



## Regulatory Note

REG2003-09

### Corn Gluten Meal

The active ingredient Prairie Gold 60% Corn Gluten Meal (CGM) and associated end-use product TurfMaize, a Domestic Class product for use on established residential lawns where the predominant grass is Kentucky bluegrass, have been granted temporary registration under Section 17 of the Pest Control Products (PCP) Regulations.

This Regulatory Note provides a summary of data reviewed and the rationale for the regulatory decision for these products.

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Publications Coordinator  
Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6605C  
Ottawa, Ontario  
K1A 0K9

Internet: [pmra\\_publications@hc-sc.gc.ca](mailto:pmra_publications@hc-sc.gc.ca)  
[www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)

Information Service:  
1-800-267-6315 or (613) 736-3799  
Facsimile: (613) 736-3798



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## Foreword

Health Canada's Pest Management Regulatory Agency (PMRA) has issued temporary registrations for the biopesticide active ingredient Prairie Gold 60% Corn Gluten Meal (CGM) and associated end-use product TurfMaize, manufactured by The Environmental Factor Inc., for use as a Domestic Class product on established residential lawns where the predominant grass is Kentucky bluegrass.

These submissions have been reviewed by the PMRA under the PMRA Initiative for Reduced Risk Pesticides. TurfMaize is a pre-emergence weed seed germination inhibitor which may inhibit dandelion (*Taraxacum officinale*) and smooth crabgrass (*Digitaria ischaemum*) seed germination when used in conjunction with a sound lawn maintenance program.

The Environmental Factor Inc. will be carrying out additional efficacy studies as a condition of this temporary registration. Following the review of this information, the PMRA will publish a proposed regulatory decision document (PRDD) and request comments from interested parties before proceeding with a final regulatory decision.

## 1.0 Introduction

Prairie Gold 60% Corn Gluten Meal (CGM) is a technical grade active ingredient (TGAI) that contains 100% CGM. TurfMaize is an end-use product that contains 98% CGM. Soybean oil was previously reviewed by the PMRA (PRDD99-02) and is considered to be safe for human health and the environment. CGM is a by-product of the wet milling process of corn for starch. It is also produced as a by-product during conversion of starch from dry-milled corn to corn syrup.

Corn gluten meal has been sold in Canada as a natural fertilizer for the past 5 years. The United States Environmental Protection Agency (USEPA) listed CGM on the USEPA's 25(b) list of least toxic pesticides and waived all environmental fate and toxicology data requirements for the registration of CGM. The registration of CGM as a pre-emergent herbicide in the U.S. has been exempt by the USEPA since 1994 (Reg #56872-1 and USEPA EST 56872-IN-1) and California EPA (Reg No. 1051098-3001-AA).

### 1.1 The active substance, its properties and uses Identity (OECD 2.1.1)

#### TGAI Identification

Active substance	Corn Gluten Meal
Function	Plant growth regulator
Chemical Abstracts Service (CAS) number	66071-96-3
Nominal purity of active	100%
Identity of relevant impurities of toxicological, environmental or other significance	The technical grade active ingredient corn gluten meal does not contain any impurities or micro contaminants known to be Toxic Substances Management Policy (TSMP) Track-1 substances as identified in Appendix II of Regulatory Directive DIR99-03.

## 1.2 Physical and chemical properties (OECD 2.1.2)

### Technical product: Corn Gluten Meal Technical

Property	Result	Comment
Colour and physical state	Yellow coarse solid	
Odour	Faint cereal type odour	
Bulk density	0.5–0.6 g/cm <sup>3</sup>	

### End-use product: TurfMaize

Property	Result
Colour	Yellow
Odour	Faint cereal type odour
Physical state	Solid
Formulation type	Granular
Guarantee	98% (nominal) (limits: 96.25–99.75%)
Formulants	The product does not contain any USEPA List 1 formulants or formulants known to be TSMP Track-1 substances.
Container material and description	6-mil polyethylene plastic bags; each bag has two lines of perforation to allow product to breathe.
Bulk density	0.5–0.6 g/cm <sup>3</sup>
Storage stability	Stable provided it is not exposed to open flames, electrical and static sparks, sparks from welding equipment and strong oxidizers.

