



Health
Canada

Santé
Canada

Pest
Management
Regulatory
Agency

Agence de
réglementation
de la lutte
antiparasitaire

May 11, 2016

Submission No. 2016-1813

BioWorks Inc.
C/O Laurie Tyo
TSG Canada Inc.
49-3278 Colonel Talbot Road
London, Ontario
N6P 1H4

Previous PMRA File No.:

D.3.1: 2015-2840

D.3.2: 2015-4980

Dear Ms. Tyo:

RE: URMULE - User Requested Minor Use Label Expansion for the use of RootShield WP Biological Fungicide (*Trichoderma harzianum* Strain KRL-AG2), Reg. No. 29890, for the suppression of root rot caused by *Fusarium* spp., *Rhizoctonia* spp., and *Pythium* spp. on hops in Canada

The review of your application to amend the RootShield WP Biological Fungicide label has been completed. We are pleased to inform you that, pursuant to subsection 8(1) of the *Pest Control Products Act*, amended registration has been granted.

Your Amended Registration Certificate and a copy of the PMRA approved bilingual text label are enclosed. This application is now complete.

Yours truly,

Patricia Curry
Director
Value Assessment and Re-evaluation Management Directorate
Pest Management Regulatory Agency

Enclosures: Amended Registration Certificate
PMRA Approved bilingual text label

cc.: Jim Chaput, Provincial Minor Use Coordinator
Ian Gardiner, Submissions Manager, Pest Management Centre – AAFC
Allison Plunkett, Pest Management Centre - AAFC
Provincial Minor Use Coordinators
PMRA Regional Manager

Canada



Health Canada / Santé Canada

Application for New or Amended registration
Under the *Pest Control Products Act*

Demande d'homologation ou de modification
d'homologation en vertu de la *Loi sur les produits antiparasitaires*

Date received – Date reçue
2016-03-29
Submission No. – N° de la demande
2016-1813

1. Product Name (Full Name, No Abbreviations) – Nom du produit (nom complet, aucune abréviation)* RootShield WP Biological Fungicide	2. Registration No. – N° d'homologation 29890
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3. Registrant Name and Address – Nom et adresse du titulaire d'homologation

Registrant Name (Full Legal Name – No Abbreviation) – Nom du titulaire (nom légal complet, aucune abréviation)*
BioWorks Inc.

Postal Delivery Address – Adresse de livraison postale*
100 Rawson Road, Suite 205

City / Town – Ville* Victor	Prov / State – Province / État* NY	Country – Pays* USA	Postal Code / ZIP – Code postal / ZIP* 14564
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Contact Name – Nom personne-ressource* Michael Cordaro	Job Title – Titre du poste* Regulatory Manager
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Phone – Téléphone* 585-924-4362 x342	Fax – Télécopieur	E-mail – courriel* mcardaro@bioworksinc.com
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4. Regulatory Mailing Address – Adresse postale réglementaire SAME AS BOX 3 ABOVE – MÊME QU'À LA CASE 3

Company Name (Full Name – No Abbreviation) – Nom de l'entreprise (nom complet, aucune abréviation)
Technology Sciences Group (TSG) Canada Inc.

Regulatory Mailing Address – Adresse postale réglementaire
49-3278 Colonel Talbot Road

City / Town – Ville London	Province – Province / État ON	Country – Pays Canada	Postal Code – Code postal N6P 1H4
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Contact Name – Nom personne-ressource Laurie Tyo	Job Title – Titre du poste Regulatory Consultant
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Phone – Téléphone 519-203-3056	Fax – Télécopieur 519-203-4056	E-mail – courriel ltyo@tsgcanada.ca
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5. Submission Contact – Personne-ressource au sujet de la demande SAME AS BOX 4 ABOVE – MÊME QU'À LA CASE 4 X

Company Name (Full Name – No Abbreviation) – Nom de l'entreprise (nom complet, aucune abréviation)
Technology Sciences Group (TSG) Canada Inc.

