Renewal
Assessment Report

Cydia pomonella GV

Carpovirusine

Volume 3 – B.6 Effects on human health

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.6 Effects on human health

Carpovirusine is one of four representative formulations for the renewal of approval of *Cydia pomonella* Granulovirus (CpGV). It contains a minimum of 1.1 x 10^{13} GV/L (Mexican isolate) and is formulated as a suspension concentrate.

A literature research was conducted by the notifier and the RMS (see Vol. 3 CA B.6). No study was identified to be relevant for this chapter.

Carpovirusine was a representative formulation for the first approval but the formulation has changed since then. Except for the buffer components added to yield a neutral pH the new recipe (code: ARY-04555333a-04) does not contain any substances classified for harmful effects on human health. Skin irritation as well as eye irritation was tested with the new formulation. In addition, the notifier refers to the studies for the old formulation (code: ARY-0453a-03) that were evaluated for the first approval. With respect to the low toxicity of the co-formulants the study results can be considered valid for the new formulation as well. No study data are available for acute inhalation toxicity. The calculation method based on information from the safety data sheets on the co-formulants did not indicate a need for classification.
A detailed comparison of the two formulations is given in Vol. 4. A summary of the toxicological evaluation for Carpovirusine is presented in Table B.6.1-1. The individual studies are described by the RMS in detail under B.6.1 to B.6.6.
Old studies from the first monograph were re-evaluated by the RMS according to current scientific criteria and guidelines.

Studies on the infectivity, toxicity and specificity of baculoviruses in general (Gröner, 1986, TOX2003-1179; Gröner et al., 1978, TOX2003-1154) are discussed in the toxicology section on CpGV.

Table B.6.1-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Carpovirusine

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat [1] (OECD 425)	> 5000 mg/kg bw	Yes	-	[redacted] 1991; TOX2006-2287
LD_{50} dermal, rat [1] (OECD 402)	> 2000 mg/kg bw	Yes	-	[redacted] 2005; TOX2006-2297
LC_{50} inhalation, rat	no study submitted; LD_{50} (CpGV) > 2 x 10^{13} granules of CpGV calculation method: no classification			
Skin irritation, rabbit [1] (OECD 404)	Non irritant	Yes	-	[redacted] 1991; TOX2006-2298
Skin irritation, rabbit [2] (OECD 404)	Non irritant	Yes	-	[redacted] 2015; ASB2015-6896
Eye irritation, rabbit [1] (OECD 405)	Non irritant	Yes	-	[redacted] 1991; TOX2006-2299

Eye irritation, rabbit [2] (OECD 405)	Non irritant	Yes	-	[redacted] 2015; ASB2015-6897
Skin sensitisation, guinea pig (M&K) [1] (OECD 406)	Sensitising	Yes	Skin Sens. 1B; H317	[redacted] 1991; TOX2006-2285

[1] test conducted with formulation ARY-0453a-03
[2] test conducted with formulation ARY-0453a-04

Regarding the study results Carpovirusine is considered to be of low toxicity by the oral, dermal and inhalation route. It does not meet the criteria for classification as irritant to the skin or eye but needs to be classified for skin sensitisation (Skin Sens 1B; H317).

B.6.1 Basic acute toxicity studies

B.6.1.1 Acute oral toxicity

Study evaluated in the original monograph of *Cydia pomonella* Granulovirus (December, 2007, ASB2010-10675) and re-evaluated by RMS in 2018:

Reference: OECD KIIIM1 7.1.1
Report: Acute Oral (Gavage) Toxicity Study (Subdivision F, No. 81-1) of CpGV Past in Rats, [redacted] 1991, Study No. BE-MT-99-91-04-AOR-01, TOX2006-2287
Guideline(s): EPA Guideline, Subdivision F, No. 81-1.
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	CpGV Past (Batch No. CX 91/1112)
Species	Rat, Sprague-Dawley
No. of animals (group size)	5 males and 5 females
Dose(s)	5000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	Aqua dest. (Ampuwa®)
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table B.6.1-1: Results of acute oral toxicity study in rats of CpGV Past

Dose [mg/kg bw]	**Toxicological results [1]**	**Duration of signs**	**Time of death**	**LD_{50} [mg/kg bw] (14 days)**
Male rats				
5000	0/2/5	day 1 – day 4	--	> 5000
Female rats				

5000	0/3/5	day 1 – day 3	--	> 5000

[1)] Number of animals which died/number of animals with clinical signs/number of animals used

Table B.6.1-2: Summary of findings of acute oral toxicity study in rats of CpGV Past

Mortality:	No mortality occurred.
Clinical signs:	Yes, after the application two males (until day 4) and 3 females (until day 3) showed depression, dyspnoea, hypokinesia, slow reflexes and hair bristling.
Body weight:	The body weight development was inconspicuous during the 14 days of investigation.
Macroscopic examination:	At necropsy the animals were found with little macroscopic alterations. Some little petechial bleedings with the tendency of healing (ulcera) could be found in the five animals (three of them without clinical signs). These alterations might be traced back to the application of CpGV Past. The Other findings in the kidneys and livers were a sign of well-bleeded animals and belonged to the normal range of biological variation.

