

Hydrolysed Proteins

DOCUMENT F

Notification

(copy of application for renewal)

PROALAN S.A.

HYDROLYSED PROTEIN
Application for renewal

July 2017

**APPLICATION FOR THE RENEWAL OF
ACTIVE SUBSTANCE ACCORDING TO
REGULATION 844/2012**

Active substance: HYDROLYSED PROTEIN

APPLICANT: PROALAN S.A.

Date: July 2017

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1. INFORMATION CONCERNING THE APPLICATION

- 1.1 Name and address of the applicant including the name of the natural person responsible for the application and other obligations resulting from this Regulation:

Name of the applicant: PROALAN S.A.

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2. INFORMATION TO FACILITATE IDENTIFICATION

- 2.1 Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines manufactured by the producer

Common name (ISO): Hydrolysed protein

Common name: Animal tissue hydrolysate

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2.2 Chemical name (IUPAC and CAS nomenclature)

IUPAC No.: Not applicable

CAS No.: Not applicable

2.3 CAS, CIPAC and EC numbers (if available)

CAS No.: Not applicable

CIPAC No.: 901

EC No.: Not applicable

2.4 Empirical and structural formula, molecular mass

Empirical and structural formula: Not applicable

Molecular weight: Lower than 3.000 Daltons

2.5 Specification of purity of the active substance in g/kg which must be, whenever possible, identical or already accepted as equivalent to the one listed in the Annex to Commission Implementing Regulation (EU) No 540/2011

Specification of purity of active substance: 35 % w/w

2.6 Classification and labelling of the active substance in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council (health and environment effects)

The active substance Hydrolysed protein is not classified. No labelling is therefore required.

3. NEW INFORMATION**3.1 List of new information intended to be submitted together with a justification showing that they are considered necessary, in accordance with Article 15(2) of Regulation (EC) No 1107/2009**

The dossier supporting the approval renewal will include the following new studies:

- Chemical and physical characteristics of NORLAN AMPL, S Batch analysis
- An analytical method to analyse the active substance

3.2 List of new studies intended to be submitted on vertebrate animals

No new data.

3.3 Timetable of any new and ongoing studies

New and ongoing studies are expected to be completed by the end of February 2018.

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