Hydrolysed Proteins

DOCUMENT F

Notification

(copy of application for renewal)

SANITIZED VERSION

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

Active substance: HYDROLYSED PROTEIN

APPLICANT: PROALAN S.A.

SANITIZED VERSION

Date: July 2017

PROALAN S.A. HYDROLYSED PROTEIN July 2017
Application for renewal

PROALAN S.A. HYDROLYSED PROTEIN July 2017
Application for renewal

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.

Address: Cami de Can Ninou, 16
08403 - Granollers, Barcelona
SPAIN

1.1.1 (a) Telephone No.: [redacted]

(b) Email address: [redacted]

1.1.2 (a) Contact:
[redacted]

Contact person: [redacted]
Telephone No.: [redacted]
Email address: [redacted]

(b) Alternative contact:

PROALAN, S.A

Cami de Can Ninou, 16
08403 - Granollers, Barcelona
SPAIN
Contact person: [redacted]
Telephone No.: [redacted]
Email address: [redacted]

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

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, 5 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.