Hydrolysed proteins

DOCUMENT N1

OVERALL CONCLUSIONS

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number

[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

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1 IDENTITY

1.1 Summary of identity

Applicant

Applicant	**Contact person:**	Samanta Yubero
	Address: BIOIBERICA, S.A.U. Ctra N-II, km. 680,6. Pol. Ind. "Mas Puigvert" 08389 - Palafolls (Barcelona, Spain) **Telephone:** 34 93 490 49 08 **Fax:** 34 93 490 97 11	

Producer

Manufacturer	Contact Person:	Samanta Yubero
	Address: BIOIBERICA, S.A.U. Ctra N-II, km. 680,6. Pol. Ind. "Mas Puigvert" 08389 - Palafolls (Barcelona, Spain) **Telephone:** 34 93 765 03 90 **Fax:** 34 93 765 01 02	

Molecular and Structural Formula, Molar Mass

Molecular Formula: Not applicable.
Structural Formula: Not applicable.
Molecular Mass: < 10.000 Da.

Method of manufacture, specifications, information regarding impurities, and analytical profile of batches information is considered as confidential information and provided in Document J.

2 PHYSICAL AND CHEMICAL PROPERTIES

2.1 Summary of physical and chemical properties of the active substance

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
Melting point, boiling point	Method: ASTM D56-2002	Hydrolysed proteins	102,3 ºC	Y	Analytical data In LCA-Section 2
Appearance (Physical state, colour)	Visual		Dark brown liquid		
Solubility in water	Method: PNT-M-432		Very soluble Residues after 5 h: 0,23 % Residues after 24 h: <0,05 %	Y	Analytical data In LCA-Section 2
Solubility in organic solvents			99,5 % soluble in acetone at 15ºC (100 g/l) 99,5 % soluble in acetonitrile at 15ºC (100 g/l) 99,8 % soluble in cyclohexane at 15ºC (100 g/l) 99,8 % soluble in dichloromethane at 15ºC (100 g/l) 84,2 % soluble in methane at 15ºC (100 g/l)	Y	See file "PhysChem analysis Hydrolysed proteins"
Partition co-efficient n-octanol/water	Method: PNT-M-474 (OECD 107)		-1,7657	Y	Analytical data In LCA-Section 2

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
Flash point	UNE-EN 2719/03		>80 º C	Y	18013479.01 In LCA-Section 2

EFSA review report stated that no data were available on physical and chemical properties for the active substance from BIOIBERICA, S.A.U. (Annex IIA, point 2). We provide new 5-batch analyses data and other laboratory analyses to fill the gap and complete the table above as much as possible. The complete laboratory reports are in the corresponding LC-A Section 2 folder.

BIOIBERICA, as one of the applicants for the inclusion of Hydrolysed proteins in Annex I prepared a complete report performed in an external laboratory, Laboratory Munuera (Murcia, Spain), about the Analytical Profile (5 batch analysis) of the product "TECHNICAL BIOCEBO", which is composed only by hydrolysed proteins (≥ 35.0 % w/w).
This information was not provided when submitting the application for the inclusion of the active substance.

See analytical data of 5 batches of hydrolysed proteins.

Parameter	**Batch 12/0026**	**Batch 12/0027**	**Batch 23/0028**	**Batch 23/0029**	**Batch 23/0030**
Organoleptic characteristics	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
Direct pH	4.48	4.55	4.56	4.59	5.12
Density	1.22 g/ml	1.22 g/ml	1.23 g/ml	1.22 g/ml	1.21 g/ml
Hydrolysed protein content	40.47 % w/w	42.60 % w/w	39.60 % w/w	41.84 % w/w	44.00 % w/w

The complete report is located in the J-Hydr.protein directory.

