



Environmental
Protection Authority
Te Mana Rauhi Taiao

STAFF ADVICE

APP204020 – SmartFresh Inbox

July 2020

1. Executive Summary

- 1.1 SmartFresh Inbox is a sachet containing 0.14 g/kg 1-methylcyclopropene (1-MCP) as the active ingredient, in the form of a vapour releasing powder. The sachet is intended to be directly added to boxes and containers containing fruits. The sachet allows the release of 1-MCP vapour, which can extend the shelf-life of many fruits by inhibiting the effects of ethylene, to prevent or reduce premature senescence of fruits.
- 1.2 The hazard classification of SmartFresh Inbox determined by the EPA is: 9.1C.
- 1.3 With the full suite of controls in place, the risks associated with the use of SmartFresh Inbox can be adequately managed.

2. Application Context

Background

- 2.1 SmartFresh Inbox is a sachet containing 0.14 g/kg 1-MCP as the active ingredient, in the form of a vapour releasing powder. The sachet is intended to be directly added to boxes and containers containing fruits. The sachet allows the release of 1-MCP vapour, which can extend the shelf-life of many fruits by inhibiting the effects of ethylene, to prevent or reduce premature senescence of fruits.
- 2.2 The formulation of SmartFresh Inbox is considered confidential by the applicant.
- 2.3 The active ingredient, 1-MCP, is already present in various approved substances and in higher concentrations than in SmartFresh Inbox. These substances are also used as a post-harvest treatment for fruits.
- 2.4 This substance has previously been assessed via the section 26 Statutory Determination process with application number APP203079. This assessment determined the hazard classifications of SmartFresh Inbox and that a new approval is required under the HSNO Act 1996.

Active ingredient

- 2.5 To allow evaluation of SmartFresh Inbox, key aspects of 1-MCP regulation have been summarised below.

Regulatory status

Table 1: Active ingredient regulatory status

Active ingredient name	Regulatory status and history in New Zealand	International regulatory status and history (Australia, Canada, Europe, Japan, USA)
1-methylcyclopropene	Four existing approved substance containing 1-methylcyclopropene (HSR000788 "Smart Fresh",	Approved in Australia, Canada, Europe, Japan and USA

Active ingredient name	Regulatory status and history in New Zealand	International regulatory status and history (Australia, Canada, Europe, Japan, USA)
	HSR101204 "TruPick", HSR101322 "Floritech Prolong Growth Regulator", HSR101336 "AnsiP-G")	

Regulatory parameters of active ingredient(s)

Impurities and or restrictions on purity or composition

2.6 Impurity limits for 1-MCP have been identified by the European Union (EU), the Food and Agriculture Organization of the United Nations (FAO) and the Australian Pesticides and Veterinary Medicines Authority (APVMA). These are 1-chloro-2-methylpropene and 3-chloro-2-methylpropene.

Concentration and maximum application rate

- 2.7 The concentration of 1-MCP in SmartFresh Inbox (0.14 g/kg) is lower than other approved substances with a similar use pattern.
- 2.8 A maximum application rate has previously been set for 1-MCP in "TruPick" (APP202896, HSR101204), however no maximum application rates were set for "Floritech Prolong Growth Regulator" (APP203710, HSR101322) and "AnsiP-G" (APP203743, HSR101336).

Physical form and use pattern

- 2.9 SmartFresh Inbox is a vapour releasing powder packaged in a sachet.
- 2.10 The intended use of SmartFresh Inbox is as a post-harvest treatment for extending the shelf-life of many fruits. The use pattern is summarised in Table 2 and the full outline of intended uses, application methods and application rates are detailed in the GAP table, Table 3.

