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REGISTRATION DECISION

Cellulose From Powdered Corn Cobs

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Registration Decision for Cellulose from Powdered Corn Cobs

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of the technical grade active ingredient cellulose from powdered corn cobs and the end-use products Rode-Trol Rodent Control Bait for Rats and Rode-Trol Rodent Control Bait for Mice to control rats and mice indoors where food sources can be removed.

Current scientific data from the registrant, scientific reports and information from other regulatory agencies were evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: Proposed Registration Decision, *Cellulose From Powdered Corn Cobs*, (PRD2007-04). This Registration Decision[2] describes this stage of the PMRA's regulatory process for cellulose from powdered corn cobs and summarizes the Agency's decision and reasons for it. The PMRA received no comments on Proposed Registration Decision PRD2007-04, *Cellulose From Powdered Corn Cobs*. This decision is consistent with the proposed registration decision stated in PRD2007-04.

For more details on the information presented in this Registration Decision, please refer to the science evaluation section of the related PRD2007-04.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks[3] to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration. The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *the Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Cellulose From Powdered Corn Cobs?

Cellulose from powdered corn cobs is a rodenticide applied inside buildings to control rats or mice. The mode of action for cellulose from powdered corn cobs is not clear, but it appears to interfere with the digestive system by causing blockages in the intestine and cecum, resulting in dehydration and eventually death. In order to be effective, all other potential food sources must be removed from the treatment location.

❖ Health Considerations

♦ Can Approved Uses of Cellulose From Powdered Corn Cobs Affect Human Health?

Cellulose from powdered corn cobs is unlikely to affect your health when used according to the label directions.

People could be exposed to cellulose from powdered corn cobs when handling and applying the product. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is expected to be well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient cellulose from powdered corn cobs and the end-use products Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are not expected to cause any significant toxicological effect on exposure in an acute situation. The publically available information suggests that cellulose from powdered corn cobs is not expected to exhibit chronic, developmental, reproductive or nervous system toxicity. This information also suggests that the cellulose from powdered corn cobs is unlikely to be cause cancer or to be genotoxic[5].

[5] Genotoxic chemicals are those capable of causing damage to DNA. Such damage can potentially lead to the formation of a malignant tumor, but DNA damage does not lead inevitably to the creation of cancerous cells.

♦ Residues in Water and Food

Dietary risks from food and water are not of concern.

The use of the rodenticides is limited to non-food / feed situations. It is not anticipated that the use of Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice will result in dietary risk from food and/or water.

♦ Occupational Risks From Handling Rode-Trol Rodent Control Bait for Rats and Rode-Trol Rodent Control Bait for Mice

Occupational risks are not of concern when Rode-Trol Rodent Control Bait for Rats and Rode-Trol Rodent Control Bait for Mice are used according to the label directions.

Pesticide applicators loading and/or applying Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice could come in direct contact with cellulose from powdered corn cobs on the skin or through inhalation of loose cellulose material. The low toxicity of cellulose from powdered corn cobs and minimal anticipated exposure from Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice, both in pelletized form, suggests that occupational risk due to exposure is not expected to be a concern. The presence of wheat in Rode-trol Rodent Control Bait for Rats may be of concern for individuals with wheat sensitivities. The risk due to exposure to wheat has been taken into consideration by the cautionary label statement “Warning—contains the allergen wheat.”

♦ Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern provided that directions specified on the label are observed.

The risks in residential and non-occupational environments are likely confined to incidental contact with the rodenticides in a postapplication activity, such as discarding used rodenticide or bait station maintenance, and are considered negligible in the general population. Individuals with wheat sensitivities should avoid contact with Rode-trol Rodent Control Bait for Rats. The health risks to the majority of non-occupational bystanders are not of concern. Any health risks resulting from accidental oral ingestion of wheat in Rode-trol Rodent Control Bait for Rats by individuals, especially children, have been taken into account by the cautionary label statement on the principal display panel “Warning—contains the allergen wheat”.

❖ Environmental Considerations

♦ What Happens When Cellulose From Powdered Corn Cobs Is Introduced Into the Environment?