Conclusion

Under the experimental conditions, the oral LD_{50} of CpGV Past (ARY-0453a-03) is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Conclusion by the RMS (2019):

The study is still considered to be acceptable.

B.6.1.2 Acute inhalation toxicity

No study was submitted for the first evaluation and for the renewal. The notifier refers to data for the active substance that show no toxicity or clinical signs up to a tested concentration of 2 x 10^{13} granules of CpGV. None of the co-formulants is classified for inhalation toxicity. Hence, according to the calculation method, no classification is required.

B.6.1.3 Acute percutaneous toxicity

Study evaluated in the original monograph of *Cydia Pomonella* Granulovirus (December, 2007, ASB2010-10675) and re-evaluated by RMS in 2018:

Reference: OECD KIIIM1 7.1.2
Report: Acute dermal toxicity in rats, [redacted], 2005, Study No. 30407 TAR, TOX2006-2297
Guideline(s): OECD 402 (1987), 92/69/EEC, B.3, (1992), US/EPA/OPPTS 870.1200 (1998)
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	CARPOVIRUSINE (Batch No. 1521/Cfr)
Species	Rat, Sprague-Dawley, Rj: SD (IOPS Han)
No. of animals (group size)	5 males und 5 females (nulliparous and non pregnant)
Dose(s)	5000 mg/kg bw

Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table B.6.1-3: Results of acute dermal toxicity study in rats of CARPOVIRUSINE

Dose [mg/kg bw]	Toxicological results [1)]	Duration of signs	Time of death	LD_{50} [mg/kg bw] (14 days)
Male rats				
5000	0/0/5	--	--	> 5000
Female rats				
5000	0/0/5	--	--	> 5000

[1)] Number of animals which died/number of animals with clinical signs/number of animals used

Table B.6.1-4: Summary of findings of acute dermal toxicity study in rats of CARPOVIRUSINE

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	The body weight gain was slightly reduced in 2 females out of 5, between days 1 and 8, and in 2 other females out of 5 between day 8 and day 15. In both cases, there was no relevant consequence at the end of the observation period.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD_{50} of CARPOVIRUSINE (ARY-0453a-03) is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Conclusion by the RMS (2019):

The study is still considered to be acceptable.

B.6.2 Additional acute toxicity studies

B.6.2.1 Skin irritation

B.6.2.1.1 Study 1

Study evaluated in the original monograph of *Cydia Pomonella* Granulovirus (December, 2007, ASB2010-10675) and re-evaluated by RMS in 2018:

Reference: OECD KIIIM1 7.1.4
Report Acute Dermal Irritation/Corrosion Study (Subdivision F, No. 81-5) of

CpGV Past in Rabbits, [redacted]., 1991, Study No. BE-MT-99-91-01-DIK-01, TOX2006-2298

Guideline(s): EPA Guideline, Subdivision F, No. 81-5.
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	CpGV Past (Batch No. CX 91/1112)
Species	Rabbit, New Zealand White
No. of animals (group size)	6 males
Initial test using one animal	No
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table B.6.2-1: Skin irritation of CpGV Past

Animal No.		Scores after treatment [1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	0 0	0 0	0 0	0 0	0.0 0.0	- -
2	Erythema Oedema	0 0	0 0	0 0	0-1 0	0.3 0.0	- -
3	Erythema Oedema	0 0	0 0	0 0	0-1 0	0.3 0.0	- -
4	Erythema Oedema	0 0	0 0	0 0	0 0	0.0 0.0	- -
5	Erythema Oedema	0 0	0 0	0 0	0 0	0.0 0.0	- -
6	Erythema Oedema	0 0	0 0	0 0	0 0	0.0 0.0	- -

[1)] scores in the range of 0 to 4

Clinical signs:	None

Conclusion

Under the experimental conditions, CpGV Past (ARY-0453a-03) is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Conclusion by the RMS (2019):

The study is still considered to be acceptable.

