Renewal
Assessment Report

Cydia pomonella GV

Carpovirusine

Volume 3 – B.4 Further information

Rev. 0 – 16 October 2020

Rapporteur Member State: Germany

Co-Rapporteur Member State: The Netherlands

Version history

When	What
16 October 2020	First version submitted to EFSA

The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS.

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B Summary, evaluation and assessment of the data and information

B.4 Further information on the plant protection product

B.4.1 Packaging and compatibility of the preparation with proposed packaging materials

Only new data submitted in the Renewal process are summarised here since new packaging materials are used.

B.4.1.1 Packaging

Reference:
Anonymous (2009), Specifications of 0.5L PEHD bottle Agrochem, Arysta LifeScience S.A.S. (BVL no 3306360)
Anonymous (2006), Specifications of 1L PEHD bottle Agrochem, Arysta LifeScience S.A.S. (BVL no 3306361)
Anonymous (2005), Certificate of agreement of packaging type 1L, 6717, Arysta LifeScience S.A.S. (BVL no 3306362)
Anonymous (2008), Specifications of 5L PEHD bottle Agrochem, SPEC 5 AO-63 GB, Arysta LifeScience S.A.S. (BVL no 3306363)
Anonymous (2004), Certificate of agreement of packaging type 5L, 6434, Arysta LifeScience S.A.S. (BVL no 3306364)

The following containers are proposed for the product:

0.5 L bottle:	Material:	HDPE
	Colour:	White
	Capacity and size:	Capacity: 500 mL Volume to overflowing: 561 mL ± 15 mL Weight: 50 g ± 2 g External height: 187 mm External diameter: 69 mm
	Size of opening:	External diameter of the neck: 49.4 mm Internal diameter of the neck: 45.6 mm Neck height: 48.3 mm
	Type of closure:	Screw cap with standardized thread reference KS50, with an airtight disc which may be welded.
1 L bottle:	Material:	HDPE
	Colour:	White
	Capacity and size:	Capacity: 1000 mL Volume to overflowing: 1200 mL ± 25mL Weight: 100 g ± 3 g External height: 238 mm External diameter: 89 mm Minimum thickness of the walls: 0.8 mm
	Size of opening:	External diameter of the neck: 49.4 mm Internal diameter of the neck: 45.6 mm Neck height: 25.5 mm
	Type of closure:	Screw cap with standardized thread reference R100501 01, with an airtight disc which may be welded.
5 L canister:	Material:	HDPE

Colour:	-
Capacity and size:	Capacity: 5000 mL Volume to overflowing: 5740 mL Weight: 233 g External height: 305 mm ± 3 mm External width: 193 mm ± 2 mm x 142 mm ± 2 mm Minimum thickness of the walls: 0.6 mm
Size of opening:	External diameter of the neck: 63 mm
Type of closure:	Screw cap with standardized thread, with an airtight disc which may be welded.

B.4.1.2 Packaging suitability

Information about the packaging has been provided in the storage stability tests. No adverse effects were observed.

B.4.1.3 Resistance of packaging to contents

Information about the packaging has been provided in the storage stability tests. No adverse effects were observed.

B.4.2 Procedures for cleaning application equipment

Equipment cleaning procedure: Rinse each used container three times, and then pour the rinsed water into the tank sprayer. It is compulsory to send any empty containers to a recycling company.

Protective clothing cleaning procedure: Wash protective clothing with soap or washing powder and water, aside from other clothing.

B.4.2.1 Effectiveness of the cleaning procedures

Information on the effectiveness of the cleaning procedure are missing.

B.4.3 Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

B.4.3.1 Pre-harvest intervals, re-entry or withholding periods to minimise residues in crops, plants, plant products, treated areas or spaces

Pre-harvest interval (in days) for each relevant crop

Crop	**Application**				
	Formulation (type & content of a.s.)	**No.**	**Rate kg a.s./ha**	**Spray conc. kg a.s./hl**	**Proposed pre-harvest interval (days)**

Pome fruit (apple, pear, quince, nashi) Stone fruit (peach, apricot) Walnut	CARPOVIRUSINE SC formulation, 1×10^{13} GV/L	1	1×10^{13} GV/ha	The application rate of 1 L/ha corresponds to 0.1 L/hL in 1000 L water/ha or 0.7 L/ha LWA (leaf wall area)	F* The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.
Pome fruit (apple, pear, quince, nashi) Stone fruit (peach, apricot) Walnut	CARPOVIRUSINE SC formulation, 1×10^{13} GV/L	2	1×10^{13} GV/ha	The application rate of 1 L/ha corresponds to 0.1 L/hL in 1000 L water/ha or 0.7 L/ha LWA (leaf wall area)	F*

B.4.3.2 Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used

There are no specific conditions under which the preparation may or may not be used.