Cellulose from powdered corn cob poses a negligible risk to the environment.

The Rode-trol products must be used as rodenticides indoors (i.e. buildings, warehouses, barns and empty feed storage areas); therefore, only negligible amounts will enter the environment. The powdered corn cob is a natural product and is expected to readily break down in the environment. Because the products are used indoors, there will be minimal environmental exposure of non-target species to the products. Target rodents that have consumed the products may travel outdoors. These products pose negligible risk to avian and mammalian predators and scavengers that may feed on dead or dying rodents.

❖ Value Considerations

♦ What Is the Value of Cellulose From Powdered Corn Cobs?

Cellulose from powdered corn cobs is a rodenticide for control of rats and mice indoors (e.g. buildings, barns, empty feed storage areas, warehouses) where no other food sources are available.

Rode-trol LLC submitted an application to register Rode-Trol Rodent Control Technical Grade Active Ingredient (45% cellulose made from powdered corn cobs) as a rodenticide. The Rode-trol Technical is to be used in two end-use products Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice. Both products are to be applied in commercially available bait stations indoors where food sources can be removed. Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are lower-risk alternatives to conventional rodenticides used for the control of rats and mice indoors where no alternative food sources are available.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. The PMRA is requiring key risk-reduction measures on the label of Rode-trol Rodent Control Bait for Rats.

Key Risk-Reduction Measures

- **Human Health**

Rode-trol Rodent Control Bait for Rats contains the allergen wheat; therefore, there are concerns that individuals, particularly children, with sensitivities to wheat may experience an allergic reaction if Rode-trol Rodent Control Bait for Rats is accidentally ingested. A label statement identifying the presence of wheat is necessary for Rode-trol Rodent Control Bait for Rats. No key risk-reduction measures are required for Rode-trol Rodent Control Bait for Mice.

Other Information

The relevant test data on which the decision is based (as referenced in the above-mentioned Evaluation Report) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[6] regarding this registration decision on Cellulose From Powdered Corn Cobs within 60 days from the date of publication of this Registration Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[6] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies / Information Submitted by Registrant

2.0 Chemistry

PMRA 909708 Chemistry Requirements, Rode-trol LLC, undated, 4 pages, DACO 3.2.2, 3.4.1 and 3.5.

PMRA 910968 Chemistry Requirements, Rode-trol LLC, undated, 4 pages, DACO 3.2.2, 3.4.1 and 3.5.

PMRA 1143714 Chemistry Requirements - Rode-Trol® Rodent Control Bait Technical Grade Active Ingredient - Tab 1, Rode-trol LLC, undated, 6 pages, DACO 2.11.2, 2.11.3, 2.13.3.

PMRA 1143718 Journal of Chromatography A, 671 (1994) 339-350, 12 pages, Determination of Carbohydrates in Wood, Pulp and Process Liquor Samples by High-Performance Anion-Exchange Chromatography with Pulsed Amperometric Detection.

PMRA 1143720 Technical Service Contract Report, Testing of Rode-Trol Products, Paprican Technical Service Contract Report TSC 048580, September 21, 2004, 3 pages, DACO 2.13.1.

PMRA 1143721 JR Laboratories Inc., Analysis Certificate, Certificate ID: 7135, 04/07/28, 2 pages, DACO 2.16.

3.0 Impact on Human and Animal Health

PMRA 910947 Request for waiver: toxicology, Rode-trol LLC, October 29, 2004, 2 pages, DACO 4.0.

PMRA 910950 Comprehensive data summaries: cellulose, Rode-trol LLC, October 29, 2004, DACO 12.7.

PMRA 909709 Request for waiver: toxicology, Rode-trol LLC, undated, 2 pages, DACO 4.0.

PMRA 909712 Effects of orbis molasses pellet on rats when fed ad libitum, Delmar Company, sample orbis molasses pellet, Leberco Testing, Inc., Lab report number 9415100, October 11, 1994, 20 pages, DACO 4.6.1 and 4.8.

