SVMA14-004

DOCUMENT M-CP, Section 9

FATE AND BEHAVIOUR IN THE ENVIRONMENT

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
21/02/2020	Additional data and information on potential for groundwater exposure, vapour pressure and transport via air in CP 9.2.4.1 and CP 9.3.1 highlighted in yellow	SVMA14-004 document M-CP 9

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CP 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

SVMA14-004 is a representative formulation supporting the application for the renewal process of the active substance Hydrolysed Proteins in Europe. Exposure assessment were conducted based on agricultural use pattern as summarized in the below table.

Table 9.1-1: Critical use pattern of the formulated product

Use No.	1	2
Crop	Citrus	Persimmon
Application rate (g as/ha)	450	450
Number of applications/minium interval	#	#
Crop growth stage (BBCH)	#	#
Application method	Foliar spray	Foliar spray

corresponds to the GAP of the insecticide used in mixture

CP 9.1 Fate and Behaviour in Soil

CP 9.1.1 Rate of degradation in soil

CP 9.1.1.1 Laboratory studies

Laboratory studies examining the rate of degradation in soil with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.1.2.1.

CP 9.1.1.2 Field studies

CP 9.1.1.2.1 Soil dissipation studies

Dissipation studies in soil with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.1.2.2.1.

CP 9.1.1.2.2 Soil accumulation studies

Soil accumulation studies with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.1.2.2.2.

CP 9.1.2 Mobility in soil

CP 9.1.2.1 Laboratory studies

Studies on mobility in soil with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.1.4.1.

CP 9.1.2.2 Lysimeter studies

Lysimeter studies with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.1.4.2.

CP 9.1.2.3 Field leaching studies

Field leaching studies with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.1.4.3.

CP 9.1.3 Estimation of concentrations in soil

Predicted environmental concentrations in soil (PEC_S)

Due to the nature of the hydrolysed proteins and their characteristics regarding the fate and behaviour in the environment, it is deemed very unlikely the existence of relevant residues resulting from applications as plant protection product in the soil.

However, as primary information, the initial PEC_{soil} from the use of SVMA14-004 in agriculture was estimated using a worse case calculation. Input parameters and PEC_{soil} calculations are presented in the table 9.1.3-1 and 9.1.3-2, respectively.

Table 9.1.3-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1	2
Crop	Citrus	Persimmon
Application rate (g as/ha)	450	450
Number of applications	#	#
Crop growth stage (BBCH)	#	#
Application method	Foliar spray	Foliar spray
Crop interception (%)	80	65

corresponds to the GAP of the insecticide used in mixture

It should be noted that the product SVMA14-004 is intended to be used in mixture with insecticides, which are usually applied when the first flights of the fruit flies are observed, that is to say when the fruits are already formed. Therefore, for risk assessment purposes, a crop interception of 65% was considered in persimmon as a worst case corresponding the full canopy in Apples (worse case among fruit trees).
Due to the nature of the active substance Hydrolysed Proteins, no DT_{50} is available and it can be considered that Hydrolysed Proteins are rapidly broken down into its constituent parts on contact with soil and/or crop material. Therefore, it is appropriate to calculate the PEC_S following a single application only, using the following equation:

$$PEC_S(mg/kg) = \frac{\text{Application rate (g/ha)} \times (1 - F)}{100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3)}$$

Table 9.1.3-2: PEC_{soil} calculations

Active substance	Application rate (g/ha)	Crop interception (%)	PECs (mg/kg)
Hydrolysed Proteins	450	65	0.210

CP 9.2 Fate and Behaviour in Water and Sediment

CP 9.2.1 Aerobic mineralisation in surface water

Laboratory studies examining the aerobic mineralisation in surface water with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.2.2.2.

CP 9.2.2 Water/sediment study

Water/sediment studies with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.2.2.3.

CP 9.2.3 Irradiated water/sediment study

Irradiated water/sediment studies with the formulation SVMA14-004 were not performed, since it is possible to extrapolate from data obtained with the active substance in accordance with the requirements addressed in Section M-CA 7.2.2.4.

CP 9.2.4 Estimation of concentrations in groundwater

CP 9.2.4.1 Calculation of concentrations in groundwater

Predicted environmental concentrations in groundwater (PEC_{GW})

Due to the nature of the hydrolysed proteins and their characteristics regarding the fate and behaviour in the environment, it is deemed very unlikely the existence of relevant residues resulting from applications as plant protection product in the soil and even more unlikely the existence of relevant residues reaching the groundwater.

