



To: MINISTRY OF RURAL DEVELOPMENT & FOOD
GENERAL DIRECTORATE OF PLANT PRODUCE
DIRECTORATE OF PLANT PRODUCE PROTECTION
DEPARTMENT OF PESTICIDES
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Attn. Mrs Pitarokoili
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Shimatari 08/08/2016

Subject: Application for the renewal of active substance Hydrolysed protein according to regulation 844/2012

According the Regulation EU 844/2012, an application for the renewal of an approval of an active substance shall be submitted to the rapporteur Member State and to the co-rapporteur Member State, no later than three years before the expiry of the approval. In the particular case of Hydrolysed proteins the deadline for the submission of the application is 31/08/2016.

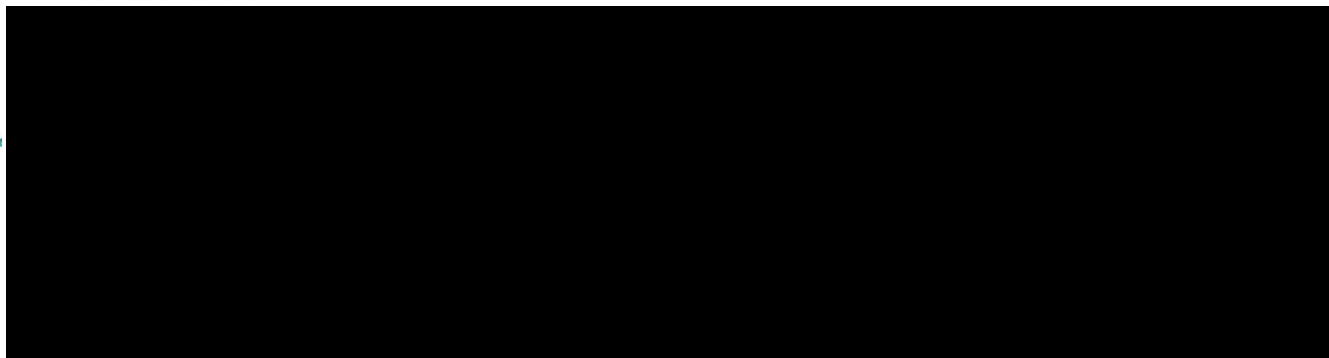
The three applicants supported the approval of Hydrolysed protein under reg. 1107/2009

- 1) BIOIBERICA
- 2) SICIT SPA
- 3) PHYTOPHYL – N.G. STAVRAKIS

Submit to you a joint application for renewal according to the model in annex of regulation EU 844/2012.

For any further information do not hesitate to contact us.

Yours sincerely
Dr. Nick Stavrakis





HYDROLYSED PROTEIN

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

August 2016

HYDROLYSED PROTEIN

APPLICATION FOR THE RENEWAL OF ACTIVE SUBSTANCE

1. INFORMATION CONCERNING THE APPLICANT

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 1: SICIT 2000 S.p.A

Address of the applicant:

Via Arzignano 80
36072 Chiampo (VI), Italy

1.1.1. (a) Telephone No.: +39 0444 45 946

(b) Email address: sicit2000@sicit2000.it

1.1.2. (a) Contact:

Oreste Odelli

Address: as above

Telephone: as above

Email: oodelli@sicit2000.it

(b) Alternative Contact: Fabio Agnolon

Address: as above

Telephone: as above

Email: fagnolon@sicit2000.it

Name of the applicant 2: BIOIBERICA, S.A.

Address of the applicant:

Headquarters:

Plaza Francesc Macià, 7, 8-B

08029 Barcelona

SPAIN

Facilities:

Ctra. N-II Km. 680.6. Polígono Industrial "Mas Puigvert"

08389 Palafolls (Barcelona)

SPAIN

Name of the person responsible for the application:

Ms. Laura Vicente

Nutritional Affairs Manager

Regulatory Affairs Department

1.1.1. (a) Telephone No.