PMRA 909711 The effect of the Delmar product pellets on Rattus norvegicus behaviour and mortality when fed predetermined amounts of product, Biological Control Products SA Ltd, no report number, September 14, 1994, 34 pages, DACO 4.8.

PMRA 909713 Exposure (occupational and/or bystander) request for waiver, Rode-trol LLC, undated, 2 pages, DACO 5.0.

PMRA 1071802 Use pattern/exposure studies: pellet, cellulose from powdered corn cob, Rode-trol LLC, undated, 7 pages, DACO 5.2.

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PMRA 910976 Acute oral toxicity study, LD50 Delmar Company sample: orbis molasses pellet, September 14, 1994, 21 pages, DACO 4.6.1.

PMRA 910977 Request for waiver: exposure-pellet-mice, Rode-trol LLC, undated, 2 pages, DACO 5.0.

PMRA 1071775 Use pattern/exposure studies: Eradimouse, Rode-trol LLC, September 7, 2005, 6 pages, DACO 5.2.

4.0 Impact on the Environment

PMRA 1071776 Susceptibility of the guinea pig (*Cavia porcellus*) to Eradimouse. Landcare Research. Landcare Research Contract Report: LC0203/117. Study Report Date: June 2003. 15 pages. DACO 9.9.

PMRA 1071777 Susceptibility of the European rabbit (*Oryctolagus cuniculus cuniculus*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/116. Study Report Date: June 2003. 14 pages. DACO 9.9.

PMRA 1071778 Susceptibility of the duck (*Anas platyrhynchos*) to Eradimouse. Landcare Research. Landcare Research Contract Report: LC0203/122. Study Report Date: June 2003. 15 pages. DACO 9.9.

PMRA 1071779 Susceptibility of the brush-tail possum (*Trichosurus vulpecula*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/115. Study Report Date: June 2003. 18 pages. DACO 9.9.

PMRA 1071780 Susceptibility of the cat (*Felis catus*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/118. Study Report Date: June 2003. 11 pages. DACO 9.9.

PMRA 1071782 Susceptibility of the dog (*Canis familiaris*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/119. Study Report Date: June 2003. 14 pages. DACO 9.9.

PMRA 1071788 Susceptibility of the ferret (*Mustela furo*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/120. Study Report Date: June 2003. 11 pages. DACO 9.9.

PMRA 1071781 Susceptibility of the chicken (*Gallus gallus*) to Eradimouse. Landcare Research. Landcare Research Contract Report: LC0203/121. Study Report Date: June 2003. 11 pages. DACO 9.9.

PMRA 910949 Document 1-2 Overall Summary and Conclusion, 2004. 8 pages. DACO 12.5.

5.0 Value

PMRA 909717 Confirming Effects of Eradirat on Rats When Fed Ad Libitum. Celsis Laboratory Group. Study No. GLP31755. Study report date: 14-November-2002 to 09-December-2002. pages. 13. DACO 10.2.3.2.

PMRA 909718 Efficacy of Eradimouse against Norway Rats. Landcare Research. Study No. LC0203/054. Study report date: December-2002. 25 pages. DACO 10.2.3.2.

PMRA 909719 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 2. Natrocell Technologies Limited. Study report date: 13-December-1995. 19 pages. DACO 10.2.3.4.

PMRA 909721 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 4. Natrocell Technologies Limited. Study report date: 04-January-1996. 10 pages. DACO 10.2.3.4.

PMRA 909722 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 6. Natrocell Technologies Limited. Study report date: 14-March-1996. 13 pages. DACO 10.2.3.4.

PMRA 909723 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 5. Natrocell Technologies Limited. Study report date: 16-January-1996. 14 pages. DACO 10.2.3.4.

PMRA 909724 The use of Eradirat in the control of the Brown rat (*Rattus norvegicus*) in an urban environment. Pest Management Consultants. Study report date: 2001. 19 pages. DACO 10.2.3.4.

PMRA 909725 A brief assessment of the performance of Ecorat on the control of the Brown rat (*Rattus norvegicus*) in Singapore. Pest Management Consultants. Study report date: 2001. 4 pages. DACO 10.2.3.4.

