Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.3, 3.8 Application

Application Number: 2021-1184
Application: B.2.1 (Product Chemistry - guarantee)
B.2.3 (Product Chemistry - identity of formulants)
B.2.4 (Product Chemistry - proportion of formulants)
B.3.3 (Product Labels - application number or frequency)
B.3.8 (Product Labels - re-entry interval)
Product: SmartFresh ProTabs
Registration Number: 30872
Active ingredients (a.i.): 1-methylcyclopropene (MEU)
PMRA Document Number: **2194425**

Purpose of Application

The purpose of this application was to register SmartFresh ProTabs for use on apples, pears, tomatoes and bananas to control post-harvest ethylene production during indoor storage. This use pattern falls within the currently registered use pattern for 1-methylcyclopropene (Registration number 27777). This active is registered in four precedent products from the same applicant: Smartfresh Technology (3.3% a.i.; Registration number 27778), EthylBloc Technology (0.14% a.i.; Registration number 28438), SmartFresh Technology for Tomatoes (3.3% a.i.; Registration number 28569) and SmartFresh SmartTabs (0.63% a.i.; Registration number 28781)**.**

Chemistry Assessment

SmartFresh ProTabs is formulated as tablets containing 1-methylcyclopropene at a nominal concentration of 2.0%. This end-use product has a density of 0.9 g/mL and pH of 8.4. The chemistry requirements for SmartFresh ProTabs have been completed.

Health Assessments

SmartFresh ProTabs is of low toxicity to rats via the oral (LD_{50} ♀ > 5000 mg/kg bw), dermal (LD_{50} >5000 mg/kg bw), and inhalation routes (LC_{50} >5.13 mg/L). It is minimally irritating to the eye and mildly irritating to the skin of rabbits. It is not a dermal sensitizer in mice.

Residue data for 1-methylcyclopropene were not submitted to support the registration of the new plant growth regulator SmartFresh ProTabs for use on apples, pears, bananas and tomatoes. The active ingredient 1-methylcyclopropene (1-MCP) is currently registered in Canada for post-harvest use on apples, pears, bananas and tomatoes at the same application rates and timing as indicated on the label for SmartFresh ProTabs. The new formulation is not expected to alter the

residues in crops treated with the end-use product. The registration of SmartFresh ProTabs for post-harvest use on apples, pears, bananas and tomatoes will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

SmartFresh ProTabs for use on apples, pears, tomatoes and bananas to control post-harvest ethylene production fits within the registered use pattern for 1-MCP. The potential exposure for mixers, loaders, applicators is not expected to exceed the current exposure to registered products. In addition the reduction of the re-entry interval from 30 minutes to 15 minutes is not expected to result in risks of concern.

Environmental Assessment

There are no environmental concerns associated with the new end-use product SmartFresh ProTabs. The new product uses similar rates and application frequencies as those currently registered in Canada. No further environmentally-related data are required under the current use pattern.

Value Assessment

One study was submitted in which it was determined that the rate of release of 1-methylcyclopropene (1-MCP) from SmartFresh ProTabs was comparable to that from other registered formulations, including SmartFresh Technology for Tomatoes, Ethylbloc Technology, and SmartFresh SmartTabs.

As the rate of release of 1-MCP from SmartFresh ProTabs within a particular volume was similar to that of other registered products containing 1-MCP and as the use rates (concentrations) for SmartFresh ProTabs are the same as those of other registered products on an active ingredient basis, the use pattern and efficacy claims for SmartFresh ProTabs were extrapolated from other registered precedent products, including SmartFresh Technology for Tomatoes, SmartFresh SmartTabs, and SmartFresh Technology.

It is anticipated that the use of "SmartFresh ProTabs" in accordance with the label will be just as effective in maintaining the quality of apples, pears, bananas and tomatoes as other registered products containing 1-MCP, in that internal ethylene production is reduced, thereby delaying fruit ripening and senescence. The two sizes of SmartFresh ProTabs (0.84 and 4.2 g), containing 2% 1-MCP, and the three sizes of SmartFresh ProPack release vessels that contain 200 ml (for the 0.84 g tablets), 1 litre or 4 litres (for the 4.2 g tablets) of activating solution, allow the user to tailor product quantity to narrow ranges of room volumes to ensure that the correct 1-MCP concentration is achieved.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the registration of SmartFresh ProTabs.

References

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