B.6.2.1.2 Study 2

Study submitted with the dossier for the Renewal Assessment Report:

Reference:	OECD KIIIM1 7.1.4
Report	ARY-0453a-04 = ALI1136aa - Assessment of acute dermal irritation [redacted], 2015, Study No. IC-OCDE-PH-14/0612, ASB2015-6896
Guideline(s):	OECD Guideline 404 (Acute Dermal Irritation / Corrosion) EU Method B.4 (Acute Toxicity: Dermal Irritation / Corrosion)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	ARY-0453a-04 (Batch No. 2567/Cfr)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 females
Initial test using one animal	Yes
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	7 days
Remarks	None

Results and discussions

Table B.6.2-2: Skin irritation of ARY-0453a-04

Animal No.		Scores after treatment*				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	0 0	2 0	2 0	1 0	1.67 0	7 -
2	Erythema Oedema	2 0	0 0	0 0	0 0	0 0	1 -
3	Erythema Oedema	2 1	0 0	0 0	0 0	0 0	1 1

* Scores in the range of 0 to 4

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, ARY-0453a-04 is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

B.6.2.2 Eye irritation

B.6.2.2.1 Study 1

Study evaluated in the original monograph of *Cydia Pomonella* Granulovirus (December, 2007, ASB2010-10675) and re-evaluated by RMS in 2018:

Reference: OECD KIIIM1 7.1.5
Report: Acute Eye Irritation/Infection Study (Subdivision M, No. 152A-14) of CpGV Past in Rabbits, [redacted], 1991, Study No. BE-MT-99-91-02-EIK-01, TOX2006-2299
Guideline(s): EPA Guideline, Subdivision M, No. 152A-14
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	CpGV Past (CX 91/112)
Species	Rabbit, New Zealand White
No. of animals (group size)	6 males
Initial test using one animal	No
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	Yes (24 hour after observation with aqua dest)
Vehicle/Dilution	None
Post exposure observation period	21 days
Remarks	None

Results and discussions

Table B.6.2-3: Eye irritation of CpGV Past

Animal No.		Scores after treatment [1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Corneal opacity	0	0	0	0	0.0	-
	Iritis	0	0	0	0	0.0	-
	Redness conjunctivae	1	1	0-1	0-1	1.0	4
	Chemosis conjunctivae	1	0-1	0	0	0.3	2
2	Corneal opacity	0	0	0	0	0.0	-
	Iritis	0	0	0	0	0.0	-
	Redness conjunctivae	1	1	1	0	0.7	3
	Chemosis conjunctivae	1	1	0	0	0.3	2
3	Corneal opacity	0	0	0	0	0.0	-
	Iritis	0	0	0	0	0.0	-
	Redness conjunctivae	1	2	1	1	1.3	13
	Chemosis conjunctivae	1	2	1	0	1.0	3
4	Corneal opacity	0	0	0	0	0.0	-
	Iritis	0	0	0	0	0.0	-
	Redness conjunctivae	1	2	2	1	1.7	13

	Chemosis conjunctivae	1	2	1	0	1.0	3
5	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 1 1	0 0 2 2	0 0 2 2	0 0 2 1-2	0.0 0.0 2.0 2.0	- - 16 13
6	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 1 1	0 0 1 1	0 0 2 1	0 0 1 1	0.0 0.0 1.3 1.0	- - 10 10

[1)] scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	None

Conclusion

Under the experimental conditions, CpGV Past (ARY-0453a-03) is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Conclusion by the RMS (2019):

The study is still considered to be acceptable.

B.6.2.2.2 Study 2

Study submitted with the dossier for the Renewal Assessment Report:

Reference: OECD KIIIM1 7.1.5

Report: ARY-0453a-04 = ALI1136aa - Assessment of acute eye irritation [redacted]., 2015, Study No. IO-OCDE-PH-14/0612, ASB2015-6897

Guideline(s): OECD Guideline 405 (Acute Eye Irritation / Corrosion)
EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	ARY-0453a-04 (Batch No. 2567/Cfr)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 females
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	3 days
Remarks	None

Results and discussions

Table B.6.2-4: Eye irritation of ARY-0453a-04

Animal No.		Scores after treatment*				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity	0	0	0	0	0	-
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	1	1	0	0	0.33	2
	Chemosis conjunctivae	0	0	0	0	0	-
2	Corneal opacity	0	0	0	0	0	-
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	2	1	0	0	0.33	2
	Chemosis conjunctivae	0	0	0	0	0	-
3	Corneal opacity	0	0	0	0	0	-
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	2	1	0	0	0.33	2
	Chemosis conjunctivae	0	0	0	0	0	-

* Scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, ARY-0453a-04 is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

B.6.2.3 Skin sensitisation

Study evaluated in the original monograph of *Cydia Pomonella* Granulovirus (December, 2007, ASB2010-10675) and re-evaluated by RMS in 2018:

Reference: OECD KIIIM1 7.1.6
Report: Acute Dermal Sensitization Study (Subdivision M, No. 152A-15) of CpGV Past in Guinea Pigs (Maximisation Test), [redacted], 1991, Study No. BE-MT-99-91-03-SIK-01, TOX2006-2285
Guideline(s): OECD 406
Deviations: Yes, reliability check is missing.
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	CpGV (CX 91/1112)
Species	Guinea pig, Hartley albino
No. of animals (group size)	Test substance group: 22 male guinea pigs Vehicle control goup: 22 male guinea pigs
Range finding:	Yes
Exposure (concentration(s), no. of applications)	Intradermal induction: 1 % Topical induction: Undiluted Challenge: 50 %
Vehicle	Aqua dest. (Ampuwa®)

Reliability check	None
Remarks	Reliability check is missing

Results and discussions

Table B.6.2-5: Skin sensitisation of CpGV Past

	24 hours	**48 hours**
	After challenge	
CpGV	13/22	0/22
Test Vehicle Control Group	3/22	0/22
Positive control	Not given	Not given

1) Number of animals with positive dermal response (scores of 1-3) /number of animals in dose group

Clinical signs:	None

Conclusion

Under the experimental conditions, CpGV Past (ARY-0453a-03) is a skin sensitiser. Thus, classification with Skin Sens. 1B; H317 is required according to Regulation (EC) No. 1272/2008.

Conclusion by the RMS (2019):

The notifier argues that the study is not reliable since severe skin reactions were observed on control and test animals after the topical application. The study authors explained this by exposure to FCA which initially caused erythema and crusts after intradermal injection. In the pre-test no skin reactions were observed for the highest tested concentration of 50% test item; the undiluted test item used for the topical induction was not tested in the pre-test. Since similar skin reactions after the inductions were detected for both the test group and the control group not treated with the test item this effect seems to be not related to the test material. The result for the test group after the challenge is clear despite the few positive reactions in the control group. Hence, the RMS considers the study as acceptable.
The notifier also argues that the OECD guidelines for sensitisation are not appropriate for microorganisms and viruses and that no positive results were yet published for CpGV or other viral species currently approved in the EU (Martel et al, 2010, ASB2011-9441; Hackl et al., 2015, ASB2015-4072). In addition, none of the co-formulants is classified for skin sensitisation. However, as already stated in the first evaluation of the study in the DAR from 2007, it is likely that proteins from the larval matrix material provoked the sensitisation. Therefore, the RMS is of the opinion to keep the classification with H317.

B.6.3 Data on exposure

Carpovirusine is used against codling moth and oriental fruit moth in pome fruit, stone fruit and walnut. The product can be applied up to ten times (with a minimum interval of 10 days) at a rate of 1 x 10^{13} GV/ha in 1000 L/ha water. Authorisation is sought for professional use and home and garden use.

No toxicological reference value has been derived for *Cydia Pomonella* Granulovirus since toxicity, pathogenicity or infectivity in mammals has not been observed for this virus. CpDG is naturally present in the environment. Hence, a risk for operators, workers, bystanders and residents is not expected when the product is used as intended.

Regarding the classification of the product for skin sensitisation PPE is required for the operator.

B.6.4 Available toxicological data relating to non-active substances

Toxicological information on the co-formulants is presented in Vol. 4. No additional classification is required.

B.6.5 Supplementary studies for combinations of plant protection products

Not necessary as no combinations of plant protection products are recommended.

B.6.6 Summary and evaluation of health effects

The toxicological studies on CpGV and the formulated product Carpovirusine reveal that except for a skin sensitising potential no health risks have to be anticipated for operators, workers, bystanders and residents.

Due to the potential for skin sensitisation operators will have to wear PPE, which will reduce exposure.

