



## Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.13 Application

**Application Number:** 2008-0883  
**Application:** B.2.3, B.2.4 Product chemistry – Identity of formulants/Proportion of formulants  
B.3.13 Product labels - Precautions  
**Product:** Primextra II Magnum Agricultural Herbicide  
**Registration Number:** 29358  
**Active ingredients (a.i.):** S-metolachlor and R-enantiomer [AME] and atrazine and elated triazines [ATR]  
**PMRA Document Number:** 1774261

### Purpose of Application

The purpose of this application was to register a new end-use product, Primextra II Magnum Agricultural Herbicide, based on the precedent product, Primextra II Magnum Herbicide (Reg. No. 25730).

### Chemistry Assessment

PRIMEXTRA II Magnum Agricultural Herbicide is a liquid containing the active ingredients S-metolachlor and R-enantiomer at a nominal concentration of 400 g/L and atrazine and related triazines at a nominal concentration of 320 g/L. This product has a density of 1.12 g/mL and pH of 5.95 for a 1 % solution in water. The chemistry requirements for PRIMEXTRA II Magnum Agricultural Herbicide have been completed.

### Health Assessments

Primextra II Magnum Agricultural Herbicide is of low toxicity to rats via the oral ( $LD_{50} > 5000$  mg/kg), dermal ( $LD_{50} > 5050$  mg/kg), and inhalation ( $LC_{50} > 2.67$  mg/L) routes. It is minimally irritating to the eye and non-irritating to skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The proposed use of Primextra II Magnum Agricultural Herbicide fits within the existing use pattern of the active ingredients, S-metolachlor/ R-enantiomer and atrazine. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

To support the establishment of maximum residue limits (MRLs) for atrazine on field corn, sweet corn, popcorn, fat, meat and meat-byproducts of cattle, goats, hogs, horses, poultry and sheep, milk and eggs, previously reviewed data on animal and plant metabolism of atrazine, the methodology for determination of atrazine residues, and residue data on corn and corn fractions from atrazine field trials were reassessed.

No new residue data were submitted to support the registration of Primextra II Magnum Agricultural Herbicide. The use pattern for this end-use product is identical to that of registered precedent product Primextra II Magnum Herbicide in terms of application rates and target areas, therefore the food residue exposure is expected to be similar. No increase in dietary exposure of atrazine and S-metolachlor/R-enantiomer is anticipated. The new formulation of S-metolachlor/R-enantiomer and atrazine will not pose an unacceptable health risk to any population subgroup in Canada, including infants, children, adults and seniors.

- **Maximum Residue Limits**

Recommendations for MRLs for atrazine in/on corn, fat, meat, meat by-products, milk and eggs were made at the combined LOQs of the enforcement method for each of the four analytes, based on the fact that no quantifiable residues were observed.

Based on the residue data, an MRL of 0.2 ppm on field corn, sweet corn kernels plus cob with husks removed and popcorn grain to cover residues of atrazine and the chlorometabolites will be established as shown in Table 1. Residues of atrazine and the chlorometabolites in processed commodities of field corn, sweet corn and popcorn will be covered under the established MRLs for the raw agricultural commodities (RACs).

| <b>TABLE 1. Summary of Atrazine Field Trial and Processing Data Used to Establish Maximum Residue Limit(s) (MRLs).</b> |  |            |                |       |  |                           |   |
|--|--|------------|----------------|-------|--|---------------------------|---|
| Commodity  | Application Method/ Total Application Rate   | PHI (days) | Residues (ppm) |       | Experimental Processing Factor                           | Currently Established MRL | MRL   |
|  |  |            | Min            | Max   |  |                           |   |
| Field Corn   | Preplant surface, preplant incorporated, pre-emergence and postemergence/ 1.5 kg a.i./ha | 80 days    | <0.05          | <0.05 | No concentration of residues observed in corn fractions. | None                      | 0.2 ppm (on field corn, sweet corn kernels plus cob with husks removed and popcorn grain) |

Based on the dietary burden and residue data, an MRL of 0.04 ppm on fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep, milk and eggs to cover residues of atrazine and the chlorometabolites will be established.

Residues of atrazine and the chlorometabolites in/on field corn, sweet corn, popcorn and animal commodities at the recommended MRLs will not pose an unacceptable risk to any segment of the population including infants, children, adults and seniors.

## **Environmental Assessment**

No new environmental fate or ecotoxicological data were submitted to support Primextra II Magnum Agricultural Herbicide. As the subject product has the same use rate of active ingredients per hectare, application timing, proposed label claims, pre-harvest intervals, and grazing restrictions as the registered precedent product, no increase in environmental risk from the subject end-use product is expected.

## **Value Assessment**

The registration of Primextra II Magnum Agricultural Herbicide can be supported from a value standpoint based on the following facts:

- Primextra II Magnum Agricultural Herbicide has identical claims and use patterns as that of the registered precedent product, Primextra II Magnum Herbicide.
- The formulation of Primextra II Magnum Agricultural Herbicide includes the same functional groupings that are present in approximately the same proportion as the presently registered precedent product.
- The formulation of Primextra II Magnum Agricultural Herbicide did not change the guarantees of the active ingredients in the product (400 g/L of S-metolachlor/R-enantiomer and 320 g/L atrazine/related triazines).
- The new formulation is nonylphenol ethoxylate (NPE)-free.

