

# **Renewal Assessment Report**

***Cydia pomonella* GV**

**Virgo**

**Volume 3 – B.2 Physical and chemical properties**

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**Rapporteur Member State: Germany**

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## Version history

| When            | What                            |
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*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.2 Physical and chemical properties of the plant protection product VIRGO

Formulation: Suspension concentrate (SC)

For the physical and chemical properties tests the following batch was used:

Batch number: VR321110 (2 x 10<sup>13</sup> GV/L)

The composition of the product VIRGO has been maintained from the original inclusion of CpGV. No new studies have been provided for physical and chemical properties of VIRGO. The studies evaluated in the DAR were reevaluated for renewal and are still considered acceptable by RMS if not stated otherwise.

Data gap:

- Storage stability test regarding the growth of contaminating micro-organism is missing.
- For storage stability studies information on packing material is missing.

| Study  | Guideline and method | Test material   | Results   | Conclusion/ Comment   | GLP | Reference               |
|--|----------------------|-----------------|---|---|-----|-------------------------|
| <b>B.2.1 Appearance (MP 2.1)</b>                       |                      |                 |   |   |     |                         |
| Appearance   | Visual assessment    | Batch: VR321110 | Colour: dark blue<br>Odour: characteristic<br>Physical state: liquid  | acceptable (DAR)  | N   | Fifi (2005) PHY2006-364 |
| <b>B.2.2 Storage stability and shelf life (MP 2.2)</b> |                      |                 |   |   |     |                         |
| Storage stability                                      | CIPAC MT 46.3        | Batch: VR321110 | 4 weeks at 40 °C. Information on packing material is missing. There are no significant changes in suspensibility, spontaneity of dispersion, wet sieve test and pourability after storage at 40 °C for 4 weeks. The LD <sub>50</sub> before and after storage were found to be 2874 (GV per mL diet) and 5060 (GV per mL diet) respectively.<br><br><b>RMS Renewal: Additional information from the study</b> | <b>DAR</b> acceptable<br><br><b>Renewal</b><br>The product is not biologically stable at storage for 4 weeks at | N   | Fifi (2005) PHY2006-364 |

| Study                                   | Guideline and method   | Test material   | Results   |  | Conclusion/<br>Comment                                | GLP | Reference               |
|---|--|-----------------|---|--|---|-----|-------------------------|
|   |  |                 | Before storage  | After storage  | 40 °C.<br>Information on packing material is missing. |     |                         |
|   | Visual assessment  |                 | Homogenous fluid, dark blue   | Homogenous fluid, dark blue  |   |     |                         |
|   | Biological activity (GV/ml of diet)                                |                 | LD <sub>50</sub> : 2874 GV/ml of diet<br>LD <sub>90</sub> : 9598 GV/ml of diet  | LD <sub>50</sub> : 5060 GV/ml of diet<br>LD <sub>90</sub> : 33962 GV/ml of diet  |   |     |                         |
|   | CIPAC MT 75.3 (pH)   |                 | 6.25 (1 % dispersion)   | 6.29 (1 % dispersion)  |   |     |                         |
|   | CIPAC MT 184 (Suspensibility) Determination by bioassay            |                 | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (0.5% in CIPAC water C)  | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (0.5% in CIPAC water C) |   |     |                         |
|   | CIPAC MT 160 (Spontaneity of dispersion) Determination by bioassay |                 | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (5% in CIPAC water C)  | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (5% in CIPAC water C)   |   |     |                         |
|   | CIPAC MT 185 (Wet sieve)   |                 | 0.01 % residue (75 µm sieve)  | 0.01 % residue (75 µm sieve)   |   |     |                         |
|   | CIPAC MT 148 (Pourability)   |                 | Residue : 0.34 %<br>Rinsed Residue 0.14 %   | Residue : 0.40 %<br>Rinsed Residue 0.25 %  |   |     |                         |
| Effect of low temperatures on stability | CIPAC MT 39.3  | Batch: VR321110 | 7 days at at 0 °C. Information on packing material is missing. The formulation shows no significant differences of physical properties before and after storage at 0 °C for 7 days. |  | <b>DAR</b> acceptable                                 | N   | Fifi (2005) PHY2006-364 |
|   |  |                 | <b>RMS Renewal: Additional information from the study</b>   |  |   |     |                         |
|   |  |                 | Before storage  | After storage  |   |     |                         |
|   | Visual assessment  |                 | Homogenous fluid, dark blue   | Homogenous fluid, dark blue  |   |     |                         |

