

Hydrolysed Proteins

DOCUMENT L-CA, Section 2

PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Reference list

Version history¹

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

Reference for Hydrolysed Proteins

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
KCA 2.1 KCA 2.4 KCA 2.6	Montse Sala Vila	2018	OFICE S.L., Report No.125255 No GLP (derogation proposed) Unpublished	N	Y	Study required according to Regulation (EU) no. 283/2013	PROALAN S.A.
KCA 2.3	Demangel Benjamin	2015	Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on SVMA14-004 Defitraces, Report No. 15-919069-002 GLP Unpublished	N	Y	Study required according to Regulation (EU) no. 283/2013	SERVALESA S.L.
KCA 2.9 KCA 2.10 KCA 2.11 KCA 2.12 KCA 2.13	Demangel Benjamin	2015	Physico-chemical tests on SVMA14-004 Defitraces, Report No. 15-919069-001 Amendment R 1 (25 November 2016) GLP Unpublished	N	Y	Study required according to Regulation (EU) no. 283/2013	SERVALESA S.L.