

# **Renewal Assessment Report**

***Cydia pomonella* GV**

**Virgo**

**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.*

## Table of contents

### **B Summary, evaluation and assessment of the data and information**

|            |   |          |
|------------|---|----------|
| <b>B.4</b> | <b>Further information on the plant protection product.....</b>   | <b>4</b> |
| B.4.1      | Packaging and compatibility of the preparation with proposed packaging materials .....  | 4        |
| B.4.1.1    | Packaging .....   | 4        |
| B.4.1.2    | Packaging suitability .....   | 4        |
| B.4.1.3    | Resistance of packaging to contents .....   | 4        |
| B.4.2      | Procedures for cleaning application equipment .....   | 4        |
| B.4.2.1    | Effectiveness of the cleaning procedures .....  | 5        |
| B.4.3      | Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment .....                        | 5        |
| B.4.3.1    | Pre-harvest intervals, re-entry or withholding periods to minimise residues in crops, plants, plant products, treated areas or spaces ..... | 5        |
| B.4.3.2    | Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used.....  | 5        |
| B.4.4      | Recommended methods and precautions concerning: handling, storage, transport or fire .....  | 5        |
| B.4.4.1    | Handling procedures for the storage .....   | 5        |
| B.4.4.2    | Transport .....   | 6        |
| B.4.4.3    | Fire .....  | 6        |
| B.4.4.4    | Protective clothing and equipment.....  | 6        |
| B.4.5      | Measures in the case of an accident .....   | 6        |
| B.4.5.1    | Containment of spillages.....   | 6        |
| B.4.5.2    | Decontamination of areas, vehicles and buildings.....   | 7        |
| B.4.5.3    | Disposal of damaged packaging, absorbents and other materials.....  | 7        |
| B.4.5.4    | Protection of emergency worker and residents, including bystanders.....   | 7        |
| B.4.5.5    | First aid measures .....  | 7        |
| B.4.6      | Procedures for destruction or decontamination of the plant protection product and its packaging .....                                       | 7        |
| B.4.6.1    | Controlled incineration .....   | 8        |
| B.4.6.2    | Others .....  | 8        |
| B.4.7      | References relied on.....   | 9        |

## **B.4 Further information on the plant protection product**

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

#### **B.4.1.1 Packaging**

##### **Information already presented in the DAR for Virgo:**

###### **Reference:**

Anonymous (1989), Description of packaging - Salconplast Disegno Nr. 229, Serbios srl (PHY2006-370)

VIRGO is packaged in 1 litre bottles fitted with a screw cap:

###### **1 litre bottle**

Bottle dimensions: 235 x 88.5 mm (height x diameter)

Opening size: 44.5 mm

Materials: High density polyethylene, coex. containers (EVOH or polyamide), sealed cans.

Type of closure: For polyethylene and coex: up to 1 litres, DIN cap tamper-evident or induction type, over 1 litres, DIN 63 cap tamper-evident or induction type; Sealed can: flex spout or similar.

#### **B.4.1.2 Packaging suitability**

##### **Information already presented in the DAR for Virgo:**

Taking into account the composition of the product and its physical properties, VIRGO is characterised as non-reactive and non-hazardous; no further investigations and tests were conducted. The chemically inert product does not require special stability or resistance properties of the packaging or the material used in packaging. In addition, there are no changes of the packaging after storage for 4 weeks at 40 °C and after 7 days at 0 °C.

#### **B.4.1.3 Resistance of packaging to contents**

For storage stability studies information on packing material is missing.

### **B.4.2 Procedures for cleaning application equipment**

##### **Information already presented in the DAR for Virgo:**

###### **Equipment cleaning procedure:**

Rinse application equipment thoroughly with water and spray over already treated area.

###### **Protective clothing cleaning procedure:**

Protective clothing shall be washed in the usual way.

#### **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)<br>Walnut | VIRGO<br>SC – formulation<br>2 × 1013 GV/L | 1   | $1.5 \times 10^{13}$<br>GV/ha | 0.441 × 1013<br>GV/hL  | Not authorised in DE                 |

##### **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: VIRGO, Serbios srl (BVL no 3306683)

##### **B.4.4.1 Handling procedures for the storage**

|   |  |
|---|--|
| Precaution for safe handling:                           | The usual precaution for handling chemicals should be followed. Wear personal protective equipment (PPE). Ventilation/extraction of the working place should be good. Recommendations to prevent explosions and fire: keep away from heat, do not smoke  |
| Safe storage requirements and possible incompatibility: | Storage: store the product in ventilated and fresh place, away from heat, sun and open sewerage. Requirements for warehouses and containers: keep the product in its original drum. Recommendations for mixed storage: Do not store in contact with food. Do not store in contact with oxidants. Further recommendations for storage: Protect from ice. Keep containers sealed. Keep in a dry place. |

#### **B.4.4.2 Transport**

Not subjected to transport regulation.

