

Hydrolysed Proteins

DOCUMENT L-CA, Section 8

ECOTOXICOLOGICAL STUDIES ON THE ACTIVE SUBSTANCE

Reference list

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
21/02/2020	Additional reports highlighted in yellow	Hydrolysed Proteins document L-CA 8

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

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 8.1.5/01 KCA 8.2.3/01	[REDACTED]	2004	Bioefficacy of parentally-administered Norlan L 25 in piglets [REDACTED] Report No. P-214 Unpublished	Y	Y	Study required to support the active substance according to Regulation (EU) no. 283/2013	PROALAN S.A.
KCA 8.1.5/02 KCA 8.2.3/02	P. Costa Batlori	2004	Supplementary report for the trial entitled “Bioefficacy of parentally- administered Norlan L25 in piglets” Institut de Recerca I Tecnologia Agroalimentaries (IRTA) Report No. 22268/0602 Unpublished	N	Y	Study required to support the active substance according to Regulation (EU) no. 283/2013	PROALAN S.A.
KCA 8.2.1	[REDACTED]	2019	ACUTE TOXICITY TEST ON AQUATIC ORGANISMS (<i>Danio rerio</i>) ON “NORLAN AMPL 201901001007” [REDACTED] Report No [REDACTED] GLP Unpublished	Y	Y	Study required to support the active substance according to Regulation (EU) no. 283/2013	PROALAN S.A.

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KCA 8.2.4.1	C. Giarei	2019	ACUTE TOXICITY ON AQUATIC ORGANISMS (<i>Daphnia sp.</i>) ON “NORLAN AMPL 201901001007” EUROFINs BIOLAB SRL Report No STULV19AA4423-1 GLP GLP Unpublished	N	Y	Study required to support the active substance according to Regulation (EU) no. 283/2013	PROALAN S.A.
KCA 8.2.6.1	C. Giarei	2019	FRESHWATER ALGA, GROWTH INHIBITION TEST ON “NORLAN AMPL 201901001007” EUROFINs BIOLAB SRL Report No STULV19AA4421-1 GLP GLP Unpublished	N	Y	Study required to support the active substance according to Regulation (EU) no. 283/2013	PROALAN S.A.