Submission Contact Mailing Address – Adresse postale de la personne-ressource pour la demande d'homologation
49-3278 Colonel Talbot Road

City / Town – Ville London	Prov / State – Province / État ON	Country – Pays Canada	Postal Code / ZIP – Code postal / ZIP N6P 1H4
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Contact Name – Nom personne-ressource Laurie Tyo	Job Title – Titre du poste Regulatory Consultant
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Phone – Téléphone 519-203-3056	Fax – Télécopieur 519-203-4056	E-mail – courriel ltyo@tsgcanada.ca
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6. Communication – Communication

Formal correspondence, including the Registration Letter, Certificate of Registration, and Approved Label text will be sent to the Regulatory Mailing Address identified in block 4 – Toute correspondance formelle, notamment la lettre et le certificat d'homologation ainsi que le libellé de l'étiquette approuvée, sera envoyée à l'adresse indiquée à la case 4.

Would you like a copy sent to the Submission Contact identified in Block 5? – Voulez-vous que l'ARLA envoie une copie à la personne-ressource indiquée à la case 5? No – Non Yes – Oui

7. Application for – Type de demande*

<input type="checkbox"/> New – Nouvelle	<input checked="" type="checkbox"/> X	<input type="checkbox"/> Amendment – Modification	<input type="checkbox"/> Reinstatement – Rétablissement
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8. Type of product, Code(s) – Type de produit, Code(s)*

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9. Proposed classification – Classification proposée*

End Use Product – Préparation commerciale

<input type="checkbox"/> Domestic Domestique	<input checked="" type="checkbox"/> X	<input type="checkbox"/> Commercial Commercial	<input type="checkbox"/> Restricted Restreint
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Manufacturing Use Product – Produit de fabrication

<input type="checkbox"/> Manufacturing Concentrate Concentré de fabrication	<input type="checkbox"/> Technical Technique	<input type="checkbox"/> Integrated System Product Produit de système intégré
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10. Container Material – Matériau du contenant*

<input type="checkbox"/> Metal – Métal	<input type="checkbox"/> Glass – Verre	<input checked="" type="checkbox"/> X	<input type="checkbox"/> Plastic – Plastique	<input checked="" type="checkbox"/> X	<input type="checkbox"/> Paper – Papier
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Other (specify) - Autre (préciser) :

Container Type – Type de contenant :
polyethylene bag in cardboard box or bulk size plastic drum

Size of container – Grandeur du contenant Size range / units – Étendue des formats / unités: 0.453 kg to / à: 90.9 kg

or Size(s) / units – Formats / unités

11. Nanotechnology – Nanotechnologie*

Does the product contain nanomaterials? – Est-ce que le produit contient des nanomatériaux? Yes – Oui X No – Non

12. Master/Initial Product Status – Statut de produit étalon/initial

Applying for Initial Product status – Demande pour le statut de produit initial Applying for Master Product status – Demande pour le statut de produit étalon

Proposed new Uses and / or Uses to be Withdrawn - Nouveaux usages proposés ou les usages à retirer*

Date received – Date reçue
2016-03-29
Submission No. – N° de la demande
2016-1813

1. Product Name (Full Name, No Abbreviations) – Nom du produit (nom complet, aucune abréviation)*
RootShield WP Biological Fungicide

2. Registration No. – N° d'homologation
29890

Form 6023 submitted, Proposed for New Uses and/or Uses to be Withdrawn from the Label? – Avez-vous envoyé un formulaire déclarant Formulaire 6023: Formulaire visant les nouveaux usages proposés ou les usages à retirer ?

<input checked="" type="checkbox"/>	Yes – Oui	<input type="checkbox"/>	No – Non
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Purpose – Rôle*

Category A – New active ingredient – Catégorie A – Nouvelle matière active

Canadian Registration - Homologation canadienne

Import MRL only - LMR à l'importation seulement

URMUR – PHULDU

Category A – Catégorie A

Major New Use - Nouvel usage important

Category B – Catégorie B

New or amended product chemistry - Caractéristiques chimiques nouvelles ou modifiées

New MRL(s) for previously assessed active ingredient - Nouvelle(s) LMR pour une matière active déjà évaluée