In response to the RMS request, the applicant wants to highlight that hydrolysed proteins are naturally occurring compounds whose degradation leads to simple metabolites called amino acids that are abundant organic molecules in living cells.
Furthermore, amino acids from hydrolysis of animal proteins are used as fertilisers in Spain according to the Real Decreto 506/2013 (please refer to p 35, group 4.1 called “Aminoácidos”). In addition, hydrolysed

proteins of category 3 materials is part of the proposal of the future new EU regulation for fertilisers products (please refer to the proposal of December, the 4th, page 83)
Therefore, these compounds are considered to be of low risk for soil and water compartments and considering that they are widely used as fertilisers in Europe, the amount of hydrolysed proteins added to the environmental compartments linked to the application as plant protection product is considered to be negligible in comparison to the amounts derived from the use as fertilisers.

The applicant is of the opinion that this information provide an argumentation strong enough to justify the exemption of further calculations, considered as unnecessary from a scientific and rational point of view.

CP 9.2.4.2 Additional field tests

No data submitted, not required.

CP 9.2.5 Estimation of concentrations in surface water and sediment

Predicted environmental concentrations in surface water (PEC_{SW})

Due to the nature of the hydrolysed proteins and their characteristics regarding the fate and behaviour in the environment, it is deemed very unlikely the existence of relevant residues resulting from applications as plant protection product in the soil, surface water or sediment.
Furthermore, due to the characteristics of Hydrolysed proteins, no DT_{50} in water system nor Koc value in soil are available indicating that the use the recommended FOCUS Steps 1-2 model is not appropriate.
Therefore, due to the differing and unknown dissipation times of the constituents of Hydrolysed proteins in aquatic systems, it was only possible to calculate the maximum instantaneous PEC_{SW} value from entry through spray-drift that occurred immediately after a single application. The PEC_{SW} was calculated using the following equation:

$$PEC_{SW}\ (\mu g/L) = \frac{\%\ Drift_{90th\ \%ile} \times \text{Application rate}\ (g/ha)}{\text{Water depth (cm)} \times 10}$$

The resulting maximum instantaneous PEC_{SW} value is presented in the table 9.2.5-1.

Table 9.2.5-1: Maximum instantaneous PEC_{SW}

Active substance	Crop	Application rate (g/ha)	Water depth (cm)	Distance (m)	Drift* (%)	Max PEC_{sw} (µg/l)
Hydrolysed Proteins	Citrus/persimmon	450	30	3	15.7	23.550

* Based on Rautmann drift values

Potential of eutrophication in surface water
According to its composition, the active substance Hydrolyse Proteins contains a significant content of nitrogen, and therefore the eutrophication potential must be assessed.
As there is no current guideline to assess the eutrophication potential, the following approach have been considered here:

According to composition of the active substance Hydrolysed Proteins and the product SVMA14-004 (please refer to documents J), a maximum nitrogen content of 6% w/w in the product SVMA14-004 is considered as an appropriate worst case for the calculations. Therefore, the corresponding application rate would be 103.95 g of nitrogen/ha, considering a density of 1.155.
By using the formula above, the resulting maximum instantaneous PEC_{SW} value for nitrogen is equal to 5.440 µg/L.
This PECsw is far below the environmental water quality standard for NO3 of 50 mg/l (equivalent to 11.3 mg N/l), indicating that Hydrolysed Proteins do not have any eutrophication potential.

Predicted environmental concentrations in soil (PEC_{SED})

Due to the nature of the hydrolysed proteins and their characteristics regarding the fate and behaviour in the environment, it is deemed very unlikely the existence of relevant residues resulting from applications as plant protection product in the soil, surface water or sediment.
Therefore, no PEC_{SED} are required.

CP 9.3 Fate and Behaviour in Air

CP 9.3.1 Route and rate of degradation in air and transport via air

Study on degradation in air with the representative formulation SVMA14-004 was not performed, since it is possible to extrapolate from data obtained with the active substance. Data for the active substance are covered by information given in M-CA 7.3.

Predicted environmental concentrations from airborne transport

In response to the RMS request, the applicant wants to highlight that hydrolysed proteins are naturally occurring compounds whose degradation leads to simple metabolites called amino acids that are abundant organic molecules in living cells.
Furthermore, amino acids from hydrolysis of animal proteins are used as fertilisers in Spain according to the Real Decreto 506/2013 (please refer to p 35, group 4.1 called "Aminoácidos"). In addition, hydrolysed proteins of category 3 materials is part of the proposal of the future new EU regulation for fertilisers products (please refer to the proposal of December, the 4th, page 83)
Therefore, these compounds are considered to be of low risk for soil and water compartments and considering that they are widely used as fertilisers in Europe, the amount of hydrolysed proteins added to the environmental compartments linked to the application as plant protection product is considered to be negligible in comparison to the amounts derived from the use as fertilisers.

The applicant is of the opinion that these information provide an argumentation strong enough to justify the exemption of further studies, considered as unnecessary from a scientific and rational point of view.

