

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1, 3.2 Application

**Application Number:** 2006-1292  
**Application:** Category B, Subcategory 2.1 (guarantee), 2.3 (identity of formulants), 2.4 (proportion of formulants), 3.1 (application rate increase), 3.2 (application timing)  
**Product:** MaxCel  
**Registration Number:** 28851  
**Active ingredients (a.i.):** 6-benzylaminopurine (or 6-benzyladenine)  
**PMRA Document Number:** 1775194

### Purpose of Application

The purpose of this application is to register a new end-use product, MaxCel, containing 6-benzyladenine (1.9%) (Reg. No. 25321) a naturally occurring cytokinin, to be used as a plant growth regulator.

This product is for use on apples to increase fruit size, as a fruit thinning agent, and to enhance the return bloom. The product can be applied 2 to 4 times per season, at a single application rate of 10 - 200 g ai/ha (depending upon intended effect, e.g. enhancement of fruit size), at an interval of 3 to 10 days, for a maximum seasonal rate of 446 g ai/ha for all uses. It is to be applied at petal fall for enhancement of fruit size or when the average diameter of king fruitlets is between 5 to 15 mm for purposes of fruit thinning and enhanced return bloom.

### Chemistry Assessment

MaxCel Plant Growth Regulator is formulated as a solution containing 6-benzyladenine at a nominal concentration of 1.9 %. This end-use product has a density of 1.046 g/mL and pH of 3.45. The chemistry requirements for MaxCel Plant Growth Regulator are complete.

### Health Assessments

MaxCel Plant Growth Regulator is of low acute toxicity, with an acute oral LD<sub>50</sub> (σ♀) > 5000 mg/kg, acute dermal LD<sub>50</sub> (σ♀) > 5000 mg/kg, and acute inhalation LC<sub>50</sub> (σ♀) > 4.99 mg/L. As such, MaxCel Plant Growth Regulator is expected to have low acute toxicity, regardless of the route of exposure.

Both the primary eye irritation and the primary dermal irritation of MaxCel Plant Growth Regulator may be categorized as minimally irritating in rabbits.

MaxCel Plant Growth Regulator was not found to be a dermal sensitizer in guinea pigs. The end use product will not be considered a dermal sensitizer.

Information related to [N]-6-benzyladenine did not result in findings of significant concern with respect to short-term toxicity, developmental toxicity, reproductive toxicity, or genotoxicity.

The current label statements for MaxCel Plant Growth Regulator, coupled with the low toxicity are considered adequate to address any potential risk due to exposure of the mixer, loader, applicator, and/or bystander to the end-use product.

As per the re-evaluation document, PACR2005-11, *Re-evaluation of 6-Benzylaminopurine*, there are currently no dietary concerns related to the ingestion of 6-benzylaminopurine on food crops.

### **Maximum Residue Limit**

6-Benzylaminopurine, also known as [N]-6-benzyladenine, is currently registered in Canada and has an established Maximum Residue Limit (MRL) of 0.1 ppm for the parent compound and related metabolites.

### **Environmental Assessment**

An environmental assessment was required and data were required to support the increased application rate.

6-benzyladenine enters the environment when it is used as a plant growth regulator on apples. Although 6-benzyladenine will partition rapidly into sediment and soil, it is not persistent and is rapidly degraded. There are no major degradation products produced. Based on its low volatility (vapour pressure and Henry's law constant), 6-benzyladenine residues are not expected in the air.

6-benzyladenine presents a low risk to freshwater invertebrates, freshwater alga, fish, birds, mammals, honeybees, and other beneficial arthropods, except for parasitoid wasps which may be temporarily suppressed. Therefore, hazard statements and specific instructions for reducing spray drift to terrestrial insects are provided on the product label.

Risks to beneficial terrestrial organisms such as parasitoid wasps will be mitigated by the use of environmental hazard statements.

