

Evaluation Report for Category B, Subcategory 3.2, 3.4, 3.12-S-N-EP Application

Application Number: 2005-1475
Application: Evaluation Report for Category B, Subcategory 3.2, 3.4, 3.12
Product: SmartFresh Technology for Tomatoes
Registration Number: 28569
Active ingredients (a.i.): 1-Methylcyclopropene - 3.3%
PMRA Document Number: 1381884

Background

The purpose of this submission is to register a new commercial plant growth regulator (PGR), SmartFresh Technology for Tomatoes, which contains the active ingredient 1-methylcyclopropene (1-MCP; Reg. No. 27777) at 3.3%. This submission is categorized as B.3.2, B.3.4 and B.3.12 (changes to application timing and method, new site/host). The proposed USC is 12 - Stored Food and Feed.

SmartFresh Technology for Tomatoes is a PGR end-use product to be used on tomato fruits. It helps maintain fruit firmness and delays colour development through its effect in delaying the rise in internal ethylene production and respiration that normally occur during ripening. It also lowers the decline of titratable acidity in tomatoes during storage. The product is a powder that, when mixed with water, releases the volatile active ingredient 1-MCP. A single application at a maximum rate of 500 ppb is recommended on the proposed label. The product is to be used within air tight treatment areas or rooms such as storage rooms. As stated on the label, the product must not be used outdoors or in non-enclosed areas.

The guarantee and formulation of this new EP are identical to the registered EP SmartFresh Technology (Reg. No. 27778). Both the active 1-MCP and SmartFresh Technology have temporary registration for post-harvest use on apples. The temporary status is due to outstanding data requirements regarding the efficacy of the product. The PMRA has established an MRL for 1-MCP of 0.01 ppm in apples. In the United States, the US EPA exempted the tolerance requirement for residues of 1-MCP in or on fruits and vegetables when used as a postharvest plant growth regulator, i.e., for the purpose of inhibiting the effects of ethylene (Federal Register: July 26, 2002).

Purpose of Application

To register a new commercial plant growth regulator, containing the registered active 1-methylcyclopropene (1-MCP), for use on tomatoes.

Chemistry Assessment

A chemistry assessment was not required, as SmartFresh Technology for Tomatoes is identical in guarantee and formulation to SmartFresh, a product currently registered for use in Canada on apples (Reg. No. 27778). A very slight change in the % w/w of the active is as a result of the new guarantee for the TGAI (Reg. No. 27777). This amendment to the TGAI is currently being assessed under submission 2006-3289.

Health Assessments

A toxicology assessment was not required as there was no change to the product formulation.

The proposed use fits within the registered use pattern of 1-methylcyclopropene. EthylBloc⁷ Technology is already registered for pot-harvest application to apples at a rate that is higher than the proposed rate for tomatoes. Therefore, exposure to mixer/loader/applicators or exposure to post-application handling of treated product should not be greater than that for apples.

To support the establishment of a domestic maximum residue limit (MRL) on tomatoes, residue data was considered and the postharvest use of 1-methylcyclopropene was deemed to be acceptable.

MRL recommendations

Based on the submitted and previously reviewed residue data, maximum residue limit (MRL) to cover residues of 1-MCP in/on tomatoes will be established at 0.01 ppm.

Residues of 1-MCP in processed commodities are covered under the established MRLs for the raw agricultural commodity (RACs).

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL ¹	Recommended MRL ²
			Min	Max			
Tomato	Postharvest treatment/ 0.5 ppm	n.a.*	ND	ND	--	none	0.01 ppm

MRL(s) currently established in Table II, Division 15 of the FDA&R

MRL(s) to be established in Table II, Division 15 of the FDA&R as a result of the current submission

* Preharvest intervals (PHIs) are not applicable (n.a.) to post harvest application uses.

Conclusion

Following the review of all available data, an MRL of 0.01 ppm for tomatoes will be established to cover total residues of 1-methylcyclopropene in tomatoes. Residues of 1-methylcyclopropene in tomatoes treated at the MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

An environmental assessment was not required because the guarantee and formulation of this new EP are identical to those already registered for the EP SmartFresh Technology (Reg. No. 27778). Also, the maximum application rate is lower than for SmartFresh Technology and the use site category and method of application are similar. Therefore, the use of the new EP is not expected to increase environmental exposure to 1-MCP as compared to the registered use.

Value Assessment

Efficacy data were submitted from 26 trials. Tomatoes were harvested and treated at various stages of development. All trials included an untreated check. The effect of product rate, temperature during treatment, exposure period, fruit maturity at exposure, and tomato variety on the efficacy of 1-MCP in: 1) maintaining fruit firmness, 2) delaying colour development, and 3) providing a lower decline in titratable acidity during storage, was evaluated. Not all variables were tested in each trial, and the effects of the treatment variables were not always reported for each label claim.

The use of 1-MCP (applied as Smartfresh or Ethylbloc) on tomatoes was effective in maintaining fruit firmness, delaying colour development, and slowing the decline in titratable acidity. An application rate of 500 ppb 1-MCP proved to be optimum in eight of the eleven trials that compared application rates. The results were more pronounced when 1-MCP was applied at earlier maturation stages (i.e., breaker and turning).

In two trials the effect of exposure period on the efficacy of 1-MCP was assessed. It was determined that a minimum of 6 hours was required for optimum efficacy of the 500 ppb application rate. The applicant has however proposed that under commercial conditions in large storage rooms, longer treatment duration is required to ensure adequate time release and distribution of 1-MCP throughout the room and packaging material to provide sufficient contact time with fruit. Consequently, a 12-hour exposure period recommended by the applicant for commercial application of Smartfresh was supported.