PMRA 909726 Brief notes on the control of anticoagulant resistant rats (*Rattus norvegicus*). Pest Management Consultants. Study report date: 2000. 14 pages. DACO 10.2.3.4.

PMRA 910982 Effects of Eradimouse on Mice When Fed Ad Libitum. Celsis Laboratory Group. Study No. GLP31754. Study report date: 07-October-2002 to 09-December-2002. 13 pages. DACO 10.2.3.2.

PMRA 910983 Efficacy of Eradimouse against Feral House Mice. Landcare Research. Study No. LC0203/05. Study report date: December-2002. 16 pages. DACO 10.2.3.2.

PMRA 910984 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 1. Natrocell Technologies Limited. Study report date: 30-October-1995. 30 pages. DACO 10.2.3.4.

PMRA 910985 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 7. Natrocell Technologies Limited. Study report date: 11-April-1996. 13 pages. DACO 10.2.3.4.

PMRA 910987 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 9. Natrocell Technologies Limited. Study report date: 01-May-1996. 12 pages. DACO 10.2.3.4.

PMRA 910988 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 10. Natrocell Technologies Limited. Study report date: 20-May-1996. 15 pages. DACO 10.2.3.4.

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PMRA 910990 A brief assessment of the performance of the Delmar Product on populations of the house mouse (Mus domesticus) in an agricultural environment. Study report date: 2000. 9 pages. DACO 10.2.3.4.

PMRA 1071803 Clarifications from Rode-trol LLC. Rode-trol LLC Inc. Dated: 07-September-2005. 2 pages.

PMRA 1071804 Request for Waiver of Food Choice Trial with preliminary results of food-choice trial from Biagro Technical Services. Rode-trol LLC Inc. 3 pages. DACO 10.2.3.2.

PMRA 1071805 Efficacy of Eradirat against Sprague-Dawley Laboratory Rats and Assessment of Mode of Action and Effects. Landcare Research. Study No. LC0203/061. Study report date: February-2003. 32 pages. DACO 10.2.3.2.

PMRA 1071784 Trials to Support Canadian Registration of Rodetrol: Time-to death tests. Biagro Technical Services. Study No. 2005/9/36D. Study report date: 05-August-2005. 6 pages. DACO 10.2.3.2.

PMRA 1071785 Clarifications from Rode-trol LLC. Dated: 07-September-2005. 2 pages.

PMRA 1071786 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 8. Natrocell Technologies Limited. Study report date: 04-January-1996. 10 pages. DACO 10.2.3.4.

PMRA 1071787 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 3. Natrocell Technologies Limited. Study report date: 04-January-1996. 10 pages. DACO 10.2.3.4.

B. Additional Information Considered

I) Published Information

2.0 Chemistry

None.

3.0 Impact on Human and Animal Health

PMRA 1420965 Anderson, R.L. *et al.* 1992. The toxicity of purified cellulose in studies with laboratory animals. Cancer Letters. 63: 83-92.

PMRA 1420967 Cullen, R.T. *et al.* 2000. Pulmonary and intraperitoneal inflammation induced by cellulose fibres. Journal of Applied Toxicology. 20: 49-60.

PMRA 1420966 WHO. 1998. Microcrystalline cellulose (WHO food additive series 40). WHO Document 899. World Health Organization, Geneva, Switzerland.

4.0 Impact on the Environment

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PMRA 1415330 USEPA, Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach. December 2002. United States Environmental Protection Agency. Publicly available in EPA Docket OPP-2002-0049.

5.0 Value

PMRA 1323120 United States Patent Application: Rodenticide and Method of Screening. Bandwidth Market, Ltd. http://bandwidthmarket.com/resources/patents/apps/2002/10/20020160031.html Study report date: 31-October-2002. 15 pages. Accessed by PMRA: 08-December-2005.

PMRA 1323121 Efficacy and palatability testing. Danish Pest Infestation Laboratory Annual Report 2001. www.dpil.dk/dpil2005/pdf/annrep/2001/ar01c10.pdf. Accessed by PMRA: 19-December-2005. p.42–48.

II) List of Unpublished Information Considered

None.