2.2 Summary of physical and chemical properties of the plant protection product

GLP-certified laboratories have performed all tests using batch Batch 12/0001, containing 30 g/l active substance ***(12-3638-01, 12-3638-03)***

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
Appearance	Not applicable, visual	Hydrolysed proteins 300 g/l SL formulation	Soluble concentrate (Dark brown liquid)		12-3638-01
Explosive and oxidising properties	EEC A.14 and EEC A.17	Hydrolysed proteins 300 g/l SL formulation	Not explosive Not applicable		
Flammability and self-heating	Not applicable	Hydrolysed proteins 300 g/l SL formulation	Not flammable Not a solid or gas		
Acidity/alkalinity and pH value	CIPAC MT 75.3	Hydrolysed proteins 300 g/l SL formulation	pH = 5.01	Y	12-3638-01
Viscosity and surface tension	Not applicable CEE A.5	Hydrolysed proteins 300 g/l SL formulation	Not applicable 36.5 nM/m	N Y	12-3638-01
Relative density and bulk density	CIPAC MT 3.3.2. Not applicable	Hydrolysed proteins 300 g/l SL formulation	1.14 g/ml (20 ºC) Not a powder or granule	Y	12-3638-01

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
Storage Stability and shelf-life: effects of temperature on technical characteristics of the plant protection product	Storage Stability after 14 days at 54º C CIPAC MT 46.3	Hydrolysed proteins 300 g/l SL formulation	No variation of active ingredient was observed after 14 days at 54ºC.	Y	12-3638-01
	Stability after storage for other periods and/or temperatures CIPAC MT 39.1	Hydrolysed proteins 300 g/l SL formulation	After storage at 0ºC ±2 for 7 days, the volume of solid and/or liquid which separates was not more than 0.3 mL.	Y	12-3638-01
Wettability	Not applicable	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation		
Persistence of foaming	CIPAC MT 47.1	Hydrolysed proteins 300 g/l SL formulation	The maximum volume of foam was of 11 mL after 12 minutes of the test item at room temperature	Y	12-3638-01
Suspensibility, spontaneity and dispersion stability	Suspensibility: CIPAC MT 15, 161 or 168 Spontaneity and dispersion: CIPAC MT 160 or 174	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation Not applicable: Biocebo is not a solid formulation		
Degree of dissolution and dilution stability	CIPAC MT 41.1	Hydrolysed proteins 300 g/l SL formulation	30 min. Clear solution, not separated material 24 h. Clear solution, not separated material	Y	12-3638-01

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
Physical and chemical compatibility with other products including other plant protection products with which its use is to be authorised	Not applicable	Hydrolysed proteins 300 g/l SL formulation	BIOCEBO is compatible with insecticides regularly used for the control of olive and fruit flies, such as dimethoate.		
Other studies					12-3638-03. Storage stability for two years at room temperature

Reference Report: 12-3638-01: Physico-chemical characterisation of BIOCEBO (hydrolysed proteins 30% w/v). Laboratorios Munuera, S.L.U. (Murcia, Spain). 2013.

Reference Report: 12-3638-03: Storage stability for two years at room temperature of BIOCEBO (hydrolysed proteins 30% w/v). Laboratorios Munuera, S.L.U. (Murcia, Spain). 2015.

3 DATA ON APPLICATION AND EFFICACY

3.1 Summary of effectiveness

Efficacy trials are summarized in the following tables:

Summary data on trials site and application details per use:

