

Evaluation Report for Category B, Subcategory 3.1, 3.10, 3.11 Application

Application Number: 2013-6158
Application: New Product Labels - Application rate increase or decrease, tank mixes, new pests
Product: PTZ 480SC Seed Treatment Fungicide
Registration Number: 31839
Active ingredients (a.i.): Prothioconazole
PMRA Document Number : 2411850

Purpose of Application

The purpose of this application was to register a new end-use product, PTZ 480SC Seed Treatment Fungicide (guarantee 480 g/L prothioconazole), for use as a seed treatment to control seed-borne and soil-borne diseases of cereal grains, corn, dry beans, dry peas, chickpeas, lentils and soybeans.

With one exception, all of the disease claims proposed for PTZ 480SC Seed Treatment Fungicide are already registered on a similar prothioconazole-containing product, JAU 6476 100 FS Seed Treatment Fungicide (Registration Number 30101), with identical active ingredient application rates (i.e. 5 g a.i./100 kg of seed). A new claim for suppression of anthracnose stalk rot on corn was proposed at a rate of application that is higher than those currently registered for the precedent product JAU 6476 100 FS Seed Treatment Fungicide (i.e. 30-60 g a.i./100 kg of seed).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

PTZ 480SC Seed Treatment Fungicide is of low toxicity to rats via the oral (LD_{50} between 2000 and 5000 mg/kg bw) and dermal (LD_{50} >5000 mg/kg bw) routes, and is slightly acutely toxic via the inhalation route (LC_{50} >0.852 mg/L). It is non-irritating to the eye and minimally irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

Exposures from commercial or on-farm treatments, and planting of cereal, chickpea, corn (sweet, pop, and seed), dry bean, dry pea (including field pea), lentil and soybean seeds treated with PTZ 480SC Seed Treatment Fungicide at 10.4mL/100kg seed fit within the exposures from the currently registered use pattern of prothioconazole. The risks to commercial seed treatment

workers, and farmers and custom planters when handling corn seeds (sweet, pop, field) treated at the increased application rate range are acceptable when wearing coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes, a NIOSH-approved dust mask, using a closed mix, load, and transfer seed treatment system, and closed-cab planting equipment. No risks of concern are expected for bystanders when all label statements and precautions are followed.

Residue data from field trials conducted in Europe were submitted to support the registration of PTZ 480SC Seed Treatment Fungicide on corn (field, sweet, and popcorn) at a higher application rate of 30-60 g a.i./100 kg seed for control against anthracnose stalk rot. Previously reviewed residue data from field trials conducted on cereal grains (wheat, barley, corn, and oat), dry beans, dry peas, chickpeas, lentils and soybeans were also reassessed in the framework of this petition.

Residues of prothioconazole and prothioconazole-desthio in/on corn when treated at the higher application rate and in/on cereal grains, dry beans, dry peas, chickpeas, lentils and soybeans when treated at the approved application rates are not expected to exceed the currently established maximum residue limits. Therefore, the dietary exposure to the petitioned crops when treated with PTZ 480SC Seed Treatment Fungicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The overall risk to birds and mammals from the consumption of corn seeds treated with PTZ 480SC Seed Treatment Fungicide at the application rate of 60 g a.i./kg seed for the suppression of stalk rot (*Colletotrichum graminicola*) in corn is considered to be acceptable.

Value Assessment

The value of all claims, with the exception of anthracnose stalk rot on corn, was supported on the basis of the precedent registration of JAU 6476 100 FS Seed Treatment Fungicide and rationales submitted by the applicant. Efficacy and crop safety data obtained from four assays conducted under controlled conditions (laboratory and greenhouse trials) and six field trials with artificial inoculation and yield assessments was used to demonstrate the value of the suppression claim for corn anthracnose stalk rot at the proposed rates. Prothioconazole was shown to reduce disease severity by up to 82% under low disease pressure and 34% under high disease pressure under controlled environments. Averaged across the six field trials, prothioconazole seed treatment increased grain yield by up to 11%.

The information provided by the applicant was deemed sufficient to support the value of all the disease claims on the PTZ 480SC Seed Treatment Fungicide label including the claim for suppression of corn anthracnose stalk blight at a rate range of 30-60 g a.i./100 kg of seed. Certain tank mix recommendations proposed for the PTZ 480SC Seed Treatment Fungicide label were not supported on the basis that the partner products are not currently registered in Canada.