| Study                                       | Guideline and method                                    | Test material   | Results  |  | Conclusion/<br>Comment   | GLP | Reference                  |
|---|---|-----------------|--|--|--|-----|----------------------------|
|   | CIPAC MT 75.3 (pH)                                      |                 | 6.25 (1 % dispersion)  | 6.37 (1 % dispersion)  |  |     |                            |
|   | CIPAC MT 184 (Suspensibility) Determination by bioassay |                 | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (0.5% in CIPAC water C)   | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (0.5% in CIPAC water C) |  |     |                            |
|   | CIPAC MT 185 (Wet sieve)                                |                 | 0.01 % residue (75 µm sieve)   | 0.01 % (75 µm sieve)   |  |     |                            |
| Shelf life                                  |   |                 | Shelf life less than 2 years (see below)   |  |  |     |                            |
| Shelf life in months (if less than 2 years) |   | Batch: VR321110 | 12 month at room temperature. Information on packing material is missing.<br>The formulation shows no significant differences of physical properties (appearance, pH, density, viscosity, persistent foaming, suspensibility, spontaneity of dispersion, wet sieve test, pourability) before and after storage at room temperature for 12 months. The LC <sub>50</sub> before and after storage were found to be 2874 (GV per mL diet), 2164 (GV per mL diet) and 2400 (GV per mL diet), respectively. |  | <b>DAR</b><br>acceptable, the formulation is stable for 12 months at room temperature.<br><br><b>Renewal</b><br>Growth of contaminating micro-organisms before and after storage is missing. Information on packing material is missing. | Y   | Fifi (2006) BVL no 3335406 |
|   |   |                 | <b>RMS Renewal: Additional information from the study</b>  |  |  |     |                            |
|   |   |                 | Before storage   | After storage  |  |     |                            |
|   | Visual assessment                                       |                 | Homogenous fluid, dark blue  | Homogenous fluid, dark blue  |  |     |                            |
|   | Biological activity (GV/ml of diet)                     |                 | LC <sub>50</sub> : 2874 GV/ml of diet  | LC <sub>50</sub> : 2400 GV/ml of diet  |  |     |                            |
|   | CIPAC MT 75.3 (pH)                                      |                 | 6.25 (1 % dispersion)  | 6.28 (1 % dispersion)  |  |     |                            |
|   | CIPAC MT  |                 | 1.240 g/mL   | 1.242 g/mL   |  |     |                            |