New or amended label statements - Énoncés nouveaux ou modifiés sur l'étiquette

Conversion/Renewal of Conditional Registration - Conversion/renouvellement d'une homologation ou utilisation temporaire ou à période limitée

Other (specify in covering letter) - Autre (préciser dans lettre d'accompagnement)

Category C – Catégorie C

New or amended product chemistry - Caractéristiques chimiques nouvelles ou modifiées

New or amended label statements - Énoncés nouveaux ou modifiés sur l'étiquette

Similar product or use already registered – Produit ou usage similaire déjà homologué | Number of precedent product – N° d'homologation la produit déjà homologué :

Administrative changes – Changements administratifs:

Change in source of registered active ingredient - Changement de source de la matière active

Registration or addition of minor use - Homologation ou ajout d'un usage limité

Other (specify in covering letter) - Autre (préciser dans lettre d'accompagnement)

Category D – Catégorie D

IMEP – PIPAFE

Label Improvement Program - Programme d'amélioration des étiquettes

New Master Copy based on Master Product Regn. No. - Nouvelle copie étalon basée sur le produit étalon portent le n° d'homol. :

15. Declaration – Déclaration du demandeur*

In compliance with the Pest Control Products Act, application is hereby made for the registration of a control product as outlined in this application, product specification form and labelling. It is certified that the information is true and complete – Conformément à la Loi sur les produits antiparasitaires, nous demandons l'homologation de ce produit tel qu'il est décrit dans la présente demande, celle des spécifications du produit et sur l'étiquette. Nous attestons que ces renseignements sont véridiques et complets.

Signature – Signature du demandeur Laurie Tyo	Printed Name – Nom en lettres moulées Laurie Tyo	Date 2016-03-28
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Company affiliation of the signer – Compagnie du signataire TSG Canada	Phone – Téléphone 519-203-3056	Email-Courriel ltyo@tsgcanada.ca
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Pursuant to the application and attachments and subject to amendments (if any) made therein, registration is granted and the above registration number is hereby assigned. – Conformément à cette demande et aux pièces jointes, et sous réserve des modifications qui lui sont apportées (s'il y a lieu), l'homologation est accordée et le numéro d'homologation ci-dessus attribué.

This certificate is for the registration period ending December 31, 2018
Ce certificat est valable pour la période d'homologation prenant fin le 31 décembre 2018

Note: This registration is not an endorsement or an approval by Health Canada of this control product. – Nota : Cette homologation ne constitue ni une acceptation ni une approbation de ce produit antiparasitaire par Santé Canada.

HC/PMRA Official – Représentant de SC/ARLA	<i>P. Curry</i>	Date May 11, 2016
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PMRA APPROVED -KM
2016-1813
MAY2016

RootShield® WP - Biological Fungicide

For the Suppression of Root Rot caused by Pythium spp., Rhizoctonia spp. and Fusarium spp. in Greenhouse Crops, Outdoor Nursery Plants, Greenhouse Transplants, Ginseng, Hops, and Cannabis (marihuana) produced commercially indoors.

COMMERCIAL
WETTABLE POWDER
READ THE LABEL BEFORE USING

GUARANTEE: *Trichoderma harzianum* Rifai strain KRL-AG2 contains a minimum of 1.0×10^7 colony forming units per gram of dry weight

Warning, contains the allergens wheat and sulfites.

POTENTIAL SENSITIZER

LIVE ORGANISMS

REGISTRATION No. 29890 PEST CONTROL PRODUCTS ACT

NET CONTENTS: 0.45 – 90.9 kg

Manufactured by BioWorks, Inc. 100 Rawson Road, Suite 205, Victor, NY 14564
Telephone: 1.585.924.4362

Distributed by BioWorks, Inc., P.O. Box 1125, Fonthill, Ontario, L0S 1E0
Telephone: 800-877-9443

Lot No.:

Date of Manufacture: Use within 12 months of date of manufacture.

