

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.4 Application

Application Number: 2016-3387
Application: New End-Use Product- Product Chemistry, Guarantee, Identity of Formulants, Proportion of Formulants, Formulation Type
New Product Labels- Application Method
Product: FYSIUM
Registration Number: 33072
Active ingredients (a.i.): 1-methylcyclopropene
PMRA Document Number: 2773825

Purpose of Application

The purpose of this application was to register the end-use product, FYSIUM, based on a registered precedent product, by a new registrant. The proposed use of FYSIUM is in stored apples.

Chemistry Assessment

FYSIUM is formulated as a gas containing 1-methylcyclopropene at a nominal concentration of 98.0%. This end-use product has a density of 2.24 g/L and pH of 7.2. The required chemistry data for FYSIUM have been provided, reviewed and found to be acceptable.

Health Assessments

Potential exposure to 1-methylcyclopropene may occur by applying the end use product, entering treated sites, or consuming food and water. 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 levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Registration is only supported for uses that are determined as having no health risks of concern.

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed.

FYSIUM is of low acute toxicity by inhalation route. The acute oral toxicity, acute dermal toxicity, primary skin and eye irritation, and dermal sensitization could not be determined due to the gaseous nature of the end-use product.

Impurities generated from the in situ production of FYSIUM are not a health concern.

Occupational exposure to individuals handling FYSIUM is not expected to result in unacceptable risk when the product is used according to label directions. Precautionary and hygiene statements on the product label aimed at mitigating worker exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Bystander exposure is not expected to result in health risks of concern when the product is used according to label directions.

Residential and non-occupational exposure is not expected to result in health risks of concern when the product is used according to label directions.

Maximum Residue Limit

The Food and Drug Act prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that is at or below the established MRL does not pose an unacceptable health risk.

The dietary risks from food and drinking water are not a concern given that FYSIUM is of low acute toxicity. However, an MRL of 0.1 ppm for 1-methylcyclopropene on apples was previously established and applies to the proposed use on this crop.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

Following harvest, apples lose quality, reflected as a softening of the fruit, development of mealiness and loss of acidity, and the development of physiological disorders, such as superficial scald. The loss of quality is due to the increase in internal ethylene production by the fruit that results in advanced ripening. As FYSIUM inhibits ethylene production, fruit quality is maintained for a longer period. The availability of FYSIUM for application to apples in enclosed airtight spaces will offer apple fruit growers and distributors an additional product option to delay ripening and maintain fruit quality, whether fruit are to enter marketing channels shortly after harvest or following refrigerated air or controlled atmosphere storage.

Value information was submitted in the form of performance data generated in small-scale and operational trials conducted in Austria, Belgium, Spain, Moldova, South Africa, Argentina, Chile, and the U.S. FYSIUM was applied at one or more concentrations of 1-methylcyclopropene (1-MCP) ranging from 325 to 1300 ppb to evaluate its effect in slowing apple ripening and maintaining fruit quality, assessed as one or more of several parameters, such as internal ethylene production, fruit firmness, fruit acidity and incidence and severity of superficial scald. Evaluations were conducted within a few weeks after application or following various lengths of storage in refrigerated air or controlled atmosphere conditions. The fruit of several cultivars were collectively tested, including several that are commonly grown in Canada.

The studies collectively demonstrate that FYSIUM applied at up to 1 ppm 1-MCP can be expected to delay fruit ripening and senescence, thereby maintaining fruit quality. This was demonstrated as a reduction in fruit firmness loss, internal ethylene production, superficial scald and loss in titratable acidity. As respiration is known to increase with advancing fruit maturity, a claim of reduced fruit respiration is supported. The claim of protection from external sources of ethylene is supported since 1-MCP acts to block the binding of ethylene within plant cells.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found the information sufficient to support the registration of FYSIUM.

References

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2657071	2013, Small Scale Trial Greenstar Apples, DACO: 10.2
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ISSN: 1911-8082

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