**CANADA GAZETTE, PART II**

**FOOD AND DRUG REGULATIONS - AMENDMENTS**

**WILL BE PUBLISHED IN CANADA GAZETTE, PART II OF APRIL 6, 2005**

**SCHEDULE NO. 1386 (KAOLIN)**

**P.C. 2005-390 OF MARCH 21, 2005**

**SOR/2005-67 OF MARCH 21, 2005**

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)[a] of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1386 — Kaolin)*.

[a] S.C. 1999, c. 33, s. 347

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REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1386 — KAOLIN)

AMENDMENT

**1. Subsection B.15.002(2) of the *Food and Drug Regulations*[1] is amended by striking out the word "or" at the end of paragraph (*e*), by adding the word "or" at the end of paragraph (*f*) and by adding the following after paragraph (*f*):**

(*g*) kaolin.

COMING INTO FORCE

**2. These Regulations come into force on the day on which they are registered.**

[1] C.R.C., c. 870

**REGULATORY IMPACT ANALYSIS STATEMENT**
(This statement is not part of the Regulations)

**Description**

Under authority of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA), of Health Canada, has approved an application for the registration of the pest control product (pesticide) kaolin as an insecticide for the control of a variety of insects on numerous crops. All pest control products that are registered for food uses under the *Pest Control Products Act* are considered agricultural chemicals under the *Food and Drugs Act* and are subject to its provisions regarding residues in food. Under the *Food and Drugs Act*, it is prohibited to sell food containing residues of agricultural chemicals at a level greater than the general Maximum Residue Limit (MRL) of 0.1 parts per million (ppm), as specified in subsection B.15.002(1) of the *Food and Drug Regulations*, unless a higher MRL has been established in the Regulations or the agricultural chemical has been exempted from subsection B.15.002(1) by listing it in subsection B.15.002(2). This regulatory amendment will list kaolin in subsection B.15.002(2), in order to permit the sale of food containing these residues.

Kaolin is a naturally occurring mineral. It is a soft, white or yellowish white powder with a clay-like taste. Humans consume kaolin in a variety of anti-diarrhea medications. A typical use of these medications includes ingestion of 30-60 ml of medication (containing 10-20 g of kaolin) following each loose stool defecation. The kaolin adsorbs material and fluid from the gastrointestinal tract and forms a protective coating on the intestinal mucous membrane. Cholera patients have been fed 600 g of kaolin (plus water) over a 12 hour period without ill effects. The acute toxicity of kaolin is limited to its classification as a nuisance dust, which may cause respiratory irritation. Humans are also exposed to kaolin on a daily basis in products such as antiperspirants, tooth paste and cosmetics. In addition, kaolin is used in animal feed as an anti-caking agent in amounts up to 2.5 per cent of the finished feed. The use of these products have resulted in chronic oral and dermal exposure of the general population to kaolin, with no adverse effects reported.

Before making a registration decision regarding a new use of a pest control product, the PMRA conducts the appropriate assessment of the risks and value of the product specific to its proposed use. The registration of the pest control product will be amended if:

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the data requirements for assessing value and safety have been adequately addressed; the evaluation indicates that the product has merit and value; and the human health and environmental risks associated with its proposed use are acceptable. In the case of kaolin, waivers were requested and granted for subchronic, chronic, reproductive, developmental and neurological toxicity, based on the long history of use of kaolin without any indication of deleterious effects.

Kaolin is not expected to be absorbed in large quantities from the gastrointestinal tract into the systemic circulation. Based on this information and the absence of any systemic toxicity or other toxicological concerns following oral exposure, no quantitative dietary risk assessment is needed for kaolin.

After the review of all available information, the PMRA has determined that the domestic use of kaolin on a variety of crops will not pose a risk to any segment of the population, including infants, children, adults and seniors when food is subjected to the normal process of washing or peeling, and cooking for human consumption.

Therefore, the *Food and Drug Regulations* is being amended to include kaolin in the exemption provisions specified under subsection B.15.002(2).

**Alternatives**

Under the *Food and Drugs Act*, it is prohibited to sell food containing residues of agricultural chemicals at a level greater than 0.1 ppm unless a higher MRL has been established in Table II, Division 15 of the *Food and Drug Regulations* or the agricultural chemical has been exempted from subsection B.15.002(1) by listing it in subsection B.15.002(2). In the case of kaolin, exempting kaolin from subsection B.15.002(1) is necessary to support the use of a pest control product which has been shown to be both safe and effective.

**Benefits and costs**

The use of kaolin will benefit both the agricultural industry and consumers as a result of improved management of pests and will contribute to a safe, abundant and affordable food supply.

Since this amendment will exempt kaolin from the provisions of B.15.002(1), there will be no costs involved in administering the

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regulation.

## Consultation

Registration decisions made by the PMRA are based on internationally recognized risk management principles, which are largely harmonized among member countries of the Organization for Economic Cooperation and Development.

This schedule of amendment was published in the *Canada Gazette*, Part I, on October 2, 2004. Interested parties were invited to make representations concerning the proposed amendment. No responses were received.

## Compliance and Enforcement

Since kaolin would be exempt from the provisions of subsection B.15.002(1) of the *Food and Drug Regulations*, compliance monitoring will not be necessary.

## Contact

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