B.6.7 References relied on

Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	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 7	Gröner, A.	1986	SPECIFICITY AND SAFETY OF BACULOVIRUSES not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes BVL-3416321, BVL-3489330, TOX2003-1179	no	no	not protected	-	Y KIIIM 7
KMP 7.1.1	[redacted]	1991	ACUTE ORAL (GAVAGE) TOXICITY STUDY (SUBDIVISION F, NO 81-1) OF CPGV PAST IN RATS Arysta LifeScience S.A.S., BE-MT-99-91-04-AOR-01 [redacted] GLP/GEP: no Published: no BVL-3489317, TOX2006-2285	yes	no	not protected	ALS	Y KIIIM 7.1.1
KMP 7.1.2	Gröner, A., Huber, J., Krieg, A.	1978	INVESTIGATIONS WITH BACULOVIRUSES IN MAMMALS not available, not applicable Z Angew Zool, 65, 69-80 GLP/GEP: no Published: yes BVL-3489320, TOX2003-1154	no	no	not protected	-	Y KIIIM 7.1.3
KMP 7.1.3	[redacted]	2005	ACUTE DERMAL TOXICITY IN RATS Arysta LifeScience S.A.S., 30407 TAR [redacted] GLP: yes Published: no BVL-3485318, TOX2006-2297	yes	no	not protected	ALS	Y KIIIM 7.1.2

Data point	**Author(s)**	**Year**	**Title** **Owner, Report No.** **Source (where different from owner)** **GLP or GEP status** **Published or not**	**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 7.2.1	[redacted]	1991	ACUTE DERMAL IRRITATION/CORROSION STUDY (SUBDIVISION F 81-5) OF CPGV PAST IN RABBITS Arysta LifeScience S.A.S., BE-MT-99-91-01-DIK-01 [redacted] GLP: yes Published: no BVL-3489322, TOX2006-2298	yes	no	not protected	ALS	Y KIIIM 7.1.4
KMP 7.2.1/01	[redacted]	2015	ASSESSMENT OF ACUTE DERMAL IRRITATION Arysta LifeScience S.A.S., IC-OCDE-PH-14/0612 [redacted] GLP/GEP: no Published: no BVL-3306368, ASB2015-6896	yes	yes	New data for existing formulation, not previously submitted nor evaluated	ALS	N
KMP 7.2.2	[redacted]	1991	ACUTE EYE IRRITATION/INFECTION STUDY (SUBDIVISION M, NO. 152A-14) OF CPGV PAST IN RABBITS Arysta LifeScience S.A.S., BE-MT-99-91-02-EIK-01 [redacted] GLP: yes Published: no BVL-3489323, TOX2006-2299	yes	no	not protected	ALS	Y KIIIM 7.1.5
KMP 7.2.2/01	[redacted]	2015	ASSESSMENT OF ACUTE EYE IRRITATION Arysta LifeScience S.A.S., IO-OCDE-PH-14/0612 [redacted] GLP: yes Published: no BVL-3306369, ASB2015-6897	yes	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N

Data point	**Author(s)**	**Year**	**Title** **Owner, Report No.** **Source (where different from owner)** **GLP or GEP status** **Published or not**	**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 7.2.3	[redacted]	1991	ACUTE DERMAL SENSITIZATION STUDY (SUBDIVISION M, NO. 152A-15) OF CPGV PAST IN GUINEA PIGS (MAXIMIZATION TEST) Arysta LifeScience S.A.S., BE-MT-99-91-03-SIG-01 [redacted] GLP: yes Published: no BVL-3489324, TOX2006-2285	yes	no	not protected	ALS	Y KIIIM 7.1.6
KMP 7.2.3/01 1.additional submission	Hackl, E., Pacher-Zavisin, M., Sedman, L., Arthaber, S., Bernkopf, U., Brader, G., Gorfer, M., Mitter, B., Mitropoulou, A., Schmoll, M., van Hoesel, W., Wischnitzky, E., Sessitsch, A.	2015	LITERATURE SEARCH AND DATA COLLECTION ON RA FOR HUMAN HEALTH FOR MICROORGANISMS USED AS PLANT PROTECTION PRODUCTS REFERENCE not available, not stated EFSA Journal, 2015 EN-801, 173pp GLP/GEP: no Published: yes BVL-3306739, ASB2015-4072	no	no	not protected	-	N
KMP 7.2.3/02 1.additional submission	Martel, C., Nielsen, G.D., Mari, A., Licht, T.R., Poulsen, L.K.	2010	BIBLIOGRAPHIC REVIEW ON THE POTENTIAL OF MICROORGANISMS, MICROBIAL PRODUCTS AND ENZYMES TO INDUCE RESPIRATORY SENSITIZATION not available, not applicable EFSA Eur. Food Saf. Auth., CFP/EFSA/FEEDAP/2009, 1-95 GLP/GEP: no Published: yes BVL-3306740, ASB2011-9441	no	no	not protected	-	N