Test report (1)	**Trial location(2); Crop cultivar ; F/G (3); N/A (4)**	**Testing Unit (5)**	**Test method (6); Plot size; Sample Size (7)**	**Treatment**			
				Growth stage (8)	Interval	Total number	Spray volume (L/ha)
2012023	Les Franqueses, 59 baixos E-25600 Balaguer, Lleida (ES)	Devreg Consulta SLU. EOR nº 73/11	EPPO: PP 1/135(3), PP 1/181(3), PP 1/152(3), PP 1/106(2) 1040 m^2 per plot	BBCH 76 and BBCH 81. Adult	7 days intervals	2 treatments	125 L / ha
11_bio.i01	C/ El Reguero s/n 30559 Abarán - Murcia (ES)	Métodos y Servicios Agrícolas S.L. EOR nº 51/03	EPPO: PP1/152(3),PP 1/135(3), PP1/181(3), PP1/106(2) 800 m^2 per plot	BBCH 81 - 83 Adult	6 days interval	3 treatments	80 L/ha
PC12 BBR 33	Caserta ViaMazzini Vico VI, n.1 - 81047 – Macerata Campania– (IT)	Biofarm s.r.l. GEP prot 2525 + 2527 (IT)	EPPO: PP1/106(2), PP1/135(3), PP1/152(3), PP1/181(3) 625 m^2 per plot	BBCH 79-81 BBCH 81-85 BBCH 85-87 Adult	9 days intervals	3 treatments	100 L / ha
2012024 T1	Les Franqueses, 59 baixos E-25600 Balaguer, Lleida (ES)	Devreg Consulta SLU. EOR nº 73/11	EPPO: PP 1/108 (2), PP 1/135(3), PP 1/181(3), PP 1/152(3) 5000 m^2 per plot aprox	BBCH 79 and BBCH 85. Adult	20 days interval	2 applications	125 L / ha

Test report (1)	Trial location(2); Crop cultivar ; F/G (3);	Testing Unit (5)	Test method (6); Plot size; Sample Size (7)	Treatment			
11_bio.i02	C/ El Reguero s/n 30559 Abarán - Murcia (ES)	Métodos y Servicios Agrícolas S.L. EOR nº 51/03	EPPO: PP 1/135(2),PP 1/181(3), PP 1/152(3), PP 1/108(2) 2000 m^2 per plot aprox	BBCH 81 BBCH 85 BBCH 87 Adult	7 days intervals	3 treatments	80 L/ha
PC12 BBR 34	Caserta ViaMazzini Vico VI, n.1 - 81047 – Macerata Campania– (IT)	Biofarm s.r.l. GEP prot 2525 + 2527 (IT)	EPPO: PP1/280(1), PP1/135(3), PP1/152(3), PP1/181(3) At least 640.0 m2	BBCH 79 - 80 BBCH 81 BBCH 85 Adult	9 days intervals	3 treatments	100 L / ha

Summary of data on trials site and application details per use:

Test report (1)	**Harmful organism/ weed species or intended use**	**Assessed part and variable (2)**	**Untreated (3)**	**Efficacy treatments (4)**				**Remarks (5)** **All data based on damaged fruits**
				Product	Standard (s)			
				BIOCEBO + insecticide rate	Conventional insecticide rate	Attractant A + insecticide rate	Attractant B + insecticide rate	
2012023	*Ceratitis capitata*	Assessed: Fruits Variable: % damaged fruits	12.50 %	1.25 %	2.75 %	0.75 %	1.75 %	
11_bio.i01	*Ceratitis capitata*	Assessed: Fruits Variable: % damaged fruits	31.78 %	0.37 %	0.25 %	0.47 %	0.47 %	
PC12 BBR 33	*Ceratitis capitata*	Assessed: Fruits Variable: % damaged fruits	57.60 %	13.5 %	9.75 %	13.3 %	14.6 %	Slightly lower efficiency but a noticeable reduction in the use of insecticide.
2012024 T1	*Bactrocera oleae*	Assessed: Fruits Variable: % damaged fruits	0.91 %	0.20 %	0.18 %	0.23 %	0.47 %	
11_bio.i02	*Bactrocera oleae*	Assessed: Fruits Variable: % damaged fruits	6.25 %	0.00 %	0.00 %	0.00 %	0.25 %	
PC12 BBR 34	*Bactrocera oleae*	Assessed: Fruits Variable: % damaged fruits	94.6 %	32.4 %	25.8 %	32.6 %	34.8 %	Slightly lower efficiency but a noticeable reduction in the use of insecticide.

Efficacy and selectivity of Flyral® and Biocebo® when applied as bait application together with conventional insecticide over peach/nectarine for *Ceratitis capitata* control.