B.4.4 Recommended methods and precautions concerning: handling, storage, transport or fire

Reference:
Anonymous (2016), Material safety data sheet – I1136aa, Arysta LifeScience S.A.S. (BVL no 3306365)

B.4.4.1 Handling procedures for the storage

Precautions for safe handling:	Do not eat, drink or smoke when using. Wear appropriate protective clothes, adequate gloves (nitril), glasses or mask. Avoid all contact of skin, eyes or clothes with new or old product. Respect good hygienic body conditions and cleanliness of the working area. Wash hands abundantly after handling. Do not wash working clothes with household linen.
Conditions for safe storage, including any incompatibilities	Keep away from food, drink and animal feedingstuffs. Store in a well closed container, in a fresh and well ventilated place. To prevent fires and explosions: rags soaked with product, paper, or materials used to absorb spillage may cause fire. Avoid accumulation of these rags. Eliminate them safely immediately after using. The product must be kept frozen (-18°C) for long period storage (at least 2 years following manufacturing date). Thaw at least 1 day before the treatment at ambient temperature. The product can be frozen several times.

Out of the freezer, it can be kept in the refrigerator or cold room (+4°C) for maximum 8 months, or at room temperature for maximum 1 month (not exceeding 25°C)
Keep away from food, drink and animal feeding stuffs.

B.4.4.2 Transport

Not subjected to transport regulation.

B.4.4.3 Fire

Extinguishing media:	Suitable: Water spray, dry chemical powder Unsuitable: Water jet
Special hazards arising from the substance or mixture:	By thermal decomposition, possibility of formation of toxic gases (sulphur oxide, phosphorus oxide, nitrogen oxide, carbon oxide, chlorides).
Advice for fire-fighters:	Intervention personnel should wear mask and individual respiratory equipment. Retain water or extinguishing media and eliminate safely.

B.4.4.4 Protective clothing and equipment

General protective and hygienic measures:	When using refer in priority to information written on the label.
Respiratory protection:	Preferably wear a mask covering all face with filter appropriate to organic vapor, powder or aerosol. A.P. Type filters.
Hand protection:	Wear single-use gloves of good quality.
Eye protection:	Preferably wear a mask, a face screen or protective glasses.
Skin and body protection:	Wear appropriate protective clothes, covering all parts of the body.
Control of environment exposure:	Respect European and National Regulations in term of environment.

B.4.5 Measures in the case of an accident

Reference:
Anonymous (2016), Material safety data sheet – I1136aa, Arysta LifeScience S.A.S. (BVL no 3306366)

B.4.5.1 Containment of spillages

Personal precautions, protective equipment and emergency procedures	Wear protective adapted equipment and take back non protected people. Withdrawal combustion and ignition sources and block bringing in oxygen (ventilation).

Environment precautions:	Avoid sewage, surface water, ground water and soil contamination. Retain spilled liquids and collect them with sand or other absorbent inert material (sepiolite). Absorbent inert material stocks have to be sufficient to face reasonably predictable spillage. Keep sewers from potential spillage to minimize pollution hazards. Do not throw washing waters into sewers. Contact competent authorities when a situation cannot be controlled rapidly and efficiently. In the case of spillage into water, stop dispersion of the product with adequate barrier.
Methods and material for containment and cleaning up:	Collect contaminated products on the surface concerned, transfer to closed drums before sending in a specialized incineration treatment centre. Wash the contaminated surface with water and collect washing waters for treatment. Cover the contaminated zone using absorbent materials such as sand or sepiolite.

B.4.5.2 Decontamination of areas, vehicles and buildings

See B.4.5.1

B.4.5.3 Disposal of damaged packaging, absorbents and other materials

Product/packaging:	Disposal of important amounts must be made by duly authorized specialists. Incineration should be made in authorized and specialized plant. Eliminate the product and its packaging with care and in a responsible way. Do not throw near ponds, rivers, ditches or into sewers. Wash contaminated surfaces with water and collect washing waters for treatment. Make sure that local Regulations are respected.
Washing products:	Do not throw into sewer. Do not contaminate natural waters. Clean up application materials on the treated area and eliminate waters by spraying on one area.