Table 2: Summary of use pattern for SmartFresh Inbox

Substance category	Wide dispersive use?	Home use?	Concentration	Application rate(s)
Other – control of produce ripening in storage	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	0.14 g/kg	See GAP table below

Table 3: GAP Table for SmartFresh Inbox (as provided by the applicant)

Crop and/or situation (a)	Use pattern (b)	Pests or group of pests controlled (c)	Mixture		Application				Application rate per treatment			Remarks (l)
			Type (d-f)	Conc of ai (g)	Method and kind (h-i)	Growth stage & season (j)	Number Min max (k)	Interval between applications – days (minimum)	kg ai/hL min max	water L/ha min max	kg ai/ha max	
Post-harvest fumigation within boxes of kiwifruit or apples	I	Post-harvest treatment of fruits for improved quality after shipping, storage or handling	Vapour releasing powder	0.14 g/kg	Fumigation within shipping boxes containing fruit	Immediately post-harvest	1	n/a	n/a	n/a	n/a	Min application rate is based on 1 x 0.625 g sachet in a box containing 9 kg fruit. Max application rate is based on 10 x 2.5 g sachet in a box containing 145.1 kg fruit.

a Where relevant, the use situation should be described (eg fumigation of soil)

b Outdoor or field use (F), glasshouse application (G) or indoor application (I).

c eg biting and sucking insects, soil borne insects, foliar fungi, weeds

d eg wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

e CropLife international, 2008. Technical Monograph no 2, 6th edition. Catalogue of pesticide formulation types and international coding system

f All abbreviations used must be explained

g g/kg or g/l or others



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- h Method, eg high volume spraying, low volume spraying, spreading, dusting, drench, aerial, etc
- i Kind, eg overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated. If spraying include droplet size spectrum
- j growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell (ISBN 3-8263-3152-4) , including where relevant, information on season at time of application
- k Indicate the minimum and maximum number of application possible under practical conditions of use
- l Remarks may include: Extent of use/economic importance/restrictions

3. Hazard Assessment

Hazard classification of SmartFresh Inbox

3.1 The hazard classification of SmartFresh Inbox was determined by the EPA in the frame of the section 26 application APP203079 (July 2018) and is: 9.1C. Table 4 shows the method used for classification and indicates the main component that contributes to each hazard classification.

Table 4: Hazard classification of SmartFresh Inbox

Hazard Class/Subclass	Mixture classification		Method of classification			Remarks
	Applicant's classification	EPA classification	Mixture data	Read across	Mixture rules ¹	
Class 1 Explosiveness	ND	NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Class 2, 3 & 4 Flammability	ND	NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Class 5 Oxidisers/Organic Peroxides	ND	NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.1 Metallic corrosiveness	ND	NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.1 Acute toxicity (oral)	ND	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LD ₅₀ > 5000 mg/kg bw (rat)
6.1 Acute toxicity (dermal)	ND	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LD ₅₀ > 5000 mg/kg bw (rat)
6.1 Acute toxicity (inhalation)	ND	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LC ₅₀ > 5.14 mg/kg bw (rat)
6.1 Aspiration hazard	ND	NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.3/8.2 Skin irritancy/corrosion	ND	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Not irritating (rabbit)
6.4/8.3 Eye irritancy/corrosion	ND	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Not irritating (rabbit)
6.5A Respiratory sensitisation	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
6.5B Contact sensitisation	ND	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Not sensitising (mouse)
6.6 Mutagenicity	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
6.7 Carcinogenicity	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
6.8 Reproductive/ developmental toxicity	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

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Hazard Class/Subclass	Mixture classification		Method of classification			Remarks
	Applicant's classification	EPA classification	Mixture data	Read across	Mixture rules ¹	
6.8 Reproductive/ developmental toxicity (via lactation)	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
6.9 Target organ systemic toxicity	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
9.1 Aquatic ecotoxicity	9.1C	9.1C	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	EC ₅₀ = 46 mg/L (<i>Pseudokirschneriella subcapitata</i>)
9.2 Soil ecotoxicity	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
9.3 Terrestrial vertebrate ecotoxicity	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
9.4 Terrestrial invertebrate ecotoxicity	ND	No	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

-: No information provided by the applicant

NA: Not Applicable. For instance, testing for a specific endpoint may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance e.g. highly volatile, highly reactive or unstable substances cannot be tested; mixing of the substance with water may cause danger of fire or explosion; or the radio-labelling of the substance required in certain studies may not be possible.

ND: Not Determined. Data were unavailable for one or more components.

No: Data are available for the formulation or for all components and classification is not triggered.

¹ Use of mixture rules may not adequately take into account interactions between different components in some circumstances and must be considered of lower reliability than data on the mixture itself.

