of products directly pertaining to the mitigation of disease-bearing human health organisms and certain designated quarantine pests, i.e., ticks, mosquitoes, fleas, Mediterranean fruit flies, gypsy moths, Japanese beetles, etc. For a list of organisms considered by the Agency as "public health pests," please refer to Pesticide Registration Notice 2002-1 ([http://www.epa.gov/PR\\_Notices/pr2002-1.pdf](http://www.epa.gov/PR_Notices/pr2002-1.pdf)).

Efficacy data were not submitted, or reviewed by EPA, in association with the U.S. pesticide registration applications for *Typhula phacorrhiza* strain 94671. The PMRA received and reviewed efficacy data in support of the Canadian registration application. For PMRA's summary of these data, see the "Value Considerations" section of [http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/\\_prd2010-23/prd2010-23-eng.php](http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_prd2010-23/prd2010-23-eng.php).

## **V. RISK MANAGEMENT DECISION**

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The four criteria of the eligibility determination for pesticidal active ingredients are satisfied by the science assessments supporting products containing *Typhula phacorrhiza* strain 94671. Such products are not expected to cause unreasonable adverse effects, and are likely to provide protection as claimed when used according to label instructions. Therefore, *Typhula phacorrhiza* strain 94671 is eligible for registration for the labeled uses.

## **VI. ENVIRONMENTAL JUSTICE**

EPA seeks to achieve environmental justice - the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income - in the development, implementation, and enforcement of environmental laws, regulations, and policies. At this time EPA does not believe that use of pesticide products containing *Typhula phacorrhiza* strain 94671 will cause harm or a disproportionate impact on at-risk communities.

*For additional information regarding environmental justice issues, please visit EPA's website at: <http://www.epa.gov/compliance/environmentaljustice/index.html>.*

## **VII. TERMS OF THE REGISTRATION(S)**

Storage stability and corrosion characteristics (OCSPP Guideline numbers 830.6317 and 830.6320, respectively) testing is currently underway and the study results are required to be submitted for EPA review upon completion.

**VIII. APPENDIX A. Data Requirements (40 CFR Part 158-Subpart V)**

\*NOTE: MRID numbers listed in the following tables are representative of supporting data for the original registration of the product containing this active ingredient. Subsequent to this registration, there may be additional MRIDs that support registration of other products containing this active ingredient.

<b>TABLE 1. Physical and Chemical Properties for the Technical Grade of the Active Ingredient (TGAI), <i>Typhula phacorrhiza</i> strain 94671 (40 CFR § 158.2120)<sup>a</sup></b>			
<b>OCSP Guideline Number</b>	<b>Property</b>	<b>Description of Result</b>	<b>Methods</b>
830.6302	Color	Beige.	Visual observation
830.6303	Physical State	Solid granule.	Visual observation
830.6304	Odor	Odorless to faintly anise-like.	Olfactory inspection
830.6313	Stability	Expected to be stable at normal temperatures and when exposed to metals and metal ions. Not stable at temperatures >30°C.	Growth temperature analysis
830.6314	Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product does not contain oxidizing or reducing agents.	
830.6315	Flammability	Not applicable, the product is a solid.	
830.6316	Explosibility	Not applicable, the product does not contain explosive ingredients.	
830.6317	Storage Stability	One-year study is ongoing.	
830.6319	Miscibility	Not applicable, the product is not an emulsifiable liquid to be mixed with petroleum solvents.	
830.6320	Corrosion Characteristics	One-year study is ongoing.	
830.6321	Dielectric Breakdown Voltage	Not required for MP.	
830.7000	pH	6.8 (aqueous solution).	pH meter
830.7100	Viscosity	Not applicable, the product is a solid.	
830.7200	Melting Range	Not applicable, the product is not pure active ingredient.	
830.7220	Boiling Range	Not applicable, the product is a solid.	
830.7300	Density/Relative Density/Bulk Density	0.475 g/cm <sup>3</sup>	CIPAC MT-33
830.7370	Dissociation Constant in Water	Not applicable, the product is not pure active ingredient.	
830.7550	Partition Coefficient	Not applicable, the product is not pure active ingredient.	
830.7840	Water Solubility	Not applicable, the product is not pure active ingredient.	
830.7950	Vapor Pressure	Not applicable, the product is not pure active ingredient.	