GENERAL INFORMATION: RootShield® WP - Biological Fungicide is a biological fungicide for the suppression of root rot in greenhouse crops, outdoor nursery plants, greenhouse vegetable transplants, ginseng, hops, and Cannabis (marihuana) produced commercially indoors. The active ingredient is a beneficial microbe *Trichoderma harzianum* strain T-22 (KRL-AG2). When applied to transplants, greenhouse planting mix or soil, RootShield® WP - Biological Fungicide actively grows onto plant roots as they develop and protects roots against *Pythium*, *Rhizoctonia* and *Fusarium*. RootShield® WP - Biological Fungicide can be used alone or in conjunction with certain chemical fungicides; contact manufacturer or distributor for compatibility Technical Bulletin.

For control of seed rot and damping off of internally infected cuttings, use chemical fungicides or other appropriate measures in addition to RootShield® WP - Biological Fungicide.

Note: RootShield® WP - Biological Fungicide contains live spores of a beneficial microbe. RootShield® WP - Biological Fungicide becomes active when soil temperatures are above 10 degrees C. Control is not effective while soils remain cold and is more effective in neutral or acidic soils than in alkaline soils.

DIRECTIONS FOR USE:

DRENCH APPLICATION TO POTTING MIX OR SOIL

Greenhouse Peppers, Tomatoes, Cucumbers and Eggplant

Greenhouse Ornamental Crops

Outdoor Nursery Crops

Greenhouse Vegetable Transplants

Hops

Ginseng

Cannabis (Marihuana) produced commercially indoors

POTTING MIX: Suspend RootShield® WP - Biological Fungicide in sufficient water (eg. 30-45 g/100L) to achieve uniform application and apply at the rate of 55-110 g per cubic metre (loose) of greenhouse potting mix, soil or planting beds. RootShield® WP - Biological Fungicide can be applied through low pressure watering nozzles such as fan nozzles or other watering systems. Agitate to maintain suspension.

Cannabis (marihuana) produced commercially indoors: RootShield WP is applied to potting mix or soil as a drench prior to planting.

NURSERY DRENCH:

Suspend RootShield® WP - Biological Fungicide in sufficient water (eg. 30 – 45 g/100 L) to achieve uniform application and apply at the rate of 55 – 110 g per cubic metre (loose) of nursery potting mix, soil or planting beds. RootShield® WP - Biological Fungicide can be applied through low pressure watering nozzles such as fan nozzles or other watering systems. Agitate to maintain suspension.

GINSENG, HOPS: Suspend RootShield® WP - Biological Fungicide Wettable Powder in 1,000 litres of water and apply at the rate of 3-4 kg per hectare to the soil surface immediately around the ginseng plants. Use higher rates when conditions favour disease development or high disease pressure is anticipated. Sufficient irrigation or rainfall of at least 5 mm should occur within 24 hours after application to move the active ingredient into the root zone. Agitate to maintain suspension.

DIP APPLICATION

Bulbs: All Ornamental Crops

Dip bulbs in suspension of 60 g/L RootShield® WP - Biological Fungicide prior to planting.

It is not possible to test all ornamental varieties, and some may show delayed growth. RootShield® WP - Biological Fungicide should first be tested on small lot of plants, if the response of the variety is not known, before using it for commercial scale production.

Crops	Disease	Pathogens	Rate	Spray volume	Control/Suppression
Greenhouse Ornamental Crops	Root rot	<i>Pythium</i> spp. <i>Rhizoctonia</i> spp. <i>Fusarium</i> spp.	55-110 g/m ³	30-45 g/100 L	Suppression
Outdoor Nursery Crops					
Greenhouse Vegetable Transplants					
Bulb vegetables					
Leafy vegetables					
Brassica vegetables					
Fruiting vegetables					
Cucurbit vegetables					
Herbs					
Greenhouse Peppers, Tomatoes, Cucumbers and Eggplant					
Cannabis (marihuana) produced commercially indoors					
Ginseng			3-4 kg/ha	1000 litres/ha	
Hops			3-4 kg/ha	1000 litres/ha	
Ornamental Bulbs	Root rot	<i>Pythium</i> spp. <i>Rhizoctonia</i> spp. <i>Fusarium</i> spp.	Dip bulbs in 60 g/L suspension		Suppression