However, for completeness purposes, the applicant provides new data for vapour pressure and half-life in air for amino acids.
The new data are drawn from open literature (*Clyde, Dale Dean and Svec, Harry, "Vapor pressures of some amino acids" (1963). Ames Laboratory Technical Reports. 51.*) and from the information available on PubChem, ChemIDplus, ChemicalBook, and on the basis of AOPWin estimations.

These new data on vapor pressure found in open literature are presented below:

Amino acids	Temperature (°k)	Pressure (mm Hg)
Glycine	453	0.0587
	457	0.0859
	466	0.159
	471	0.243
l-alanine	453	0.0759
	460	0.122
	465	0.203
	469	0.258
1-α-amino-n-butyric acid	449	0.0972
	452	0.1290
	455	0.163
	462	0.360
dl-norvaline	439	0.0404
	446	0.0664
	452	0.1010
	461	0.1930
1-valine	438	0.0395
	444	0.0682
	448	0.103
	452	0.150
	456	0.233
1-leucine	464	0.216
	454	0.0936
	452	0.0844
	446	0.0440
1-methionine	463	0.0384
	472	0.0622
	478	0.105
	485	0.163
1-phenylalanine	451	0.0252
	457	0.0463
	463	0.0758
	469	0.119
1-proline	442	0.0675
	448	0.107
	451	0.171
	457	0.210
	465	0.307
	467	0.299
dl-nor1eucine	435	0.0190
	449	0.0576
	461	0.129
	469	0.184
isoleucine	442	0.0763
	448	0.106
	453	0.172
	456	0.209
	461	0.262
cycloleucine	443	0.0666

	450	0.112
	456	0.166
	462	0.269
	468	0.351
α-amino isobutyric acid	462	0.451
	452	0.218
	441	0.108
	439	0.078

These new data on vapour pressure found on PubChem, ChemIDplus, and ChemicalBook are presented below:

Amino acids	**Vapour pressure (mm Hg at 25°C)**	**Source**	**Original source**
Aspartic acid	2.60×10^{-7}	PubChem	EPA (*US EPA; Estimation Program Interface (EPI) Suite. Ver.3.12. Nov 30, 2004. Available from, as of Oct 26, 2006*)
Glutamic acid	1.70×10^{-8}	PubChem	EPA DSSTox
Serine	4.02×10^{-8}	ChemIDplus	SRC
Histidine	5.99×10^{-9}	ChemIDplus	SRC
Glycine	1.28×10^{-7}	ChemicalBook	-
Threonine	1.32×10^{-8}	PubChem	EPA (*US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.0. Jan, 2009. Available from, as of Feb 22, 2010*)
Alanine	1.05×10^{-7}	PubChem	EPA (*US EPA; Estimation Program Interface (EPI) Suite. Ver.3.12. Nov 30, 2004. Available from, as of Sept 5, 2006*)
Arginine	2.10×10^{-6}	ChemicalBook	-
Cysteine	6.73×10^{-7}	PubChem	EPA (*US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.1. Nov, 2012. Available from, as of July 12, 2016*)
Valine	5.55×10^{-9}	PubChem	EPA (*US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.0. Jan, 2009. Available from, as of Feb 22, 2010*)
Methionine	8.14×10^{-8}	PubChem	EPA (*US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.0. Jan, 2009. Available from, as of Feb 19, 2010*)
Phenylalanine	1.76×10^{-8}	PubChem	EPA (*US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.0. Jan, 2009. Available from, as of Feb 16, 2010*)
Isoleucine	6.85×10^{-9}	PubChem	EPA (*US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.0. Jan, 2009. Available from, as of Feb 22, 2010*)
Leucine	1.34×10^{-8}	ChemIDplus	SRC
Lysine	5.28×10^{-9}	PubChem	HSDB (*Daubert, T.E., R.P. Danner. Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, D.C.: Taylor and Francis, 1989*)
Proline	3.77×10^{-9}	ChemIDplus	SRC

New data on half-life in air found on PubChem and based on AOPWin estimations are presented below:

Amino acids	**DT_{50}**	**Source**	**Original source**

	(Half-life in hours)		
Aspartic acid	10	PubChem	SRC
Glutamic acid	9.4	PubChem	SRC
Glycine	4.578	-	AOPWin v. 1.92a (Sept 2010) estimation (*EPISuite 4.1; US EPA*)
Alanine	11	PubChem	SRC
Arginine	0.946	-	AOPWin v. 1.92a (Sept 2010) estimation (*EPISuite 4.1; US EPA*)
Valine	1.6	PubChem	SRC
Phenylalanine	7.5	PubChem	SRC
Isoleucine	8.7	PubChem	SRC
Lysine	3.034	-	AOPWin v. 1.92a (Sept 2010) estimation (*EPISuite 4.1; US EPA*)

CP 9.4 Estimation of Concentrations for Other Routes of Exposure

Apart from the exposure routes already discussed in the chapters above, no further routes of exposure are expected to be of any relevance for SVMA14-004.