Headquarters: +34 93 490 49 08

Facilities: +34 93 765 03 90

(b) Email address: lvicente@bioiberica.com

1.1.2. (a) Contact

Ms. Laura Vicente

Nutritional Affairs Manager

Regulatory Affairs Department

+34 93 765 03 90

lvicente@bioiberica.com

(b) Alternative Contact

Mr. Jaume Vinardell

Regulatory Affairs Director

+34 93 765 03 90

jvinardell@bioiberica.com

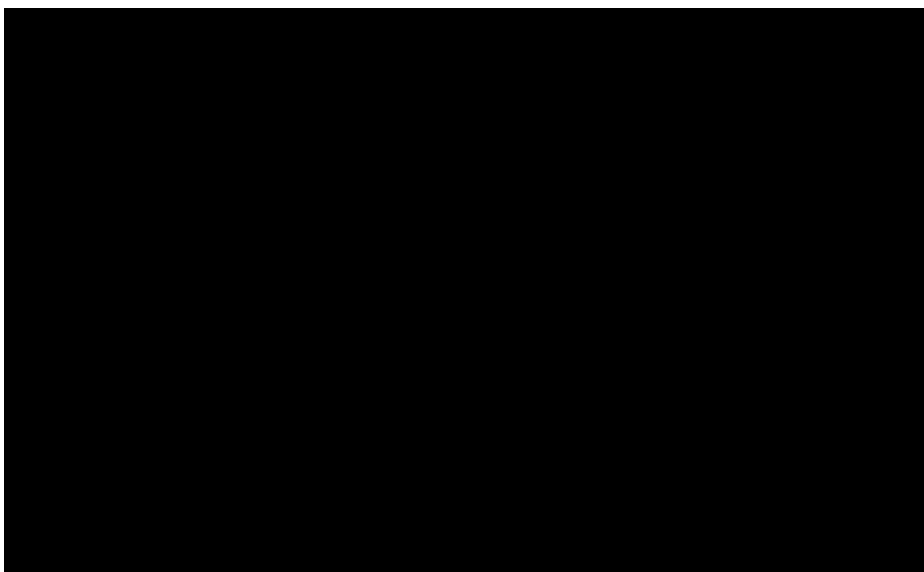
Name of the applicant 3: N. G. STAVRAKIS – PHYTOPHYL

Address of the applicant:

Office: Averof 16 10433-Athens Greece

Factory: Shimatari Viotia 32009 Greece

Name of the person responsible for the application:



2. INFORMATION TO FACILITATE IDENTIFICATION**APPLICANT 1: SICIT 2000 S.p.A**

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): Hydrolyzed protein

Common name: Collagen protein 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.: Not applicable.

EC No.: Not applicable.

2.4. EMPIRICAL AND STRUCTURAL FORMULA, MOLECULAR MASS

Empirical and structural formula: Not applicable

Molecular Mass: average molecular weight 2200 Dalton.

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: > 240 g/kg

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.

Not classified.

The label of the product Nutrel is enclosed below.

HYDROLYSED PROTEIN

APPLICATION FOR THE RENEWAL OF ACTIVE SUBSTANCE

NUTREL	
Protein bait for the preparation of insecticide baits against the olive fly, the citrus fly and the cherry fly	
Registration with the Ministry of Health no. 11502 of 22/11/2002	
Composition: PURE HYDROLYSED PROTEIN g. 30 (=378 g/L) Coformulants: as required for g. 100	SICIT 2000 SpA Via Arzignano, 80 36072 Chiampo (Vicenza) Tel. +39 0444 450946
Lot n. CONTENT: 0.250-0.5-1.5-10-20 litres	Distributed by:
CAUTION: P102 Keep out of reach of children. P262 Do not get in eyes, on skin, or on clothing. P270 Do not eat, drink or smoke when using this product. P309+P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician. P363 Wash contaminated clothing before reuse. P501 Dispose of contents/containers to local regulations. EUH210 Safety data sheet available on request. EUH401 To avoid risks to human health and the environment, comply with the instructions for use.	
SUPPLEMENTARY PRESCRIPTIONS: Keep the package tightly closed. Avoid contact with the skin, eyes and clothes. After handling and in the event of contamination, wash thoroughly with soap and water. Do not contaminate water with the product or its container.	
MEDICAL INFORMATION In the case of intoxication, call a doctor for the usual first aid, showing him the label of the product that has been mixed with NUTREL.	

INSTRUCTIONS FOR USE
Ground treatments: use NUTREL at the concentration of 1.2% mixed with the insecticide at the dose usually recommended. Carry out the treatment only on some branches, preferably those with greater exposure to the sun.
For application, use preferably pumps with a normal volume at high pressure in order to obtain perfect spraying of the insecticide mixture.
As insecticides, use products that have a persistence at least equal to that of NUTREL (e.g. Etalene 48.5 EC based on Fenitrothion).
For good results in the fight, 2-4 treatments are necessary, with an interval of about 20-30 days between them.
For a more accurate comparison, keep the appearance of adults in evidence, using appropriate trap bottles.