Conclusion

The PMRA has completed a review of all the available information supporting the PTZ 480SC

Seed Treatment Fungicide application and found it sufficient to support a full registration.

References

PMRA Document Number	Reference
2362054	2013. PTZ 480SC Seed Treatment Fungicide for Suppression of Anthracnose Stalk Rot (<i>Colletotrichum graminicola</i>) in Corn - Part 10 Efficacy/Value. 124 pp. DACO 10.1, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2
738000	2003, An Acute Oral LD ₅₀ Study in the Rat with JAU 6476 480 SC, DACO: 4.6.1
738001	2003, Tier 2 Summary of An Acute Oral LD ₅₀ Study in the Rat with JAU 6476 480 SC, DACO: 4.6.1
738002	2003, An Acute Dermal LD ₅₀ Study in the Rat with JAU 6476 480 SC, DACO: 4.6.2
738003	2002, Tier 2 Summary of An Acute Dermal LD ₅₀ Study in the Rat with JAU 6476 480 SC, DACO: 4.6.2
738004	2003, JAU 6476 480 SC Study on Acute Inhalation Toxicity in Rats According to OECD No. 403, DACO: 4.6.3
738005	2003, Tier 2 Summary of JAU 6476 480 SC Study on Acute Inhalation Toxicity in Rats According to OECD No. 403, DACO: 4.6.3
738006	2003, JAU 6476 480 SC Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
738007	2003, Tier 2 Summary of JAU 6476 480 SC Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
738008	2003, JAU 6476 480 SC Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
738009	2003, Tier 2 Summary of JAU 6476 480 SC Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
738010	2003, JAU 6476 480 SC Study for the Skin Sensitization Effect in Guinea Pigs (Guinea Pig Maximization Test According to Magnusson and Kligman), DACO: 4.6.6
738011	2004, Tier 2 Summary of JAU 6476 480 SC Study for the Skin Sensitization Effect in Guinea Pigs (Guinea Pig Maximization Test According to Magnusson and Kligman), DACO: 4.6.6
2362063	2008, Determination of the Residues of JAU 6476 in/on Corn After Seed Treatment of JAU 6476 (300 FS) in the Field in Germany, DACO: 7.4.1
2362064	2007, Determination of the Residues of JAU 6476 in/on Corn After Seed Treatment of JAU 6476 (300 FS) in the Field in Northern France and Germany, DACO: 7.4.1
2362065	2008, Determination of the Residues of JAU 6476 in/on Corn After Seed Treatment of JAU 6476 (300 FS) in the Field in Spain, Italy, the United Kingdom and Germany, DACO: 7.4.1
2362066	2007, Determination of the Residues of JAU 6476 in/on Corn After Seed Treatment of JAU 6476 (300 FS) in the Field in Southern France, Italy and Spain, DACO: 7.4.1

1855337	2010, Assessment of Worker Exposure and Risk Resulting From On-Farm and Commercial Treatment of Seed with L1397 and JAU6476 100FS, DACO: 5.2,5.3
1965958	2010, Assessment of Bayer Laboratory Dust-Off Studies Conducted in Support of Multiple Bayer Seed Treatment Formulation Risk Assessments, DACO: 5.15
1965962	2008, Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy, DACO: 5.6
2362061	2013, Occupational Exposure and Risk Assessment for Prothioconazole Based Suspension Concentrate Seed Treatment Formulation for Corn Seed Use in Canada, DACO: 5.1,5.15,5.2,5.3,5.4,5.6(A)
2362042	2013, PTZ 480 SC Seed Treatment Fungicide - General Bridging Rationale Supporting New Product Registration, DACO: 0.17.1,5.2,7.1
2362043	2013, PTZ 480 SC Seed Treatment Fungicide - General Bridging Rationale Supporting New Product Registration, DACO: 0.17.1,5.2,7.1 CBI
2464886	2014, BCS Response to DACO 5.14 Deficiencies from the PMRA (July 14, 2014) Related to PTZ 480SC Seed Treatment Fungicide (Sub. no. 2013-6158), DACO: 5.14
1885209	2010, Observational Study to Determine Dermal and Inhalation Exposure to Workers in Commercial Seed Treatment Facilities: Mixing/Treating with a Liquid Pesticide Product and Equipment Clean-Out, DACO:5.4
Additional References	
Unpublished	
Agricultural Handlers Exposure Task Force (AHETF) Survey on Commercial Seed Treatment (2012) CBI	

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