Report number: 2012023

An efficacy trial was performed in stone fruits orchards to evaluate the efficacy of the test products Biocebo® and Flyral®, applied together with conventional insecticide as bait spot application, for the control of *Ceratitis capitata.*
The application of these products was compared to another equivalent product (Protsar), which was applied with the same methodology with untreated and with conventional insecticide.

The following results were obtained:

- All treated plots achieve significantly better control levels compared with untreated plots.
- Test item Biocebo® applied together with conventional insecticide as bait spot application does not differ significantly compared with efficacy reached by conventional insecticide application for *Ceratitis capitata* control when fruit damage is observed.
- Treatment number 5, (Flyral®) efficacy level when fruit damage is observed, improves efficacy level reached by conventional insecticide application.
- No phytotoxicity effects were detected.

Testing the efficacy of the use of hydrolyzed protein on insecticide applications to the control of *Ceratitis capitata* on citrus.

Report number: 11_bio.i01

A plot of mandarin variety Okitsu was selected in Pobla de Vallbona (Valencia), elemental plots were 800 m2. Karate Zeon (bait application method) was sprayed in a mixture with the hydrolyzed proteins, applied in patch form at 80 l/ha with a backpack manual sprayer for three times. Spintor Cebo (bait application method) was sprayed in patch at 10 l/ha with a backpack manual sprayer for three times.

Results summarized as follows:

- Percentage damaged fruits: Statistically significant differences were observed between untreated and treated plots, but no between treated plots. The percentage of fruits damaged on untreated plot reached 13.5% at 7 DA-C, increased to 32% at 24 DA-C. Karate Zeon was sprayed in mixture with BIOCEBO or FLYRAL, applied in patch, and achieved excellent efficacies, similar to Karate Zeon when sprayed in

mixture with NULURE, applied in patch, and to SPINTOR CEBO.

- Number of *Ceratitis capitata* captures: Statistically significant differences were observed between untreated and treated plots, but no between treated plots. The number of captures on untreated plot reached 13.5 at 7 DA-A, increased to 59% at 7 DA-B. Karate Zeon when sprayed in mixture with BIOCEBO or FLYRAL, applied in patch, achieved excellent efficacies, similar to Karate Zeon when sprayed in mixture with LUNURE applied in patch, and to SPINTOR CEBO.

- Karate Zeon was sprayed in mixture with an hydrolyzed protein applied in patch significantly decreased the damage on fruits and number of Ceratitis capitata compared to untreated control.

- No problems were detected when handling the experimental products.

- No symptoms of phytotoxicity were detected.

Efficacy and selectivity and evaluation of Flyral (Hydrolyzed protein 36%) and Biocebo (Hydrolyzed protein 30%) for mediterranean fruit fly or medfly (*Ceratitis Capitata* CERTCA) control on peach in Campania region (Italy).

Report number: PC12 BBR 33

The trial was carried out on Peach [*Prunus persica* (L.) Batsch var. Guglielmina] , on field-grown, in Sourthern Italy (Campania), locality Vairano Patenora (CE), according to an experimental design with randomized blocks, side-by-side, length-wise layout and 4 replications.

Summarized conclusions:

- Karate Zeon 1.5 at rate 0.125 L/ha and Biocebo at rate 1.5 L/ha ensured good protection of Peach in presence of very favourable conditions for natural infestation.

- Karate Zeon 1.5 at rate 0.125 L/ha and Flyral at rate 1.25 L/ha ensured good protection of Peach in presence of very favourable conditions for natural infestation.

- All the products have effectively contained the infestation.

The test substances were dispersed in water without any problem and solubility was perfect. The water used as carrier was tap water taken from the farm. No problem was observed during handling of the test materials. The weather conditions in field were favourable for the development of the infection.

Efficacy and selectivity of different protein formulation together with conventional insecticide against *Dacus oleae*.

Report number: 2012024 T1

An efficacy trial was conducted in olives orchards to evaluate the efficacy of test materials Biocebo® and Flyral®, applied together with conventional insecticide as bait spot application, for *Dacus oleae* control, in comparison with other equivalent product as Protsar® applied with same methodology with untreated and with conventional insecticide and program.