COMPATIBILITY

The product must be mixed with insecticides, following the precautionary warnings relative to the insecticide used.

Warning: If mixed with other formulated products, the longer period of deficiency must be respected. The precautions laid down for more toxic products must also be observed. If there are any cases of intoxication, inform the doctor of the mixture made.

FOR SUSPENSION OF THE TREATMENTS, FOLLOW THE INDICATIONS IN THE PACKAGING OF THE INSECTICIDE USED IN THE MIXTURE.

Attention: To be used exclusively in agriculture, at the times and for the uses allowed; any other use is dangerous. The person using the product is responsible for any damage that may derive from the improper use of the preparation. The respect of the aforementioned instructions is an essential condition to ensure the efficacy of the treatment and to avoid damage to plants, persons and animals.

NOT TO BE APPLIED BY AIRCRAFT
TO AVOID RISKS FOR HUMANS AND THE ENVIRONMENT, FOLLOW THE INSTRUCTIONS FOR USE
DO NOT CONTAMINATE OTHER CROPS, FOOD, DRINKS AND WATERWAYS
DO NOT OPERATE AGAINST THE WIND
DO NOT SELL LOOSE

DISPOSE OF THE PACKAGING ACCORDING TO THE CURRENT REGULATIONS
THE CONTAINER WHEN COMPLETELY EMPTY MUST NOT BE DISPERSED IN THE ENVIRONMENT

THE CONTAINER MAY NOT BE REUSED
DO NOT CONTAMINATE WATER WITH THE PRODUCT OR ITS CONTAINER

Label authorized by Executive Decree no. 11502 of 22/11/2002

HYDROLYSED PROTEIN

APPLICATION FOR THE RENEWAL OF ACTIVE SUBSTANCE

APPLICANT 2: BIOIBERICA, S.A.

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

HYDROLYSED PROTEIN, PROTEIN HYDROLYSATE

3.2. CHEMICAL NAME (IUPAC AND CAS NOMENCLATURE)

Not applicable.

3.3. CAS, CIPAC AND EC NUMBERS (IF AVAILABLE)

Not applicable.

3.4. EMPIRICAL AND STRUCTURAL FORMULA, MOLECULAR MASS

Empirical and structural formula: Not applicable

Molecular Mass: < 10,000 Da.

3.5. 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.

Organoleptic Characteristics:	Dark brown liquid with characteristic odour of solutions containing soluble organic matter.
pH:	4.5 – 6.0
Density:	1.18 – 1.24 g/ml
Hydrolysed protein:	≥ 35.0% w/w

3.6. 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

Spanish Ministry of Agriculture performed the classification of the product BIOCEBO (35% w/w hydrolysed protein), resulting a non-toxic product. Only the following sentences were recommended:

- ENVIRONMENTAL CLASSIFICATION:
None
- AND HAZARD PICTOGRAM:
None
- RISK PHRASES:
None
- SAFETY RECOMMENDATIONS:
EUH 401: To avoid risks to human health and the environment, comply with the instructions for use.
- RISK PREVENTION CONDITIONING. PACKAGING:
Rinse vigorously three times each package you use, pouring washing water to the tank (sprayer). As established in Royal Decree 1416/2001, of 14 December, on packaging of plant protection products, the label shall contain the following sentence: Give empty containers or packaging waste to the collection points established by collective systems of extended responsibility or directly to the point of sale where you would acquire if such containers are put on the market through a system of deposit, refund and return.

Labeling of the product BIOCEBO (35% w/w hydrolysed protein) is enclosed hereafter:

