



Evaluation Report for Category B, Subcategories 2.1, 2.3, 2.4, 2.5, 3.4, 3.12 Application

Application Number: 2022-0620
Application: New End-use Product (Product Chemistry) – Guarantee, Identity of Formulants, Proportion of Formulants, Formulation type; New Product Labels – New Site or Host, Application Method
Product: HarvestHold Fresh
Registration Number: 35071
Active ingredient (a.i.): 1-Methylcyclopropene
PMRA Document Number: 3517955

Purpose of Application

The purpose of this application was to register the end-use product, HarvestHold Fresh, for use to delay the ripening process and extend the shelf life of harvested peaches, pears, apples, avocados, tomatoes, broccoli, and cantaloupe. The product is an impregnated film that is placed in shipping containers before or after the fresh produce has been packed into them.

Chemistry Assessment

HarvestHold Fresh is formulated as a slow-release generator containing 1-methylcyclopropene at a concentration of 0.0144%. This end-use product has a density of 1.43-1.63 g/mL. The required chemistry data for HarvestHold Fresh have been provided, reviewed and found to be acceptable.

Health Assessments

HarvestHold Fresh is of low acute dermal toxicity, is minimally irritating to the skin, and is not a dermal sensitizer.

Skin exposure is possible when handling HarvestHold Fresh. Inhalation exposure of 1-methylcyclopropene is also possible for individuals handling HarvestHold Fresh in a humid environment (85% relative humidity or higher). The label statements for HarvestHold Fresh are adequate to address the potential for exposure. Consequently, worker exposure is not expected to result in health risks of concern when the product is used according to label directions.

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 dietary risks from food and drinking water are not a concern given that HarvestHold Fresh is of low acute toxicity. A maximum residue limit (MRL) of 0.01 ppm for 1-methylcyclopropene on apples, pears, and tomatoes was previously established and applies to the use of HarvestHold Fresh on these crops. An MRL of 0.01 ppm for 1-methylcyclopropene on avocados, broccoli, peaches, and cantaloupe is required for the use of HarvestHold Fresh on these crops.

Value Assessment

HarvestHold Fresh is the first product expected to provide the fruit and vegetable industries a means of extending the marketability and useful life of certain commodities when treated in enclosed shipping boxes or containers.

Value information submitted for review consisted of seven studies conducted in the US and Mexico, precedent registrations in Canada and the US, and scientific rationales. Based on the weight of evidence, the registration of HarvestHold Fresh to delay the ripening and maintain firmness of labeled fresh fruits and vegetables is considered to have acceptable value.

Environmental Assessment

An environmental assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of HarvestHold Fresh.

References

| PMRA Document Number | Reference |
|-----------------------------|--|
| 3319554 | 2022, Value Summary 30JAN2022, DACO: 10.1,10.2.3.1 |
| 3319556 | 2022, HarvestHold Fresh Toxicology 29JAN2022, DACO: 4.1 |
| 3319557 | 2022, Exposure CS2020.docx, DACO: 5.2 |
| 3319558 | 2022, DACO 10.3 Adverse Effects, DACO: 10.3.1,10.3.2 |
| 3319559 | 2022, Efficacy Data to Support Registration of HarvestHold Fresh in California, DACO: 10.2.3.4 |
| 3319560 | 2022, Exhibit 1 - Avocado Raw Data, DACO: 10.2.3.4 |
| 3319561 | 2022, Exhibit 2 - Pear Raw Data, DACO: 10.2.3.4 |
| 3319562 | 2022, Exhibit 3 - Apple Raw Data, DACO: 10.2.3.4 |
| 3319563 | 2022, Exhibit 4 - Cantaloupe Raw Data, DACO: 10.2.3.4 |
| 3319564 | 2022, Exhibit 5 - Tomato Raw Data, DACO: 10.2.3.4 |
| 3319565 | 2022, Exhibit 6 - Broccoli Raw Data, DACO: 10.2.3.4 |
| 3319566 | 2022, Exhibit 7 - Peach Raw Data, DACO: 10.2.3.4 |
| 3319567 | 2022, HarvestHold Fresh DACO 3.5.4, 3.5.8, 3.5.11, 3.5.14, 3.5.15, DACO: 3.5.11,3.5.14,3.5.15,3.5.4,3.5.7,3.5.9 |
| 3319577 | 2021, Product Chemistry of CR206 (MRID 51577201), DACO: 3.2.1,3.2.2,3.3.1 CBI |
| 3319578 | 2021, Response to Acute Toxicity Data Requirements for End-Use Product: CR206, DACO: 4.6.1,4.6.3,4.6.4 |
| 3319579 | 2020, CR206: Dermal Sensitization Test in Guinea Pigs - Buehler Method, DACO: 4.6.6 |
| 3319580 | 2021, CR206: Acute Dermal Toxicity in Rats, DACO: 4.6.2 |
| 3337031 | 2021, CR206: Primary Skin Irritation in Rabbits, DACO: 4.6.5 |
| 3337032 | 2022, Description of Formulating Process, DACO: 3.2.2 CBI |
| 3386817 | 2022, PMRA_HarvestHold_Fresh_Category_B_Application_083122_Final, DACO: 10.2 CBI |
| 3401641 | 2020, CR201: Accelerated Storage Stability & Enforcement Analytical Method (A54006), DACO: 3.4.1,3.5.10,3.5.14 CBI |
| 3414165 | 2020, Accelerated Storage Stability, DACO: 3.5.10,3.5.14 CBI |
| 3421308 | 2019, CR202: Analysis of End-Use Product Residual Volatiles, DACO: 4.8 CBI |
| 3505732 | 2020, CR202: Determination of Worker Inhalation, DACO: 5.2 |
| 3505733 | 2023, HarvestHold Fresh 1-Methylcyclopropene Exposure Risk Supplement 14092023_Final, DACO: 5.2 |
| 3505734 | 2023, 1-MCP Quantitation in Broccoli_Canada_Final, DACO: 7.4.1 |
| 3545803 | 2022, 2022-0620_Deficiency Response_Cover Letter_3DEC2022, DACO: 3.3.1,3.4.1,3.5.10,3.5.14 |

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