#### **B.4.4.3 Fire**

|  |  |
|--|--|
| Extinguishing media:                               | Recommended extinguishing media:<br>Carbon Dioxide, Dry powder. Large fires to be extinguished with water mist or alcohol resistant foam. Do not use direct jet of water.<br>Unsuitable extinguishing media:<br>Do not use jet of water. |
| Special exposure hazards to substance/preparation: | In case of fire Carbon Monoxide (CO) can be released. Other harmful substances can be released in case of special fire conditions.   |
| Warning to firefighters – Protective equipment:    | Do not inhale gas during explosion and fire. Use a self-contained breathing appliance. Wear integral protective suit.  |

#### **B.4.4.4 Protective clothing and equipment**

|   |  |
|---|--|
| General protective and hygienic measures: | Standard safety measures must be followed for chemicals handling.<br>Remove immediately contaminated clothing.<br>Wash hands before eating and after handling the product.<br>Avoid eye and skin contact |
| Respiratory protection:                   | Short and light exposure: wear mask. Long and heavy exposure: wear a self-contained breathing appliance.<br>Recommended filters for short use: P1 filter   |
| Hand protection:                          | Safety gloves made of plastic or rubber.<br>Glove materials: Choosing the right gloves depends not only on materials but also on quality that may vary following different manufacturers.                |
| Eye protection:                           | Wearing safety glasses is recommended when pouring product.  |
| Skin and body protection:                 | Safety overalls  |

#### **B.4.5 Measures in the case of an accident**

##### **Reference:**

Anonymous (2016), Material safety data sheet: VIRGO, Serbios srl (BVL no 3306684)

#### **B.4.5.1 Containment of spillages**

|  |   |
|--|---|
| Person-related precaution measures:                          | Keep people away from the release and stay on the downwind side.<br>Wear personal protective equipment.   |
| Environment precautions:                                     | Collect and purify contaminated water. If the product has flowed out in a watercourse, sewerage or contaminated soil and vegetation, please notify the competent Authority. |
| Methods and materials to control and decontaminate releases: | Collect liquid with absorbents (sands or inert materials), do not use sawdust and rags. Spill must be collected mechanically. Keep the place ventilated.                    |

#### **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:                | The product has to undergo special treatments according to the local regulations. |
| Contaminated packaging: | Disposal according to the local regulations.                                      |

#### **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:  | Instantly take off contaminated clothes.  |
| After eye contact:  | Rinse the eyes with water for several minutes making sure the eye-lids are well-open.   |
| After skin contact:   | Wash off immediately with water and neutral soap.   |
| After inhalation:   | Take the subject to a well aerated area and for good measure contact a doctor. If the subject has fainted take him outside making sure he is well adjusted on his side. |
| After ingestion:  | Rinse the mouth with water, do not induce vomiting. Seek medical attention.   |
| Most important symptoms and effects, both acute and delayed:                | No information available  |
| Indication of any immediate medical attention and special treatment needed: | Treat according to symptoms.  |

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

Specific measures in case of an accident are not required, since CpGV is a common baculovirus, and this family imposes no risk for environment or health. The standard protection measures for workers are adequately protecting their health in case CpGV containing material is released or spilled accidentally at the manufacturing facilities.

The contaminated area may be cleaned by sweeping up spill, and spillage can be safely disposed off.

In accordance with all applicable federal, state, and local environmental regulations no specific treatment after contact with CpGV contaminated material is required since this strain is not infective for humans. As a general precautionary measure in case of direct contact to this virus.

The applicant states the first aid instructions listed below.

In addition, persons who may want to seek medical attention upon accidental contact to CpGV, should inform the physician about the identity of the virus on species level, and may show the label of the packaging as supporting information.

First aid measures:

General advice: Not hazardous, personal hygiene

Skin contact: Rinse with water for personal hygiene

Eye contact: Rinse with water for personal hygiene

Ingestion: Provide symptomatic/supportive care as necessary

Inhalation: Provide symptomatic/ supportive care as necessary

Other information: None

Reference: Anonymous (2005), Material safety data sheet – VIRGO, SCM, (CHE2006-530)  
Document MIII

The disposal of product has to be performed in accordance with all applicable federal, state and local environmental regulations. Wastes resulting from the use of VIRGO, i.e. residual water dispersion, can be disposed of at an approved waste disposal facility. Remainder of spray can also be diluted and sprayed over already treated areas. The same procedure is applicable to larger quantities, which may occur very rarely only. Totally cleaned packages can be given to the regular waste disposal.

#### **B.4.6.1      Controlled incineration**

The product has to undergo special treatment according to the local regulations.

Packaging disposal: recommendation - disposal according to the local regulations.

#### **B.4.6.2      Others**

Not applicable.



## B.4.7 References relied on

| Data point | Author(s) | Year | Title<br>Owner, Report No.<br>Source (where different from owner)<br>GLP or GEP status<br>Published or not<br>BVL registration number                 | Vertebrate<br>study<br>Y/N | Data pro-<br>tection<br>claimed<br>Y/N | Justification if<br>data protection<br>is claimed | Owner | Previously submit-<br>ted Y/N*<br><br>If Y => old data<br>point |
|------------|-----------|------|---|----------------------------|--|---|-------|---|
| KMP 4.1    | Anonymous | 1989 | DESCRIPTION OF PACKAGING - SALCONPLAST<br>DISEGNO NR. 229<br>Sipcam S.p.A., not applicable<br>Supplier<br>GLP/GEP: no<br>Published: no<br>PHY2006-370 | no                         | no                                     | not protected                                     | SIP   | Y<br>KIIIM 4.1  |
| KMP 4.4/01 | Anonymous | 2016 | MATERIAL SAFETY DATA SHEET: VIRGO<br>Serbios Srl, Italy, not applicable<br>Serbios Srl, Italy<br>GLP/GEP: no<br>Published: no<br>3306683              | no                         | no                                     | not protected                                     | SER   | N   |
| KMP 4.5/01 | Anonymous | 2016 | MATERIAL SAFETY DATA SHEET: VIRGO<br>Serbios Srl, Italy, not applicable<br>Serbios Srl, Italy<br>GLP/GEP: no<br>Published: no<br>3306684              | no                         | no                                     | not protected                                     | SER   | N   |