References

1055633	2004, Summary of SmartFresh (1-MCP) Efficacy in Tomatoes., Agro Fresh Inc., 082804, DACO: 10.1
1055634	Summary of Trials for SmartFresh For Tomatoes, and Trial Summary Table for SmartFresh for Tomatoes Application for Prolonging the Shelf Life of Tomatoes, Agro Fresh Inc., DACO: 10.2.3.1

1055635	2001, Efficacy of AgroFresh (1-MCP) in Tomatoes Influence of the Application Carrier (Water or Lauryl Sodium Sulphate), Agro Fresh Inc., 31700094 (T-094), DACO: 10.2.3.3
1055636	2001, Efficacy of AgroFresh in Tomatoes Two Different Maturation Stages, Agro Fresh Inc., 31700122, (T-122)., DACO: 10.2.3.3
1055637	2002, Efficacy of SmartFresh (1-MCP) in Tomatoes Fortaleza at Pink Stage. University of Chile, Agro Fresh Inc., 31701040 (T-040), DACO: 10.2.3.3
1055638	2002, Efficacy of SmartFresh (1-MCP) on Tomatoes R-593 Stored at 20°C, Agro Fresh Inc., 31701041 (T-041), DACO: 10.2.3.3
1055639	2002, Efficacy of SmartFresh (1-MCP) in Tomatoes Carmen Long-life, Agro Fresh Inc., 31701042, (T-042), DACO: 10.2.3.3
1055640	2002, 1-MCP Efficacy on Tomatoes Two Different Maturation Stages Stored Under 20°C, Agro Fresh Inc., 31701039, (T-072), DACO: 10.2.3.3
1055641	2003, Bola Tomatoes Variety Adelita Maturation Control with 1-MCP and Ethylene Treatment. Ciad-Culiacan., Agro Fresh Inc., 31701097, (T-097), DACO: 10.2.3.3
1055642	2003, Bola Tomato Variety Attention Ripening Control with SmartFresh and Ethylene Treatment. Ciad-Culiacan., Agro Fresh Inc., 31701098, (T-098)., DACO: 10.2.3.3
1055643	2003, Bola Tomatoes Variety Girona Ripening Control with SmartFresh and Ethylene Treatments. Ciad-Culiacan., Agro Fresh Inc., 31701099 (T-099), DACO: 10.2.3.3
1055644	2004, Postharvest Evaluations of 1-MCP for Tomatoes in California. UC Davis and AgroFresh Cooperative Research 2003., Agro Fresh Inc., (CAL 1, 2, 3A, 3B, 4, 5, 6, 7, 8, 9), DACO: 10.2.3.3
1055645	2003, Roma Tomatoes Variety Tequilla Ripening Control with SmartFresh and Ethylene Treatments. CIAD-Culiacan., Agro Fresh Inc., 31701100 (T-100), DACO: 10.2.3.3
1055646	2003, Roma Tomatoes Variety Marcia Ripening Control with SmartFresh and Ethylene Treatments. CIAD-Culiacan., Agro Fresh Inc., 31701101 (T-101), DACO: 10.2.3.3
1055647	2003, Roma Tomatoes Variety Xena Ripening Control with SmartFresh and Ethylene Treatments. CIAD-Culiacan., Agro Fresh Inc., 31701102 (T-102), DACO: 10.2.3.3

1055648	2003, Effect of Different Rates of SmartFresh on the Roma Tomato, Variety Tequila Ripening Process. CIAD-Culiacan., Agro Fresh Inc., 31701103 (T-103), DACO: 10.2.3.3
1055649	2005, 1-MCP Effect on Roma Variety Tequila Tomatoes-Length of Exposition Period. CIAD-Culiacan, Agro Fresh Inc., 31701113 (T-113), DACO: 10.2.3.3
1055650	Influence of 1-Methylcyclopropene and Ripening Stages on Vitamin C Content and Shelf Life of Cherry Tomato Fruits. Centro de Investigacion en Alimentacion y Desarrollo A.C. Unidad Culiacan, Agro Fresh Inc., DACO: 10.2.3.3
1055651	Mostofi, Y. et al., Effects of 1-Methylcyclopropene on Ripening of Greenhouse Tomatoes at Three Storage Temperatures, Agro Fresh Inc., Postharv. Bio. and Tech. 27:285-292., DACO: 10.2.3.3
1055652	Value Summary: SmartFresh for tomatoes., Agro Fresh Inc., DACO: 10.1
1055653	Adverse Effects Summary: SmartFresh Technology, Ago Fresh Inc., DACO: 10.3.1
1055654	Non-Safety-Adverse Effects: SmartFresh for Tomatoes, Agro Fresh Inc., DACO: 10.3.2
1055691	Description of Pest Problem., DACO: 10.2.2
1055766	Efficacy Summary: SmartFresh for Tomatoes, Agro Fresh Inc., DACO: 10.2.3.1
1068351	2004, Rationale for Not Conducting any Additional Residue Studies Beyond Those for Apples and Aocadoes in Support of EU Registrations on a Variety of Label Extensions., Rohm and Haas Company Report, AgroFresh 04R-005, MRID: N/S, DACO: 7.1, 7.2.1, 7.3, 7.4.1
OTHER	REG2004-07. "1-Methylcyclopropene". September 24 th 2004

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2007

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.