

# **SVMA14-004**

## **DOCUMENT L-CP, Section 5**

### **ANALYTICAL METHODS**

#### **Reference list**

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**Version history<sup>1</sup>**

<b>Date</b>	<b>Data points containing amendments or additions and brief description</b>	<b>Document identifier and version number</b>
21/02/2020	Additional reports highlighted in yellow	SVMA14-004 document L-CP 5

<sup>1</sup> 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

## Reference for SVMA14-004

It should be noted that grey script reflects studies already submitted and evaluated by Greece in 2017 in the context of the zonal registration of the product SVMA14-004 and for which data protection claims applied for at that time.

Black script reflects new studies not yet provided nor evaluated in Europe.

Data point	Author(s)	Year	Title Source (where different from company) Compagny, Report No GLP or GEP (where relevant), Published	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection	Owner
KCP 5.5.1/01	Ricau Hélène	2015	Validation of the analytical method for the determination of hydrolysed proteins in SVMA14-004 Defitraces, Report No. 15-919069-004 GLP Unpublished	N	Y	Study required to support representative formulation according to Regulation (EU) no. 284/2013	SERVALESA S.L.
KCP 5.5.1/02	Ricau Hélène	2017	Validation of the determination of hydrolysed proteins through the validation of the analytical methods for the determination of total nitrogen and of ammonium nitrogen in SVMA14-004 Defitraces, Report No. 16-919069-002 GLP Unpublished	N	Y	Study required to support representative formulation according to Regulation (EU) no. 284/2013	SERVALESA S.L.
KCP 5.1.1/03	Unknown	2019	Determination of amino acids by automated precolumn derivatization and High-Performance Liquid Chromatography Office S.L. Study summary Unpublished	N	Y	Study required to support representative formulation according to Regulation (EU) no. 284/2013	PROALAN S.A.

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Source (where different from company)</b> <b>Compagny, Report No</b> <b>GLP or GEP (where relevant),</b> <b>Published</b>	<b>Vertebrate</b> <b>study</b> <b>Y/N</b>	<b>Data</b> <b>Protection</b> <b>Claimed</b> <b>Y/N</b>	<b>Justification if data</b> <b>protection</b>	<b>Owner</b>
KCP 5.1.1/04	Unknown	2019	Schedule accreditation Office S.L. Official accreditaation by ENCA Unpublished	N	Y		PROALAN S.A.