HYDROLYSED PROTEIN

APPLICATION FOR THE RENEWAL OF ACTIVE SUBSTANCE

<p>INFORMATION ON RISKS</p> <p>P102. Keep out of reach of children.</p> <p>P270. Do not eat, drink or smoke when using this product.</p> <p>P309 + P311: IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.</p> <p>H401: To avoid risks to human health and the environment, comply with the instructions for use.</p> <p>RECOMMENDATIONS FOR ACCIDENT OR POISONINGS:</p> <p>Poisoning can occur:</p> <p>Nausea, diarrhea.</p> <p>First Aid: Remove the person from the contaminated area. Remove contaminated clothing immediately. Flush eyes with plenty of water for at least 15 minutes. Wash skin with soap and water, without rubbing. Take the patient to hospital and whenever possible, take the container or label.</p> <p>DO NOT LEAVE THE AFFECTED PERSON ALONE AT ANY TIME: IN CASE OF POISONING CALL NATIONAL INSTITUTE OF TOXICOLOGY. Phone +34 91 562 04 20</p> <p>Medical advice: Symptomatic treatment.</p> <p>TO AVOID RISKS TO HUMAN HEALTH AND THE ENVIRONMENT, COMPLY WITH THE INSTRUCTIONS FOR USE.</p> <p>NO WATER CONTAMINATION WITH THE PRODUCT OR ITS PACKAGING. (Do not clean product application equipment near surface water / Avoid contamination through water disposal systems of farms or roads).</p> <p>ENVIRONMENTAL RISKS</p> <p>Mammals: A.</p> <p>Birds: A.</p> <p>Fish: A.</p>	<div></div> <p>FLY ATTRACTANT FOR MIXING WITH PESTICIDES</p> <p>Soluble Concentrate (SL)</p> <p>COMPOSITION:</p> <p>Hydrolysed proteins 30% w/v (300g/L)</p> <p>Registered in the Official Register of Plant Protection Products with the number 22.270/15 by BIOIBERICA, S.A.</p> <p>MANUFACTURED BY: BIOIBERICA, S.A.</p> <p>Read carefully label instructions before using the product</p> <p>USE RESERVED TO FARMERS AND PROFESSIONAL APPLICATORS.</p> <p>MANAGEMENT OF PACKAGING:</p> <p>Give empty containers or packaging waste to the collection points established by collective systems of extended responsibility or directly to the point of sale where you would acquire if such containers are put on the market through a system of deposit, refund and return</p> <p>Batch and date of manufacture:</p> <p>Bioiberica S.A.: Plaza Francesc Macià 7 - 08029 – Barcelona (Spain)</p> <div></div>	<p>CHARACTERISTICS</p> <p>BIOCEBO is a formulated hydrolysed protein product obtained by enzymatic hydrolysis. This product acts as an trophic attractant of adult Diptera (flies) and serves as base material for mixing with authorized preparing insecticidal baits.</p> <p>AUTHORIZED APPLICATIONS</p> <p>Citrus: Fly (<i>Ceratitis capitata</i>)</p> <p>Olive: Fly (<i>Bactrocera oleae</i> or <i>Dacus oleae</i>)</p> <p>Deciduous fruit: Fly (<i>Ceratitis capitata</i>)</p> <p>It acts as an attractant Ceratitis and Dacus adults. In the case of cherry fruit fly (<i>Rhagoletis cerasi</i>) acts as attractant of adults in certain conditions.</p> <p>DOSAGE AND USE</p> <p>Apply a dose of 1.5 % (1.5L for 100L of water). Mix evenly at the doses indicated with the insecticide and apply by land or aerial spraying of high, low and ultra-low volume and following the instructions for use of the plant protection product. It is essential for proper effectiveness, to make good coverage of all the fruits making sure these are well wet. Insecticides BIOCEBO might be mixed with must be authorized for these specific applications.</p> <p>SAFETY TERM</p> <p>Which corresponds to insecticide mixed.</p> <p>OBSERVATIONS</p> <p>BIOCEBO can be used in organic farming mixed with authorized for this type of agricultural insecticides. Always follow the directions on phytotoxicity, toxicity and safety of the insecticide mixture applied.</p> <p>COMPATIBILITY</p> <p>BIOCEBO is compatible with insecticides used usually to control the olive fruit fly and fruit fly, as dimethoate.</p> <p>WARNING</p> <p>The recommendations and information that we give are the result of wide and severe test. However, the use may involve numerous factors beyond our control (preparation of mixtures, application, weather, etc...) The company assures the composition, formulation and content. The user shall be liable for damage caused (lack of efficacy, toxicity in general, residues, etc.) for total or partial failure to observe the instructions on the label.</p>
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APPLICANT 3: N. G. STAVRAKIS – PHYTOPHYL

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 proteins

Common name: Beet Molasses Urea Hydrolysate

2.2. CHEMICAL NAME (IUPAC AND CAS NOMENCLATURE)

IUPAC.: Not applicable.

CAS.: Not applicable

2.3. CAS, CIPAC AND EC NUMBERS (IF AVAILABLE)

CAS No.: Not applicable.