<sup>a</sup>Data from MRID 478021-01

<b>TABLE 2. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI), <i>Typhula phacorrhiza</i> strain 94671 (40 CFR § 158.2140)</b>			
<b>OCSPP Guideline Number</b>	<b>Data Requirement</b>	<b>Results</b>	<b>MRID Number</b>
<i>Tier I</i>			
870.1100	Acute Oral Toxicity	Oral LD <sub>50</sub> >5000 mg/kg bw (low acute oral toxicity) Pathogenicity and infectivity testing waived based on results from 47802106  <b>Toxicity Category IV</b>	478021-02
870.1200	Acute Dermal Toxicity	Dermal LD <sub>50</sub> >5050 mg/kg bw (low acute dermal toxicity)  <b>Toxicity Category IV</b>	478021-03
870.1300	Acute Inhalation Toxicity	Waived based on results from 47802106	
870.2400	Acute Eye Irritation	<i>Typhula phacorrhiza</i> strain 94671 was minimally irritating to the eye based on the maximum mean irritation score of 8, recorded one hour after test material instillation.  <b>Toxicity Category III</b>	478021-04
870.2500	Primary Dermal Irritation	<i>Typhula phacorrhiza</i> strain 94671 was non- to slightly-irritating to the skin, based on the maximum individual irritation and maximum irritation scores of 1 and 0.67, respectively at the one hour observation point; and the maximum average score of zero over the 24, 48 and 72 hour observation points.  <b>Toxicity Category IV</b>	478021-05
<i>Tiers II and III</i>			
Not required for <i>Typhula phacorrhiza</i> strain 94671 based on the lack of acute toxicity/pathogenicity in the Tier I studies.			
<i>Additional Studies</i>			
885.3200	Pilot Study in Preparation for Intraperitoneal Toxicity Study	This fungus could not be recovered after dose administration and has been shown to be unable to grow at mammalian body temperatures. <i>Typhula phacorrhiza</i> was not toxic or pathogenic as tested in this pilot study.	478021-06

<b>TABLE 3. Nontarget Organism Data Requirements for the Technical Grade of the Active Ingredient (TGAI), Typhula phacorrhiza strain 94671 (40 CFR § 158.2150)</b>			
<b>OCSPP Guideline Number</b>	<b>Data Requirement</b>	<b>Results</b>	<b>MRID<sup>1</sup> Number</b>
885.4050	Avian Oral Toxicity	Data waiver rationale is sufficient to determine that toxicity/pathogenicity to birds is not expected. <b>Classification: Acceptable</b>	478021-07 478021-08
885.4100	Avian Inhalation Toxicity/Pathogenicity	Data waiver rationale is sufficient to determine that toxicity/pathogenicity to birds is not expected. <b>Classification: Acceptable</b>	478021-07 478021-08
885.4150	Wild Mammal Toxicity/Pathogenicity	An acute oral toxicity test with albino rats indicates no adverse effects at 5000 mg/kg-bw. Data waiver rationale also support the conclusion that adverse effects to wild mammals are not expected. <b>Classification: Acceptable</b>	478021-07 478021-08
885.4200	Freshwater Fish Toxicity/Pathogenicity	Data waiver rationale is sufficient to determine that toxicity/pathogenicity to freshwater fish is not expected. <b>Classification: Acceptable</b>	478021-07 478021-08
885.4240	Freshwater Invertebrate Toxicity/Pathogenicity	Data waiver rationale is sufficient to determine that toxicity/pathogenicity to freshwater invertebrates is not expected. <b>Classification: Acceptable</b>	478021-07 478021-08
885.4280	Estuarine/Marine Fish Testing Estuarine/Marine Invertebrate Testing	Data waiver rationale is sufficient to determine that toxicity/pathogenicity to marine/estuarine fish and invertebrates is not expected. <b>Classification: Acceptable</b>	478021-07 478021-08
885.4300	Nontarget Plant Testing	Plant pathogenicity data show no evidence of adverse effects on two monocotyledonous plant species and three dicotyledonous plant species. <b>Classification: Supplemental;</b> Additional data waiver rationale supports the conclusion that adverse effects to nontarget plants are not expected. <b>Classification: Acceptable data waiver rationale</b>	478021-07 478021-08
885.4340	Nontarget Insect Testing	Data waiver rationale is sufficient to determine that toxicity/pathogenicity to nontarget insects is not expected. <b>Classification: Acceptable</b>	478021-07 478021-08
885.4380	Honey Bee Testing	Data waiver rationale is sufficient to determine that toxicity/pathogenicity to honey bees is not expected. <b>Classification: Acceptable</b>	478021-07 478021-08

<sup>1</sup>Publications referenced in the data waiver rationale were contained in MRID 478021-09.