## Conclusion

Following the review of all available data, the PMRA can support the full registration of Primextra II Magnum Agricultural Herbicide. The PMRA is recommending an MRL of 0.2 ppm to cover residues of atrazine and the chlorometabolites on field corn, sweet corn kernels plus cob with husks removed and popcorn grain, and an MRL of 0.04 ppm to cover residues of atrazine and the chlorometabolites on fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep, milk and eggs.

## References

| PMRA Document Number | Reference   |
|----------------------|---|
| CES:                 |   |
| 1560974              | 2007, PRIMEXTRA II MAGNUM AGRICULTURAL HERBICIDE - IDENTIFICATION, DACO: 3.1,3.1.1,3.1.3,3.1.4 CBI  |
| 1560975              | 2007, PRIMEXTRA II MAGNUM AGRICULTURAL HERBICIDE - FORMULATING PLANT, DACO: 3.1.2 CBI   |
| 1560976              | 2007, PRIMEXTRA II MAGNUM AGRICULTURAL HERBICIDE - STARTING MATERIALS, DACO: 3.2.1 CBI  |
| 1560981              | 2007, PRIMEXTRA II MAGNUM AGRICULTURAL HERBICIDE - DESCRIPTION OF FORMULATION PROCESS, DACO: 3.2.2 CBI  |
| 1560982              | 2007, PRIMEXTRA II MAGNUM AGRICULTURAL HERBICIDE - DISCUSSION OF FORMATION OF IMPURITIES, DACO: 3.2.3,3.4.2 CBI   |
| 1560985              | 2007, PRIMEXTRA II MAGNUM AGRICULTURAL HERBICIDE - CERTIFICATION OF LIMITS, DACO: 3.3.1 CBI   |
| 1560986              | 2007, ANALYTICAL METHOD SF 218/1, DACO: 3.4.1 CBI   |
| 1560987              | 2007, VALIDATION OF ANALYTICAL METHOD SF 218/1, DACO: 3.4.1 CBI   |
| 1560988              | 2007, PRIMEXTRA II MAGNUM AGRICULTURAL - PHYSICAL AND CHEMICAL PROPERTIES, DACO: 3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI                            |
| 1766200              | 2009, A9562G Content of Active Ingredient(s) after Storage in Stainless Steel for 2 years at 20C and Corrosion Characteristics after Storage in Stainless Steel for 1 year at 20C, DACO: 3.5.10,3.5.14 CBI          |
| 1766202              | 2009, A9562G: Content of Active Ingredients After Storage in Non-Fluorinated HDPE for 2 years at 20C and Corrosion Characteristics after Storage in Non-Fluorinated HDPE for 1 year at 20C, DACO: 3.5.10,3.5.14 CBI |

TOX:

- 1560990 2007, Atrazine/S-Metolachlor SC (320/400) (A9562G) - Acute Oral Toxicity Study in Rats, 10694-07, DACO: 4.6.1
- 1560991 2007, Atrazine/S-Metolachlor SC (320/400) (A9562G) - Acute Dermal Toxicity Study in Rats, 10695-07, DACO: 4.6.2
- 1560992 2007, Atrazine/S-Metolachlor SC (320/400) (A9562G) - Acute Inhalation Toxicity Study in Rats, 10696-07, DACO: 4.6.3
- 1560993 2007, Atrazine/S-Metolachlor SC (320/400) (A9562G) - Acute Eye Irritation Study in Rabbits, 10697-07, DACO: 4.6.4
- 1560994 2007, Atrazine/S-Metolachlor SC (320/400) (A9562G) - Acute Dermal Irritation Study in Rabbits Dermal Irritation Study in Rabbits, 10698-07, DACO: 4.6.5
- 1560995 2007, Atrazine/S-Metolachlor SC (320/400) (A9562G) - Skin Sensitization Study in Guinea Pigs, 10699-07, DACO: 4.6.6
- 1415745 2007, PRIMEXTRA II MAGNUM - 6003 - ALTERNATE CONTROL PRODUCT SPECIFICATION FORM, DACO: 0.1.6003
- 1415746 2007, PRIMEXTRA II MAGNUM - 6003 - BASIC CONTROL PRODUCT SPECIFICATION FORM, DACO: 0.1.6003
- 1560965 2008, PRIMEXTRA II MAGNUM AGRICULTURAL HERBICIDE - 6003 - CONTROL PRODUCT SPECIFICATION FORM (1.1), DACO: 0.1.6003
- 1560972 2008, PRIMEXTRA II MAGNUM AGRICULTURAL HERBICIDE - 6005 - PROPOSED ENGLISH LABEL, DACO: 1.1

VSAD:

- 1575384: Part 10 - Data waiver request for registration of Primextra II Magnum Agriculture Herbicide. Syngenta. DACO 10.2.3.1-10.3.2. March 17, 2008. pp. 1.

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