² Klimisch, H-J., Andrear, M., & U. Tillmann, 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Reg. Toxicol. Pharmacol. 25, 1–5 (1997)

4. Risk Assessment

- 4.1 It is considered that there is potential for exposure to people and the environment during the import, manufacture and use phase of the lifecycle. Therefore, a qualitative risk assessment was undertaken to understand the likely exposures to the substance under the use conditions proposed by the applicant.
- 4.2 It is noted that other substances with a higher concentration of 1-MCP are already approved under the HSNO Act for the same use pattern as SmartFresh Inbox.
- 4.3 During the importation, manufacture, transportation, storage and disposal of this substance it is considered that the proposed controls and other legislative requirements will sufficiently mitigate risks to a negligible level.
- 4.4 This assessment takes into account the existing EPA Notices controls around packaging, identification and disposal of hazardous substances. In addition, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's Health and Safety at Work (Hazardous Substances) (HSW (HS)) requirements all have provisions for the safe management of hazardous substances.

Human health risk assessment

- 4.5 Exposure to SmartFresh Inbox could occur during the use of the substance when sachets containing the vapour releasing powder are placed inside a box containing fruit. In particular, the gaseous component, 1-MCP, is released during the use of the substance.
- 4.6 Based on the toxicity studies provided by the applicant and assessed by the EPA in the frame of the s26 formal determination APP203079, and based on the exposure scenario associated with the use pattern of SmartFresh Inbox, it is considered that risks to human health are **negligible**.
- 4.7 Risks during other phases of the lifecycle are mitigated by the prescribed controls.

Environmental risk assessment

- 4.8 SmartFresh Inbox is classified as harmful in the aquatic environment (9.1C). Due to the proposed use pattern, exposure to SmartFresh Inbox to the environment during the use stage of its lifecycle is expected to be very limited. The substance could reach high concentrations in the aquatic environment in the case of accidental spillage of the substance, however this risk is mitigated by the prescribed controls. Quantitative exposure modelling and an ecological risk assessment was not performed as environmental risks due to the proposed use pattern of this substance are deemed low.
- 4.9 It is considered that the risks to the environment arising from the ecotoxicity of SmartFresh Inbox will be mitigated to a negligible level by applying the prescribed controls to the substance, as well as an additional control that limits the substance to be used in enclosed boxes or containers for the purpose of preserving fruit.

Risk assessment conclusion

- 4.10 Risks during other phases of the lifecycle are also mitigated by the prescribed controls.
- 4.11 With the proposed controls in place, the residual risks of the use of SmartFresh Inbox are negligible.

5. Controls

Prescribed controls (EPA Notice controls)

- 5.1 The hazard classification of SmartFresh Inbox determines a set of prescribed controls specified by the EPA Notices. There are also requirements in the Health and Safety at Work (Hazardous Substance, HSW (HS)) Regulations under the HSW Act.
- 5.2 The prescribed controls set the baseline for how the substance should be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed of, transported, handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management.

Variations to prescribed controls

Exposure limits

- 5.3 No Tolerable Exposure Limit (TEL) has been set previously for the active ingredient in SmartFresh Inbox because it is considered that exposure to this substance is not likely to result in an appreciable toxic effect to people, provided conditions of use are followed.
- 5.4 No Environmental Exposure Limit (EEL) value has been set previously for the active ingredient in SmartFresh Inbox because it is considered that exposure to these substances is not likely to result in an appreciable toxic effect to the environment, provided conditions of use are followed.

Additional controls

Use

- 5.5 To ensure that the environmental exposure is limited, the substance can only be applied to enclosed boxes or containers with the purpose of preserving fruit.

Impurity limits

- 5.6 The following limit should be set for the toxicologically relevant impurity in 1-MCP based on the Food and Agriculture Organisation (FAO) specifications:

1-chloro-2-methylpropene: maximum 0.05%

3-chloro-2-methylpropene: maximum 0.05%

6. Conclusion

- 6.1 After taking into account the prescribed controls and any proposed additions to these controls, it was concluded that the residual level of risk of any potentially significant adverse effects is negligible.