## IX. APPENDIX B. MRID and Cited Literature Bibliography

### A. Studies Submitted to Support the *Typhula phacorrhiza* strain 94671 Pesticide Products Registration

478021-00	Agrium Advanced Technologies RP, Inc. (2009) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Nivalis Technical. Transmittal of 9 Studies.	13-Jul-2009
478021-01	Cascino, J. (2009) Product Chemistry for Nivalis Technical. Project Number: 7277, 3504, SOP/TP/101. Unpublished study prepared by Sylvan Inc. and Microbac Laboratories, Inc. 121 p.	13-Jul-2009
478021-02	Kuhn, J. (2009) Acute Oral Toxicity Study (UDP) in Rats (Nivalis): Final Report. Project Number: 12372/08. Unpublished study prepared by Stillmeadow, Inc. 11 p.	13-Jul-2009
478021-03	Kuhn, J. (2009) Acute Dermal Toxicity Study in Rats (Nivalis): Final Report. Project Number: 12373/08. Unpublished study prepared by Stillmeadow, Inc. 13 p.	13-Jul-2009
478021-04	Kuhn, J. (2009) Acute Eye Irritation Study in Rabbits (Nivalis): Final Report. Project Number: 12374/08. Unpublished study prepared by Stillmeadow, Inc. 18 p.	13-Jul-2009
478021-05	Kuhn, J. (2009) Acute Dermal Irritation Study in Rabbits (Nivalis): Final Report. Project Number: 12375/08. Unpublished study prepared by Stillmeadow, Inc. 13 p.	13-Jul-2009
478021-06	Monds, K. (2009) <i>Typhula phacorrhiza</i> : Pilot Study in Preparation for IP Toxicity Study (Rat): Final Report. Project Number: 12378/08. Unpublished study prepared by Stillmeadow, Inc. 18 p.	13-Jul-2009
478021-07	Bjornson, H. (2009) Tier II Data Summaries for Nivalis Technical. Unpublished study prepared by Agrium Advanced Technologies RP Inc. 96 p.	13-Jul-2009
478021-08	Bjornson, H. (2009) Tier III Data Summaries for Nivalis Technical. Unpublished study. 54 p.	13-Jul-2009
478021-09	Roberts, A. (2009) Reference Data Volume for Tier II & III Data Summaries for Nivalis Technical. Unpublished study prepared by Agrium Advanced Technologies RP Inc. 199 p.	13-Jul-2009
479221-00	Agrium Advanced Technologies RP, Inc. (2009) Submission of Product Chemistry Data in Support of the Application for Registration of Nivalis Technical. Transmittal of 1 Study.	19-Nov-2009
479221-01	Cascino, J. (2009) Supplemental Product Chemistry for Nivalis Technical. Unpublished study prepared by Sylvan, Inc. 6 p.	19-Nov-2009
481369-00	Agrium Advanced Technologies RP, Inc. (2010) Submission of Product Chemistry Data in Support of the Applications for Registration of Nivalis Technical and Nivalis. Transmittal of 1 Study.	30-Jun-2010
481369-01	Cascino, J. (2010) Supplemental Product Chemistry for Nivalis Technical. Unpublished study prepared by Agrium Advanced Technologies RP, Inc. 16 p.	30-Jun-2010



## **B. Environmental Protection Agency Risk Assessment Memoranda**

U.S. EPA. 2010a. Review of *Typhula phacorrhiza* the active ingredient in the end-product Nivalis for control of snow mold in turfgrass from Agrium Advanced Technologies. Memorandum from J. L. Kough to D. Greenway dated May 18, 2010.

U.S. EPA. 2010b. Environmental Risk Assessment for the of FIFRA Section 3 registration of *Typhula phacorrhiza* strain 94671 (EPA File Symbol. Nos. 84888-R and 84888-E) for control of snow mold disease in turf; MRIDs 478021-07, 478021-08 and 478021-09. Memorandum from S. Borges and Z. Vaituzis to D. Greenway dated June 2, 2010.

U.S. EPA. 2010c. Review of Supplemental Information Provided by Agrium Advanced Technologies RP, Inc. and Sylvan, Inc. on the Nivalis Product Based on *Typhula phacorrhiza* isolate 94671. Memorandum from J. L. Kough to D. Greenway dated July 23, 2010.

## **X. GLOSSARY OF ACRONYMS AND ABBREVIATIONS**

BPPD	Biopesticides and Pollution Prevention Division
BRAD	Biopesticides Registration Action Document
CFR	Code of Federal Regulations
cfu	colony-forming units
cfu/lb	colony-forming units per pound
°C	degrees Celsius
EDSP	Endocrine Disruptor Screening Program
EP	end-use product
EPA	Environmental Protection Agency (the “Agency”)
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
mg/kg bw	milligram per kilogram of body weight
MRID No.	Master Record Identification Number
OCSP	Office of Chemical Safety and Pollution Prevention; formerly, Office of Pesticides and Toxic Substances (OPPTS)
OPP	Office of Pesticide Programs
PMRA	Pest Management Regulatory Agency (of Health Canada)
TGAI	technical grade of the active ingredient