## Value Assessment

The data package provided in support of MaxCel consisted of 15 trials conducted in 2002 (8 trials) and 2003 (7 trials) over 7 locations in Ontario (1 trial) and Nova Scotia (6 trials) utilizing 11 apple varieties. All trials were randomized complete block design experiments with 4 - 8 replicates. In addition, ten referenced journal articles were supplied by the applicant. Applications for the label claim of 'fruit thinning, sizing, and enhanced return bloom' were made at king fruitlet diameters (KFD) of 10-12mm, which fall within the label directions. Applications for the label claim of 'enhancement of fruit size' were made in combination with carbaryl for fruit thinning, and applied from petal fall onward, as per label directions. *No adverse effects to fruit quality or storage stability were observed.*

Percent thinning ranged from 9.1% to 50.1% for the proposed recommended range of 75-200 ppm. In addition, the use of MaxCel at 50 ppm before and after thinning resulted in thinning responses comparable to the thinning program alone (MaxCel 75 ppm + carbaryl 750 ppm). The consequence of thinning is fewer but larger and heavier fruit.

Increasing concentrations of MaxCel generally resulted in increases in fruit weight and size. Increases in fruit weight ranged from 7.8-53.7%. Additionally, the use of MaxCel at 50 ppm before and after thinning resulted in an average increase in fruit weight of 22.9%, compared with a 16.7% fruit weight increase for the thinning program alone (MaxCel 75 ppm + carbaryl 750 ppm). Apple trees treated with MaxCel had a greater percentage of fruit in the  $\geq 2.5$ " and  $\geq 3.0$ " categories than the untreated trees. Although fruit size was greater, overall fruit yield was lower with all concentrations of MaxCel tested than with the untreated check.

The use of MaxCel increased return bloom over the untreated check. The highest level of return bloom was seen with 150 ppm MaxCel (31.9% relative to control). In comparison, hand thinning resulted in an average decrease in return bloom of 9.1%.

Consistent enhancement of fruit weight while maintaining high yields and good return bloom are the most important considerations in evaluating a chemical thinning program (Stover et al, 2001). Although overall fruit yield was lower than the untreated check with treatment of MaxCel, the increase in individual fruit size must be kept in mind. This increase in size would in many instances result in a higher grade of fruit and therefore a greater selling price. Applications of MaxCel also enhanced return bloom, thereby reducing biennial bearing and attendant production fluctuations (Stover et al, 2001). As there is a wide concentration range available to the grower with MaxCel, the desired thinning effect (and overall effect on yield) can be achieved.

## Conclusion

Based on the data reviewed, PMRA can support the registration of MaxCel Plant Growth Regulator.

## References

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

### Chemistry:

PMRA Document Number: 1192930

Reference: 2001, Vbc 30001 - Active Ingredient Content (five Lots), Data Numbering Code: 3.3.1 Confidential Business Information

PMRA Document Number: 1192929

Reference: 2001, Vbc 30001 - Product Identity And Manufacturing Process, Data Numbering Code: 3.2.1,3.2.2,3.2.3 Confidential Business Information

PMRA Document Number: 1192932

Reference: 2003, Vbc 30001 Physicochemical Properties And Two Year Storage Stability, Data Numbering Code: 3.5 Confidential Business Information

PMRA Document Number: 1192931

Reference: 2004, Validation Of A Hplc Method For The Determination Of 6-benzyladenine Content In Vbc30001 Formulation, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1192933

Reference: 2005, Miscibility Of Maxcel With Water And Organics Solvents, Data Numbering Code: 3.5.13 Confidential Business Information

PMRA Document Number: 1192926

Reference: Applicants Name And Office Address, Data Numbering Code: 3.1.1 Confidential Business Information

PMRA Document Number: 1192927

Reference: Formulating Plant, Data Numbering Code: 3.1.2 Confidential Business Information

PMRA Document Number: 1192928

Reference: Trade Name, Data Numbering Code: 3.1.3 Confidential Business Information

### Health Assessment:

PMRA Document Number: 1114796

Reference: 2000, Voluntary Data - Acute Eye Irritation/corrosion Study With Abg-3191 In Albino Rabbits, Data Numbering Code: 4.2.4