B.4.5.4 Protection of emergency worker and residents, including bystanders

Use the recommended personal protective equipment.

B.4.5.5 First aid measures

General information:	Remove the affected person from the danger zone to a well-ventilated room or to fresh air, and protect from chilling. Do not administer anything by oral route and do not try to make vomit, call a treatment center for poisoning cases or a doctor. Take the label where possible.
After eye contact:	Rinse immediately and thoroughly with plenty of water during at least 10 to 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Seek medical advice if pain or red-

	ness persists.
After skin contact:	Remove contaminated clothing and thoroughly wash the affected parts of the body with soap and water.
After inhalation:	Immediately remove to fresh air. Call a doctor immediately.
After ingestion:	Call a doctor immediately and show the label. Do not induce vomiting.
Most important symptoms and effects, both acute and delayed:	No specific symptoms
Indication of any immediate medical attention and special treatment needed:	Treat symptomatically

B.4.6 Procedures for destruction or decontamination of the plant protection product and its packaging

New SDS (Anonymous, 2016, provided in Doc J for Arysta LifeScience S.A.S. as KMP 4.6/01)
Disposal considerations:

Waste treatment methods

Product/packaging	Disposal of important amounts must be made by duly authorized specialists. Incineration should be made in authorized and specialized plant. Eliminate the product and its packaging with care and in a responsible way. Do not throw near ponds, rivers, ditches or into sewers. Wash contaminated surfaces with water and collect washing waters for treatment. Make sure that local Regulations are respected.
Washing products	Do not throw into sewer. Do not contaminate natural waters. Clean up application materials on the treated area and eliminate waters by spraying on one area.

B.4.6.1 Controlled incineration

Incineration should be made in authorised and specialised plant.

B.4.6.2 Others

Controlled incineration in a specialised incineration treatment centre is the most suitable way of disposal.

B.4.7 References relied on

Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N* If Y => old data point
KMP 4.1	Anonymous	2009	SPECIFICATIONS OF 0.5L PEHD BOTTLE AGROCHEM Arysta LifeScience S.A.S., not stated PROMENS, France GLP/GEP: no Published: no 3306360	no	no	not protected	ALS	N
KMP 4.1	Anonymous	2006	SPECIFICATIONS OF 1L PEHD BOTTLE AGROCHEM Arysta LifeScience S.A.S., not stated Polimoon France GLP/GEP: no Published: no 3306361	no	no	not protected	ALS	N
KMP 4.1	Anonymous	2005	CERTIFICATE OF AGREEMENT OF PACKAGING TYPE 1L Arysta LifeScience S.A.S., 6717 BVT, Bureau de Vérifications Technique, France GLP/GEP: no Published: no 3306362	no	no	not protected	ALS	N
KMP 4.1	Anonymous	2008	SPECIFICATIONS OF 5L PEHD BOTTLE AGROCHEM Arysta LifeScience S.A.S., SPEC 5 AO-63 GB Chesapeake Plastics S.A.S., France GLP/GEP: no Published: no 3306363	no	no	not protected	ALS	N

Data point	**Author(s)**	**Year**	**Title** **Owner, Report No.** **Source (where different from owner)** **GLP or GEP status** **Published or not** **BVL registration number**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previously submitted Y/N*** **If Y => old data point**
KMP 4.1	Anonymous	2004	CERTIFICATE OF AGREEMENT OF PACKAGING TYPE 5L Arysta LifeScience S.A.S., 6434 BVT, Bureau de Vérifications Technique, France GLP/GEP: no Published: no 3306364	no	no	not protected	ALS	N
KMP 4.4	Anonymous	2016	Material safety data sheet – I1136aa Arysta LifeScience S.A.S., not stated Natural Plant Protection, Pau GLP/GEP: no Published: no 3306365	no	no	not protected	ALS	N
KMP 4.5	Anonymous	2016	Material safety data sheet – I1136aa Arysta LifeScience S.A.S., not stated Natural Plant Protection, Pau GLP/GEP: no Published: no 3306366	no	no	not protected	ALS	N