| Study  | Guideline and method   | Test material | Results  |  | Conclusion/<br>Comment             | GLP | Reference                          |
|--|--|---------------|--|--|------------------------------------|-----|------------------------------------|
|  | 3.3.2<br>(Density)   |               |  |  |                                    |     |                                    |
|  | OECD 114<br>(Viscosity)  |               | 22.30 cps at 20 °C (speed: 30 rpm)   | 22.85 cps at 20 °C (speed: 30 rpm)   |                                    |     |                                    |
|  | CIPAC MT 47.2 (Persistent foaming)                                 |               | 10 mL (0.5 % in CIPAC water D after 1 min)   | 7 mL (0.5 % in CIPAC water D after 1 min)  |                                    |     |                                    |
|  | CIPAC MT 184 (Suspensibility) Determination by bioassay            |               | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (0.5% in CIPAC water C) | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (0.5% in CIPAC water C) |                                    |     |                                    |
|  | CIPAC MT 160 (Spontaneity of dispersion) Determination by bioassay |               | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (5% in CIPAC water C)   | No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (0.5% in CIPAC water C) |                                    |     |                                    |
|  | CIPAC MT 185 (Wet sieve)   |               | 0.01 % residue (75 µm sieve)   | 0.04 % residue (75 µm sieve)   |                                    |     |                                    |
|  | CIPAC MT 148 (Pourability)   |               | Residue: 0.34 %<br>Rinsed residue: 0.14 %  | Residue: 0.28 %<br>Rinsed residue: 0.16 %  |                                    |     |                                    |
| <b>B.2.3 Explosivity and oxidizing properties (MP 2.3)</b> |  |               |  |  |                                    |     |                                    |
| Explosive properties                                       | Statement  |               | The formulation is water based and does not have explosive properties.   |  | <b>DAR</b> acceptable in this case | N   | Document M III, Section 1, Point 2 |
| Oxidising properties                                       | Statement  |               | The formulation is water based and does not have oxidising properties. The formulants used are without oxidative properties, as well.    |  | <b>DAR</b> acceptable in this case | N   | Document M III, Section 1, Point 2 |

| Study   | Guideline and method | Test material   | Results   | Conclusion/Comment                    | GLP | Reference                          |
|---|----------------------|-----------------|---|---------------------------------------|-----|------------------------------------|
| <b>B.2.4 Flash point and other indications of flammability or spontaneous ignition (MP 2.4)</b> |                      |                 |   |                                       |     |                                    |
| Flash point   | Statement            |                 | The formulation is water based and is not flammable at all.       | <b>DAR</b><br>acceptable in this case | N   | Document M III, Section 1, Point 2 |
| Flammability  |                      |                 | Not relevant as the preparation is a liquid formulation.          |                                       |     |                                    |
| Self-heating  | Statement            |                 | The formulation is water based and is not flammable at all.       | <b>DAR</b><br>acceptable in this case | N   | Document M III, Section 1, Point 2 |
| <b>B.2.5 Acidity, alkalinity and if necessary pH value (MP 2.5)</b>                             |                      |                 |   |                                       |     |                                    |
| Acidity or alkalinity and pH  |                      |                 | Not applicable  |                                       |     |                                    |
| pH of a 1 % aqueous dilution, emulsion or dispersion  | CIPAC MT 75.3        | Batch: VR321110 | pH of a 1 % dispersion: 6.25<br>pH without dilution: 5.93         | <b>DAR</b><br>acceptable              | N   | Fifi (2005) PHY2006-364            |
| <b>B.2.6 Viscosity and surface tension (MP 2.6)</b>   |                      |                 |   |                                       |     |                                    |
| Viscosity   |                      | Batch: VR321110 | 22.30 cps at 20 °C (speed: 30 rpm)                                | <b>DAR</b><br>acceptable              | N   | Fifi (2005) PHY2006-364            |
| Surface tension   | EC A.5               | Batch: VR310910 | 35.5 mN/m at 24.7 °C  | <b>DAR</b><br>acceptable              | Y   | Lucini (2005) PHY2006-369          |
| <b>B.2.7 Technical characteristics of the plant protection product (MP 2.7)</b>                 |                      |                 |   |                                       |     |                                    |
| <b>B.2.7.1 Wettability</b>  |                      |                 |   |                                       |     |                                    |
| Wettability   |                      |                 | Not relevant as the preparation is a suspension concentrate (SC). |                                       |     |                                    |