PMRA Document Number: 1114797

Reference: 2000, Voluntary Data - Sensitization Study With Abg-3191 In Guinea Pigs (maximization Test), Data Numbering Code: 4.2.6

PMRA Document Number: 1114799

Reference: 2003, Voluntary Data - Abg-3191 Two Generation Reproduction Study In Rat, Data Numbering Code: 4.5.1

PMRA Document Number: 1114800

Reference: 2003, Voluntary Data - 6-benzyladenine - In Vitro Mammalian Cell Gene Mutation Test On L5178y Mouse Lymphoma Cells Tk +/- (microwell Method), Data Numbering Code: 4.5.5

PMRA Document Number: 1192934

Reference: 2001, Vbc 30001 Acute Oral Toxicity To The Rat (acute Toxic Class Method), Data Numbering Code: 4.6.1

PMRA Document Number: 1192935

Reference: 2001, Vbc 30001 Acute Dermal Toxicity To The Rat, Data Numbering Code: 4.6.2

PMRA Document Number: 1192936

Reference: 2001, Vbc 30001 Acute (four-hour) Inhalation Study In Rats, Data Numbering Code: 4.6.3

PMRA Document Number: 1192937

Reference: 2001, Vbc 30001 Eye Irritation To The Rabbit, Data Numbering Code: 4.6.4

PMRA Document Number: 1192938

Reference: 2001, Vbc 30001 Skin Irritation To The Rabbit, Data Numbering Code: 4.6.5

PMRA Document Number: 1192939

Reference: 2001, Vbc 30001 Skin Sensitization To The Guinea Pig (magnusson & Kligman Metho), Data Numbering Code: 4.6.6

PMRA Document Number: 1192940

Reference: 2004, Operator Exposure & Risk Assessment For Maxcel, Data Numbering Code: 5.2,5.3

PMRA Document Number: 1235599

Reference: 1976, Acute Toxicology Evaluations Of Abg-3001 And Ingredients., Data Numbering Code: 4.2.1

PMRA Document Number: 1235600

Reference: 1990, An Acute Inhalation Toxicology Study Of 6-benzyladenine In The Rat, Data Numbering Code: 4.2.3

PMRA Document Number: 1235601

Reference: 1991, Primary Dermal Irritation Study In Albino Rabbits With 6-benzyladenine, Data Numbering Code: 4.2.5

PMRA Document Number: 1235602

Reference: 1990, Delayed Contact Hypersensitivity Study In Guinea Pigs Of: 6-benzyladenine, Data Numbering Code: 4.2.6

PMRA Document Number: 1235603

Reference: 1992, 13 Week Dietary Toxicity With 6-benzyladenine In Rats, Data Numbering Code: 4.3.1

PMRA Document Number: 1235604

Reference: 1990, Evaluation Of The Effects Of Orally Administered 6-benzyladenine (abbott-39313) On The Embryonic And Fetal Development Of The Rat (segment Iitfr), Data Numbering Code: 4.5.2

PMRA Document Number: 1235605

Reference: 1987, Mutagenicity Test On 6-benzyladenine In The Ames Salmonella/microsome Reverse Mutation Assay., Data Numbering Code: 4.5.4

PMRA Document Number: 1235606

Reference: 1988, Mutagenicity Test On 6-benzyladenine In The Rat Primary Hepatocyte Unscheduled Dna Synthesis Assay., Data Numbering Code: 4.5.8

PMRA Document Number: 1235607

Reference: 1987, Mutagenicity Test On 6-benzyladenine 16262 In The In Vivo Mouse Micronucleus Assay., Data Numbering Code: 4.5.7

#### Environmental Assessment:

PMRA Document Number: 1235613

Reference: 1975, Report On Four-day Static Fish Toxicity Studies Of 6-benzyladenine And Gibberellic Acid A4a7 In Bluegills, Data Numbering Code: 9.5.2.2