## 1.3 Proposed uses

TurfMaize is proposed for Domestic Class registration as a non-selective organic pre-emergent herbicide and slow-release organic fertilizer for use on residential landscapes to control dandelion (*Taraxacum officinale*) and smooth crabgrass (*Digitaria ischaemum*).

The label recommends two applications of TurfMaize per year. An early spring application before weed seed germination at a rate of 9.7 kg/100 m<sup>2</sup> (9.506 kg a.i./100 m<sup>2</sup>). For lawns with no weeds in the spring, application of

TurfMaize is recommended at half the rate (4.753 kg a.i./100 m<sup>2</sup>). A fall application, in late August until October 31, is recommended at a rate of 9.7 kg/100 m<sup>2</sup> (9.506 kg a.i./100 m<sup>2</sup>). For lawns with no weeds in the fall, application of TurfMaize is recommended at half the rate (4.753 kg a.i./100 m<sup>2</sup>).

The label warns that TurfMaize must not be applied to newly seeded grass until after the first mowing when the root systems are established, since the product inhibits seeds from germinating.

## **2.0 Analytical methods for analysis of the active substance as manufactured (OECD 2.2.1)**

The nitrogen and moisture contents in the technical product and in TurfMaize are determined using published methods. References of these methods were provided.

Corn gluten meal technical is a feed grade product and meets the requirements outlined in Canadian Feed Regulations, Schedule IV, Part 1, Section 5.3.8. Data from two batches each from three separate sites show that the product meets the protein and moisture contents as outlined in the Canada Feed Regulations. The analytical method used for protein determination in the technical and in TurfMaize end-use product is a published AOAC method.

## **3.0 Impact on human and animal health**

No toxicological studies were submitted for Prairie Gold 60% Corn Gluten Meal and TurfMaize. Instead, published literature was provided to support requests to waive all data requirements. The most common adverse effect reported in humans for corn and corn by-products in the published literature is allergy. Symptoms include dermal reactions, respiratory ailments, gastrointestinal difficulties and severe anaphylaxis. Adverse effects were also reported for corn dusts. However, these effects are limited mainly to grain and feed workers who are exposed to these dusts in enclosed spaces on a daily basis and, also, the cause of these reactions is still debated as corn and other grain dusts may contain numerous bacterial and fungal contaminants which can induce allergic and/or toxic reactions. Many of the fungi that grow on raw corn produce mycotoxins that may not be removed during wet-milling. Therefore, feed-grade corn gluten meal may also contain contaminating species of fungi particularly from the genus *Fusarium* and/or their associated mycotoxins, including fumonisins (B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub>), trichothecenes (types A and B), zearalenone, aflatoxin and ochratoxin A. The amount of these mycotoxins present in feed-grade corn gluten meal is regulated by the CFIA. Currently, aflatoxin are the only mycotoxins regulated in the *Feeds Act* and Regulations, however recommended tolerance levels have been established for many of the remaining groups of mycotoxins.

Based on the available information for corn gluten meal, Prairie Gold 60% Corn Gluten Meal and TurfMaize are expected to be minimally toxic via the oral, dermal and pulmonary routes, minimally irritating to the skin, and mildly irritating to the eyes if both products conform to the mycotoxin guidelines established by the Canadian Food Inspection Agency (CFIA). Therefore, it is required that the mycotoxin levels present in Prairie Gold 60% Corn Gluten Meal and TurfMaize do not exceed the tolerance levels established by the CFIA for feed. In addition, Prairie Gold 60% Corn Gluten Meal and TurfMaize are also expected to be potential sensitizers.

