

# **SVMA14-004**

## **DOCUMENT L-CP, Section 10**

### **ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT**

#### **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 10

<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

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KCP 10/01	[REDACTED]	2004	Bioefficacy of parentally- administered Norlan L 25 in piglets [REDACTED] Report No. P-214 Unpublished	Y	Y	Study required to support the active substance according to Regulation (EU) no. 283/2013	PROALAN S.A.
KCP 10/02	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Norlan L25 in piglets” Institut de Recerca I Tecnologia Agroalimentaries (IRTA) Report No. 22268/0602 Unpublished	N	Y	Study required to support the active substance according to Regulation (EU) no. 283/2013	PROALAN S.A.

Data point	Author(s)	Year	Title Source (where different from company, Report No GLP or GEP (where relevant), Published	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection	Owner
KCP 10.2.1-01	[REDACTED]	2019	ACUTE TOXICITY TEST ON AQUATIC ORGANISMS ( <i>Danio rerio</i> ) ON “NORLAN AMPL 201901001007” [REDACTED] Report No [REDACTED] [REDACTED] GLP Unpublished	Y	Y	Study required to support the representative formulation according to Regulation (EU) no. 284/2013	PROALAN S.A.
KCP 10.2.1-02	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 ) ON “NORLAN AMPL 201901001007” EUROFINS BIOLAB SRL Report No STULV19AA4423-1 GLP GLP Unpublished	N	Y	Study required to support the representative formulation according to Regulation (EU) no. 284/2013	PROALAN S.A.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 Source (where different from company) Compagny, Report No GLP or GEP (where relevant), Published</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Claimed Y/N</b>	<b>Justification if data protection</b>	<b>Owner</b>
KCP 10.2.1-03	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 representative formulation according to Regulation (EU) no. 284/2013	PROALAN S.A.