SVMA14-004

DOCUMENT M-CP, Section 7

TOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number

[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 7 TOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCTS

Introduction

SVMA14-004 is a representative formulation supporting the application for the renewal process of the active substance Hydrolysed Proteins in Europe. The critical use pattern is presented in the table below.

Table 7.1-1: 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 7.1 Acute Toxicity

No new data/study with the formulation SVMA14-004 was performed, since according to the composition of the product (please refer to Document J) it is possible to extrapolate from data obtained with the active substance.
No EU endpoints available for the active substance.

Due to its nature, origin and composition, Hydrolysed proteins are *per se* of low toxicological concern and therefore their use as plant protection product is considered to pose a low risk to humans and thus, no testing toxicity data are required.

Summary of acute toxicity

No data available, not required.

CP 7.1.1 Oral toxicity

No new data/study with the formulation SVMA14-004 was performed, since according to the composition of the product (please refer to Document J) it is possible to extrapolate from data obtained with the active substance. Please refer to point 7.1.

CP 7.1.2 Dermal toxicity

No new data/study with the formulation SVMA14-004 was performed, since according to the composition of the product (please refer to Document J) it is possible to extrapolate from data obtained with the active substance. Please refer to point 7.1.

CP 7.1.3 Inhalation toxicity

No new data/study with the formulation SVMA14-004 was performed, since according to the composition of the product (please refer to Document J) it is possible to extrapolate from data obtained with the active substance. Please refer to point 7.1.

CP 7.1.4 Skin irritation

No new data/study with the formulation SVMA14-004 was performed, since according to the composition of the product (please refer to Document J) it is possible to extrapolate from data obtained with the active substance. Please refer to point 7.1.

CP 7.1.5 Eye irritation

No new data/study with the formulation SVMA14-004 was performed, since according to the composition of the product (please refer to Document J) it is possible to extrapolate from data obtained with the active substance. Please refer to point 7.1.

CP 7.1.6 Skin sensitization

No new data/study with the formulation SVMA14-004 was performed, since according to the composition of the product (please refer to Document J) it is possible to extrapolate from data obtained with the active substance. Please refer to point 7.1.

CP 7.1.7 Supplementary studies on the plant protection product

No additional data/study, not required. Please refer to point 7.1.

CP 7.1.8 Supplementary studies for combinations of plant protection product

Not required. Due to its nature, origin and composition, Hydrolysed proteins are *per se* of low toxicological concern and therefore their use as plant protection product is considered to pose a low risk to humans. Furthermore, the mode of action of the Hydrolysed proteins is completely different from those of the insecticides that are intended to be used in combinations.

CP 7.2 Data on Exposure

No EU endpoints available for the active substance. No AOEL was defined due to the nature of the Hydrolysed proteins considered *per se* of low toxicological concern
Exposure assessments and risk evaluations for operators, workers, bystanders and residents are therefore not required.
The use of Hydrolysed proteins as plant protection product is considered to pose a low risk to operators, workers, bystanders and residents

CP 7.2.1 Operator exposure

No exposure assessment performed, not required. Please refer to point 7.2

CP 7.2.1.1 Estimation of operator exposure

No exposure assessment performed, not required. Please refer to point 7.2

CP 7.2.1.2 Measurement of operator exposure

Not relevant. The use of Hydrolysed proteins as plant protection product is considered to pose a low risk to operators.

CP 7.2.2 Bystander and resident exposure

No exposure assessment performed, not required. Please refer to point 7.2

CP 7.2.2.1 Estimation of bystander and resident exposure

No exposure assessment performed, not required. Please refer to point 7.2

CP 7.2.2.2 Measurement of bystander and resident exposure

Not relevant. The use of Hydrolysed proteins as plant protection product is considered to pose a low risk to bystanders and residents.

CP 7.2.3 Worker exposure

No exposure assessment performed, not required. Please refer to point 7.2

CP 7.2.3.1 Estimation of worker exposure

No exposure assessment performed, not required. Please refer to point 7.2

CP 7.2.3.2 Measurement of worker exposure

Not relevant. The use of Hydrolysed proteins as plant protection product is considered to pose a low risk to workers.

CP 7.3 Dermal Absorption

No data provided, not required. Please refer to point 7.2

CP 7.4 Available Toxicological Data Relating to Co-Formulants

CONFIDENTIAL information - data provided separately (Document J).