PMRA Document Number: 1235612

Reference: 1976, Four-day Static Aquatic Toxicity Studies With 6-benzyladenine In Rainbow Trout, Data Numbering Code: 9.5.2.1

PMRA Document Number: 1235609

Reference: 1976, Metabolism And Movement Of N-[phenylmethyl] -1h-purin-6-amine In Soils, Data Numbering Code: 8.2.3.4

PMRA Document Number: 1235610

Reference: 1990, Bee Adult Toxicity Dusting Test Evaluating Comparative Acute Contact And Stomach Poison Toxicity Of 6-benzyladenine To Honey Bee Worker Adults., Data Numbering Code: 9.2.4

PMRA Document Number: 1235604

Reference: 1990, Evaluation Of The Effects Of Orally Administered 6-benzyladenine (abbott-39313) On The Embryonic And Fetal Development Of The Rat (segment Iitfr), Data Numbering Code: 4.5.2

PMRA Document Number: 1235614

Reference: 1991, 6-benzyladenine (encapsulated): An Acute Oral Toxicity Study With The Northern Bobwhite., Data Numbering Code: 9.6.2.1

PMRA Document Number: 1235611

Reference: 1991, 6-benzyladenine Code16262: A 48 Hour Static Daily Renewal Acute Toxicity Test With The Cladoceran (daphnia Magna), Data Numbering Code: 9.3.2

PMRA Document Number: 1235615

Reference: 1991, 6-benzyladenine: A Dietary Lc50 Study With The Northern Bobwhite., Data Numbering Code: 9.6.2.4

PMRA Document Number: 1235608

Reference: 1991, Physical And Chemical Properties Characterization Of 6-benzyladenine. Code 16262, Data Numbering Code: 8.2.1

PMRA Document Number: 1235603

Reference: 1992, 13 Week Dietary Toxicity With 6-benzyladenine In Rats, Data Numbering Code: 4.3.1

PMRA Document Number: 1114804

Reference: 2000, Tno, Voluntary Data - A Study On The Adsorption/desorption Of 6-benzyladenine (abg 3191) Using [8-14c]-n-6-benzyladenine, To Two Sediment Types (OECD 106 Draft, Setac-europe And 95/36/ec), Data Numbering Code: 8.2.4.2

PMRA Document Number: 1114808

Reference: 2000, Voluntary Data - Determination Of The Effect Of 6-benzyladenine (abg-3191) On The Growth Of The Fresh Water Green Alga Selenastrum Capricornutum (guidelines OECD No. 201 And Eu C.3), Data Numbering Code: 9.8.2

PMRA Document Number: 1114807

Reference: 2000, Voluntary Data - Static Acute Toxicity Test With 6-benzyladenine And The Crustacean Species Daphnia Magna (guidelines OECD No. 202 And Eu C.2), Data Numbering Code: 9.3.2

PMRA Document Number: 1114805

Reference: 2001, Tno, Voluntary Data - A Water/sediment Degradation Study Of 6-benzyladenine Using [8-14c]n-6-benzyladenine (ctb Guideline Section G.2.1, OECD Draft Document, Setac-europe), Data Numbering Code: 8.2.3.5.4

PMRA Document Number: 1192958

Reference: 2002, Acute Toxicity To Aphidius Rhopalosiphi In The Laboratory, Data Numbering Code: 9.2.8

PMRA Document Number: 1192957

Reference: 2002, Acute Toxicity To Typhlodromus Pyri In The Laboratory, Data Numbering Code: 9.2.8

PMRA Document Number: 1114806

Reference: 2002, Voluntary Data - Abg-3191 Acute Toxicity (lc50) To The Earthworm, Data Numbering Code: 9.2.3

PMRA Document Number: 1192956

Reference: 2003, Evaluation Of The Effects Of Pesticides On The Green Lacewing Chrysoperla Carnea In The Laboratory, Data Numbering Code: 9.2.8