| Study  | Guideline and method                         | Test material   | Results  | Conclusion/Comment       | GLP | Reference                  |
|--|--|-----------------|--|--------------------------|-----|----------------------------|
| <b>B.2.7.2 Persistence foaming</b>   |  |                 |  |                          |     |                            |
| Persistence of foaming   | CIPAC MT 47.2                                | Batch: VR321110 | 0.5 % dispersion in CIPAC water D:<br>after 10 sec 10.5 mL<br>after 1 min 10 mL<br>after 3 min 7 mL<br>after 12 min 5 mL   | <b>DAR</b><br>acceptable | N   | Fifi (2005)<br>PHY2006-364 |
| <b>B.2.7.3 Suspensibility and suspension stability</b>   |  |                 |  |                          |     |                            |
| Suspensibility   | CIPAC MT 184<br>Determination<br>by bioassay | Batch: VR321110 | Homogenous distribution of the active ingredient.<br><br><b>RMS Renewal: Additional information from the study</b><br>No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (0.5% in CIPAC water C) | <b>DAR</b><br>acceptable | N   | Fifi (2005)<br>PHY2006-364 |
| Spontaneity of dispersion  | CIPAC MT 160<br>Determination<br>by bioassay | Batch: VR321110 | Homogenous distribution of the active ingredient.<br><br><b>RMS Renewal: Additional information from the study</b><br>No difference in biological activity between the 1/10 <sup>th</sup> and 9/10 <sup>th</sup> fraction was observed (5% in CIPAC water C)   | <b>DAR</b><br>acceptable | N   | Fifi (2005)<br>PHY2006-364 |
| <b>B.2.7.4 Dry sieve test and wet sieve test</b>   |  |                 |  |                          |     |                            |
| Dry sieve test   |  |                 | Not relevant as the preparation is a suspension concentrate (SC).  |                          |     |                            |
| Wet sieve test   | CIPAC MT 185                                 | Batch: VR321110 | < 0.01 % (75 µm)   | <b>DAR</b><br>acceptable | N   | Fifi (2005)<br>PHY2006-364 |
| <b>B.2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)</b> |  |                 |  |                          |     |                            |
| Particle size distribution   |  |                 | Not applicable   |                          |     |                            |

| Study  | Guideline and method | Test material   | Results  | Conclusion/Comment       | GLP | Reference                  |
|--|----------------------|-----------------|--|--------------------------|-----|----------------------------|
| Dust content   |                      |                 | Not relevant as the preparation is a suspension concentrate (SC).        |                          |     |                            |
| Attrition and friability   |                      |                 | Not relevant as the preparation is a suspension concentrate (SC).        |                          |     |                            |
| <b>B.2.7.6 Emulsifiability, re-emulsifiability, emulsion stability</b>   |                      |                 |  |                          |     |                            |
| Emulsifiability, emulsion stability and re-emulsifiability of formulation  |                      |                 | Not relevant as the preparation is a suspension concentrate (SC).        |                          |     |                            |
| Stability of dilute emulsions and of preparations which are emulsions  |                      |                 | Not relevant as the preparation is a suspension concentrate (SC).        |                          |     |                            |
| <b>B.2.7.7 Flowability, pourability (rinsability) and dustability</b>  |                      |                 |  |                          |     |                            |
| Flowability  |                      |                 | Not relevant as the preparation is a suspension concentrate (SC).        |                          |     |                            |
| Pourability  | CIPAC MT 148         | Batch: VR321110 | Residue: 0.34 %<br>Rinsed residue: 0.14 %                                | <b>DAR</b><br>acceptable | N   | Fifi (2005)<br>PHY2006-364 |
| Dustability  |                      |                 | Not relevant as the preparation is a suspension concentrate (SC).        |                          |     |                            |
| <b>B.2.8 Physical, chemical and biological compatibility with other products including plant protection products with which its use is to be authorized (MP 2.8)</b> |                      |                 |  |                          |     |                            |
| Physical and biological compatibility of tank mixtures   |                      |                 | Not applicable (tank mixtures with other pesticides are not recommended) |                          |     |                            |

| Study   | Guideline and method | Test material | Results                       | Conclusion/<br>Comment | GLP | Reference |
|---|----------------------|---------------|-------------------------------|------------------------|-----|-----------|
| <b>B.2.9 Adherence and distribution to seeds (MP 2.9)</b> |                      |               |                               |                        |     |           |
| Distribution (seed treatment)                             |                      |               | No seed dressing formulation. |                        |     |           |
| Adherence (seed treatment)                                |                      |               | No seed dressing formulation. |                        |     |           |