CIPAC No.: Not applicable.

EC No.: Not applicable.

2.4. EMPIRICAL AND STRUCTURAL FORMULA, MOLECULAR MASS

Empirical and structural formula: Not applicable

Molecular Mass: Not applicable

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.

Minimum crude protein equivalent: 360g/kg (36%w/w) for hydrolysed proteins (beet molasses urea hydrolysate)

HYDROLYSED PROTEIN

APPLICATION FOR THE RENEWAL OF ACTIVE SUBSTANCE

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.

Two products containing hydrolysed protein as active substance (Beet Mollases Urea Hysrolysate) have registered in Greece by N.G. Stavrakis – Phytophyl under the tradename ENTOMELA 50SL & ENTOMELA 75SL according to 1107/2009. For any information needed, the two registration reports of these products are presented on CIRCA site by the Greek Ministry.

We are giving you below the classification and labeling for these two products in accordance with the EC Directive on dangerous preparations 1999/45/EC as amended and according to Regulation (EC) No 1272/2008

GHS Pictogram:

GHS07

Signal word:

WARNING

Hazard statements (because of the use with insecticides on bait application):

H317 May cause an allergic skin reaction (Cat. 1)

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary statements:

P102+405 Keep out of the reach of Children. Store locked up.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P302 + 352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention

P305+351+ 338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

P363 Wash contaminated clothing before reuse

P370+260 In case of fire: Do not breathe dust/fume/gas/mist/vapours/spray.

Other precautionary phrases because of the use with insecticide:

- Take all the necessary measures for the insecticide.
- Do not spray against the wind.
- After use wash with water and soap.
- Do not spill in watercourse or water irrigating systems.

HYDROLYSED PROTEIN

APPLICATION FOR THE RENEWAL OF ACTIVE SUBSTANCE

3. NEW INFORMATION

APPLICANT 1: SICIT 2000 S.p.A

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.

Chemical and physical characteristics of NUTREL, 5 Batch Analysis.

3.2. LIST OF NEW STUDIES INTENDED TO BE SUBMITTED ON VERTEBRATE ANIMALS

Not applicable.

3.3. TIMETABLE OF ANY NEW AND ONGOING STUDIES.

Not applicable.

APPLICANT 2: BIOIBERICA, S.A.

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.

No new information is intended to be submitted but in case any additional information or studies are considered to be necessary for renewal of the active substance, the three Applicants of this form are committed to submit it on time.

3.2. LIST OF NEW STUDIES INTENDED TO BE SUBMITTED ON VERTEBRATE ANIMALS

Not applicable.

3.3. TIMETABLE OF ANY NEW AND ONGOING STUDIES

Not applicable.

HYDROLYSED PROTEIN

APPLICATION FOR THE RENEWAL OF ACTIVE SUBSTANCE

APPLICANT 3: "PHYTOPHYL"-N.G. STAVRAKIS

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.

Two products containing hydrolysed protein as active substance (Beet Molasses Urea Hysrolysate) have registered in Greece by N.G. Stavrakis – Phytophyl under the tradename ENTOMELA 50SL & ENTOMELA 75SL according to 1107/2009.

In registration reports of them we have submitted data about:

1. Specifications and origin for the components.
2. Method for urea and hydrolysed protein content determination in beet molasses urea hydrolysates.
3. Physicochemical data (Persistent Foaming, Viscosity, Dilution stability, Surface tension Physical Compatibility).
4. Shelf life.
5. Storage stability.
6. Efficacy.

All these data have been presented on CIRCA site by the Greek Ministry and could be used as supporting data if needed about the renewal of the active substance

No new information is intended to be submitted about the active substance but in case any additional information or studies are considered to be necessary for renewal of the active substance, we are committed to submit it on time.

3.2. LIST OF NEW STUDIES INTENDED TO BE SUBMITTED ON VERTEBRATE ANIMALS

Not applicable.

3.3. TIMETABLE OF ANY NEW AND ONGOING STUDIES.





Not applicable.

HYDROLYSED PROTEIN

APPLICATION FOR THE RENEWAL OF ACTIVE SUBSTANCE

All three applicants confirm that the above information submitted included in the application is correct.

Date: August 5th 2016

 	 
SICIT 2000 S.p.A.	BIOIBERICA, S.A.
Oreste Odelli	Laura Vicente
General Manager	Nutritional Affairs Manager
	Regulatory Affairs