PMRA Document Number: 1114802

Reference: 2003, Voluntary Data - 6-benzyladenine - Determination Of The Abiotic Degradation Of The Test Substance By Hydrolysis At Three Different Ph Values Following OECD Guideline 111, Data Numbering Code: 8.2.3.2

PMRA Document Number: 1114803

Reference: 2003, Voluntary Data - 6-benzyladenine - Photodegradation In Water, An Experimental Screening Test Based On The OECD Direct Photolysis Draft Guideline, Tier Ii, Data Numbering Code: 8.2.3.3.2

PMRA Document Number: 1114799

Reference: 2003, Voluntary Data - Abg-3191 Two Generation Reproduction Study In Rat, Data Numbering Code: 4.5.1

PMRA Document Number: 1114801

Reference: 2003, Voluntary Data - Validation Of A Method For The Determination Of 6-benzyladenine (6ba) In Surface Water, Data Numbering Code: 8.2.2.3

PMRA Document Number: 1192952

Reference: 2004, The Aerobic Degradation Of [14c]-6-benzyladenine In 4 Soil Types, Data Numbering Code: 8.2.3.4.2

PMRA Document Number: 1192955

Reference: 2005, Maxcel: An Acute Oral Toxicity Study With The Honey Bee - Final Report, Data Numbering Code: 9.2.8

Value:

PMRA Document Number: 1192960

Reference: 10.2.3 Efficacy Trials - Background: Cited Published References., Data Numbering Code: 10.2.3

PMRA Document Number: 1192961

Reference: 10.2.3.1 Summary + 10.2.3.2 Efficacy: Laboratory, Growth Chamber Trials + 10.2.3.3 Efficacy: Small-scale Trials (field, Greenhouse) + 10.3.2 Non-safety Adverse Effects, Data Numbering Code: 10.2.3.1,10.2.3.2,10.2.3.3,10.3.2

PMRA Document Number: 1192964

Reference: 2003, 2003 Chemical Thinning Experiments With Benzyladenine And Carbaryl Empire, Royal Gala, Gingergold, Northern Spy And Jonagold, Data Numbering Code: 10.2.3.1,10.2.3.2,10.2.3.3

PMRA Document Number: 1192963

Reference: 2004, Chemical Thinning Experiments With Benzyladenine Carbaryl, And Other Blosson Thinners On Empire, Royal Gala, And Red Delicious Apples In 2002, Data Numbering Code: 10.2.3.1,10.2.3.2,10.2.3.3

PMRA Document Number: 1192968

Reference: Data Numbering Code 10.3.2 [non-safety Adverse Effects], Data Numbering Code: 10.3.2



PMRA Document Number: 1192959

Reference: N/a, 10.2.3 Efficacy Trials - Background, Data Numbering Code: 10.2.3

PMRA Document Number: 1192966

Reference: Thinning Treatment Response On "Honeycrisp" Fruit Size And Crop-load. 2003-embree-honeycrisp., Data Numbering Code: 10.2.3.3,10.3.2

PMRA Document Number: 1192967

Reference: Thinning Treatment Response On "Redmax" Fruit Size And Crop-load. 2003-embree-redmax., Data Numbering Code: 10.2.3.3,10.3.2

PMRA Document Number: 1192965

Reference: Vbc 30001 Rate Study On McIntosh. 2003-embree-mcintosh., Data Numbering Code: 10.2.3.3,10.3.2

PMRA Document Number: 1192962

Reference: Vbc 3001 Agriculture And Agri-food Canada Data Report., Data Numbering Code: 10.2.3.1,10.2.3.2,10.2.3.3

## B. ADDITIONAL INFORMATION CONSIDERED

### i) Published Information

#### Published Information

PMRA Document Number: 1274606

Reference: , 72 6-benzylaminopurine Plant Growth Regulator In: The e-pesticide Manual (Thirteenth Edition) Version 3.1, Data Numbering Code: 12.5

PMRA Document Number: 1274808

Reference: US EPA, Red: N6-benzyyladenine. List B. Case 2040., Data Numbering Code: 12.5

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