## B.2.10 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 protection<br>claimed<br>Y/N | Justification if<br>data protection<br>is claimed | Owner | Previously submitted Y/N*<br><br>If Y => old data point |
|------------|------------|------|--|----------------------------|-----------------------------------|---|-------|---|
| KMP 2.1    | Fifi, A.P. | 2005 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/LT, SC)<br>Sipcam S.p.A., BT014/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP/GEP: no<br>Published: no<br>PHY2006-364  | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.1  |
| KMP 2.2    | Fifi, A.P. | 2005 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/LT, SC)<br>Sipcam S.p.A., BT014/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP/GEP: no<br>Published: no<br>PHY2006-364  | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.2  |
| KMP 2.2    | Fifi, A.   | 2006 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/L, SC) AT ROOM TEMPERATURE FOR ONE YEAR – <del>INTERIM REPORT AFTER 6 MONTHS OF STORAGE</del><br>Sipcam S.p.A., BT015/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP: yes<br>Published: no<br>3335406 | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.2  |

| 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 protection<br>claimed<br>Y/N | Justification if<br>data protection<br>is claimed | Owner | Previously submitted Y/N*<br><br>If Y => old data<br>point |
|------------|------------|------|---|----------------------------|-----------------------------------|---|-------|--|
| KMP 2.5    | Fifi, A.P. | 2005 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/LT, SC)<br>Sipcam S.p.A., BT014/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP/GEP: no<br>Published: no<br>PHY2006-364 | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.3.3   |
| KMP 2.6    | Fifi, A.P. | 2005 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/LT, SC)<br>Sipcam S.p.A., BT014/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP/GEP: no<br>Published: no<br>PHY2006-364 | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.3.4   |
| KMP 2.6    | Lucini, L. | 2005 | SURFACE TENSION OF THE PRODUCT VIRGO<br>Sipcam S.p.A., 014/2005<br>Research Centre "E. Gagliardini", Salerano sul Lambro, Italy<br>GLP: yes<br>Published: no<br>PHY2006-369   | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.3.4   |

| 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 protection<br>claimed<br>Y/N | Justification if<br>data protection<br>is claimed | Owner | Previously submitted Y/N*<br><br>If Y => old data<br>point |
|------------|------------|------|---|----------------------------|-----------------------------------|---|-------|--|
| KMP 2.7.2  | Fifi, A.P. | 2005 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/LT, SC)<br>Sipcam S.p.A., BT014/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP/GEP: no<br>Published: no<br>PHY2006-364 | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.4.2   |
| KMP 2.7.3  | Fifi, A.P. | 2005 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/LT, SC)<br>Sipcam S.p.A., BT014/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP/GEP: no<br>Published: no<br>PHY2006-364 | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.4.3   |
| KMP 2.7.4  | Fifi, A.P. | 2005 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/LT, SC)<br>Sipcam S.p.A., BT014/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP/GEP: no<br>Published: no<br>PHY2006-364 | no                         | no                                | not protected                                     | SIP   | Y<br>KIIIM 2.4.4   |

| 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 protection<br>claimed<br>Y/N | Justification if<br>data protection<br>is claimed | Owner | Previously submitted Y/N*<br><br>If Y => old data<br>point |
|------------|------------|------|---|----------------------------|-----------------------------------|---|-------|--|
| KMP 2.7.7  | Fifi, A.P. | 2005 | PHYSICAL, CHEMICAL, TECHNICAL PROPERTIES AND SHELF LIFE OF VIRGO CYDIA POMONELLA GRANULOSIS VIRUS (2X10EXP13 GV/LT, SC)<br>Sipcam S.p.A., BT014/05<br>Biotechnologie BT Srl, Fraz. Pantalla, Italy<br>GLP/GEP: no<br>Published: no<br>PHY2006-364 | no                         | no                                | not protected                                     | SIP   | Y<br>KIHIM 2.4.7   |