Potential exposure will be via dermal deposition and inhalation during application and re-entry onto treated lawns. The above-noted toxicological data indicate a lack of significant adverse toxicology health effects for corn gluten meal. As such, no quantitative exposure and risk assessment was conducted. However, hypersensitivity from contact with corn by dermal and inhalation routes may be of concern. Therefore, a precautionary statement regarding corn as a potential allergen will be added to the label together with personal protective equipment (PPE) recommendation for applicators.

#### **4.0 Residues**

Not applicable.

#### **5.0 Fate and behaviour in the environment**

No data were submitted on environmental chemistry and fate of CGM and TurfMaize. CGM is insoluble in water. CGM is a protein and is expected to biotransform rapidly when applied to soil. It is therefore not expected to be persistent in the environment.

#### **6.0 Effects on non-target species**

No data were submitted on the toxicity of CGM to terrestrial and aquatic organisms. CGM is a feed grade material and is used historically in the manufacturing of food material for animals, birds and fish. It is also used in the commercial fishing industry as a commercial fish food. According to the applicant, it is considered non-toxic to wild birds, mammals, fish, terrestrial and aquatic invertebrates. Studies conducted with sows (Honeyman and Zimmerman, 1990) showed that the performance (body weight and litter size) of sows fed with corn gluten feed did not differ from that of the sows fed with the control diet. CGM is listed as a feed ingredient and included in Schedule IV of the Canadian Feed Ingredient classification (Section 5.3.8, protein foods). CGM is, therefore, expected to have negligible adverse effects on non-target terrestrial and aquatic organisms.

Corn gluten meal is biodegradable and, therefore, not persistent in the environment. It is non-toxic to wild birds, mammals, fish, and terrestrial and aquatic invertebrates. CGM is, therefore, expected to have negligible adverse effects on non-target terrestrial and aquatic organisms. CGM and TurfMaize will not pose a risk to the environment with the labelled use pattern.

## **7.0 Efficacy**

Based on the data submitted, there is evidence to support a claim that TurfMaize may inhibit the seed germination of dandelions and smooth crabgrass. As a condition of registration, additional efficacy data are required to demonstrate the herbicidal effect of TurfMaize.

Sufficient crop tolerance data were submitted to demonstrate that established Kentucky bluegrass turf is expected to be tolerant to TurfMaize when applied according to the label directions. No data were submitted to demonstrate the tolerance of other grass species, such as fine fescues, bent grasses and rye grasses which may be found in established residential lawns in Canada. In lieu of crop tolerance data for other perennial grasses typically found in established lawns, the label must state that TurfMaize is for use on lawns where the predominant grass is established Kentucky bluegrass.

No data were submitted in order to establish an appropriate over-seeding or re-sodding interval of sites treated with TurfMaize. In lieu of data, the label states that if over-seeding or re-sodding in the spring, do not apply TurfMaize in the spring. If over-seeding or re-sodding in the fall, do not apply TurfMaize in the fall.

## **8.0 Toxic Substances Management Policy (TSMP) considerations**

During the review of CGM, PMRA has taken into account the federal Toxic Substances Management Policy (TSMP) and has followed its Regulatory Directive DIR99-03. It has been determined that this product does not meet TSMP Track-1 criteria and does not form any major transformation products that meet the TSMP Track-1 criteria. It does not contain any by-products or micro contaminants that meet the TSMP Track-1 criteria. The end-use product, TurfMaize, does not contain any formulants that are known to contain TSMP Track-1 substances or USEPA list 1 or 2 formulants.



## 9.0 Regulatory decision

Prairie Gold 60% Corn Gluten Meal (TGAI) and associated end-use product, TurfMaize, have been granted temporary registrations for use as pre-emergence weed seed germination inhibitors for dandelions (*Taraxacum officinale*) and smooth crabgrass (*Digitaria ischaemum*) on established residential lawns where the predominant grass is Kentucky bluegrass, pursuant to Section 17 of the Pest Control Products (PCP) Regulations, subject to the generation of the following studies:

- confirmatory efficacy data.