Bulb vegetables: chive, Chinese chive, daylily, Elegans hosta, fritillaria, garlic (bulb, great-headed, serpent), onion (bulb, green), kurrat, leek, lady's leek, wild leek, lily, onion (bulb, Chinese, green, macrostem, pearl, potato, tree, Welsh), shallot

Leafy vegetables: amaranth, arugula, cardoon, celery, Chinese celery, celtuce, chervil, chrysanthemum (edible-leaved, garland), corn salad, cress (garden, upland), dandelion, dock, endive, fennel, lettuce (head, leaf), orach, parsley, purslane (garden, winter), radicchio, rhubarb, spinach, New Zealand spinach, vine spinach, swiss chard

Brassica vegetables: broccoli (Chinese, raab), Brussels sprouts, cabbage, Chinese cabbage, cauliflower, cavolo broccoli, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, rape greens

Fruiting vegetables: cocona, eggplant (including African, pea, scarlet), groundcherry, martynia, okra, pepino, pepper (bell, non-bell), sunberry, tomatillo, tamarillo, goji berry, tomato (including bush, currant)

Cucurbit vegetables: Chinese waxgourd, citron melon, cucumber, gherkin, gourd (edible), momordica, muskmelon (cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango Persian, pineapple, Santa Claus, snake), pumpkin, squash (winter, summer), watermelon

Herbs: angelica, anise (anise seed), balm (lemon balm), basil, borage, burnet, chamomile, caraway, black caraway, catnip, celery seed, chervil (dried), chive, Chinese chive, clary, coriander (cilantro or Chinese parsley), costmary, culantro, cumin, dill, fennel, fenugreek, horehound, hyssop, juniper berry, lavender, lemongrass, lovage, marigold, marjoram, mustard, nasturtium,

parsley, pennyroyal, poppy, rosemary, rue, sage, savory (summer, winter), sweet bay (bay leaf), tansy, tarragon, thyme, wintergreen, woodruff, wormwood.

GENERAL APPLICATION INSTRUCTIONS

RootShield® WP - Biological Fungicide can be applied using hand-held backpack or ground spray equipment. AGITATION IS REQUIRED TO MAINTAIN SUSPENSION. Application equipment should be cleaned before use of this product, and prepared sprays should be used within 4 hours of preparation. To prevent nozzle tip clogging the manufacturer recommends using 50 – 100 mesh inlet screens in all spray equipment. Use higher rates when conditions favour disease development or high disease pressure is anticipated.

PRECAUTIONS: KEEP OUT OF REACH OF CHILDREN.

May cause sensitization. Avoid contact with skin, eyes or clothing. Avoid breathing dust or spray mist. Workers and handlers (includes mixer/loader and applicators) must wear a long sleeved shirt, long pants, shoes plus socks, waterproof gloves and eye goggles as well as a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products when mixing/loading or applying the product and until mists have settled and during all clean-up/repair activities. Wash thoroughly with soap and water after handling product. Remove contaminated clothing and follow manufacturer's directions for cleaning/maintaining personnel protective equipment (PPE) before use. If no such instructions are available use clothing detergent and hot water for cleaning all washable PPE. Keep and wash PPE separately from other laundry. Wash hands after use.

ENVIRONMENTAL HAZARDS:

As this pesticide is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted, fine textured, or low in organic matter such as clay).

DO NOT apply by air.

FIRST AID:

If swallowed: Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.

GENERAL: Seek medical attention immediately if irritation or signs of toxicity occur and persist or is severe. Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

TOXICOLOGICAL INFORMATION: Treat symptomatically.

STORAGE:

Store in a secure dry place at temperatures between 2°C and 5°C. Do not contaminate water, food, or feed during storage. Keep product in original container during storage and keep container lid tightly closed when not in use. This product should be used within 12 months of the date of manufacture when stored under refrigerated conditions.

DISPOSAL/ DECONTAMINATION:

1. Thoroughly empty the contents of the container into the application device or medium.
2. Make the empty container unsuitable for further use.
3. Dispose of the container in accordance with provincial requirements.
4. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

NOTICE TO USER:

This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use this product.