The following results were obtained:

- All treated plots achieved significantly better control levels compared with untreated plots.
- Test items Biocebo® and Flyral® applied together with conventional insecticide as bait spot application does not differ significantly compared with efficacy reached by conventional insecticide application for *Dacus oleae* control when fruit damage is observed.
- Treatment number 3 with Protsar® efficacy level when fruit damage is observed, show significant differences compared with untreated plots (significantly higher) and with the other treatments (significantly lower).
- Treatment number 4 Biocebo® applied together with conventional insecticide as bait spot application achieve level of *Dacus oleae* adult captures significantly lower compared with captures level from untreated plot. No significant differences are observed between the rest of treated plots and untreated plot.
- This efficacy levels when fruit damage have been assessed, have been produced with high pest pressure. However, this high pressure does not allow us to show significant differences between treated plots.
- No phytotoxicity effects were detected.

Testing the efficacy of the use of hydrolyzed protein on insecticide applications to the control of *Bactrocera oleae* on olives.

Report number: 11_bio.i02

A plot of olive variety Cuquillo was selected in Moratalla (Murcia). Elemental plots were 2000 m2. Karate Zeon (bait application method) was sprayed in a mixture with the hydrolyzed proteins, applied in patch form at 80 l/ha with a backpack motorized sprayer for three times. Spintor Cebo (bait application method) was sprayed in patch at 10 l/ha with a backpack motorized sprayer for three times.

Results summarized as follows:

- Percentage damaged fruits: Statistically significant differences were observed between untreated and treated plots, but not between treated plots. The percentage of fruits damaged on untreated plot reached 2.5% at 8 DA-B, increased to 6.3% at 14 DA-C. Karate Zeon was sprayed in mixture with BIOCEBO or FLYRAL, applied in patch, and achieved excellent efficacies, similar to Karate Zeon when sprayed in mixture with NULURE, applied in patch, and to SPINTOR CEBO.
- Number of fallen fruits on soil due to *Bactrocera oleae*: Statistically significant differences were observed between untreated and treated plots, but not between treated plots. The number of fallen fruits on soil on untreated plot reached 30.0 at 14 DA-C. Karate Zeon was sprayed in mixture with BIOCEBO or FLYRAL, applied in patch, and achieved excellent efficacies, similar to Karate Zeon when sprayed in mixture with NULURE, applied in patch, and to SPINTOR CEBO.
- Number of *Bactrocera oleae* captures: Statistically significant differences were observed between untreated and treated plots, but not between treated plots. The number of captures on untreated plot reached 8.0 at 8 DA-A, increased to 12 at 8 DA-B and 10 at 7 DA-C. Karate Zeon when sprayed in mixture with BIOCEBO or FLYRAL, applied in patch, achieved excellent efficacies, similar to SPINTOR CEBO, and slightly higher than Karate Zeon when sprayed in mixture with LUNURE applied in patch at 7 DA-C.
- Karate Zeon was sprayed in mixture with an hydrolyzed protein applied in patch significantly decreased the damage on fruits and number of *Bactrocera oleae* compared to untreated control.
- No problems were detected when handling the experimental products.
- No symptoms of phytotoxicity were detected.

Efficacy and selectivity and evaluation of Flyral (Hydrolyzed protein 36%) and Biocebo (Hydrolyzed protein 30%) for olive fruit fly (*Bactrocera oleae* or *Dacus oleae* Dacuol) control on olive in Campania region (Italy).

Report number: PC12 BBR 34

The trial was carried out on Olive [*Olea europaea* L.var. Oliva Caiazzana], on field-grown, in Sourthern Italy (Campania), locality San Prisco (CE), according to an experimental design with randomized blocks, side-by-side, length-wise layout and 4 replications.

One untreated plot is served as control, Karate Zeon 1.5 is not authorized on Olive; Flyral and Biocebo are not authorized on Olive, even if their active substance was already authorized on Olive.

Summarized conclusions:

- Karate Zeon 1.5 at rate 0.125 L/ha and Biocebo at rate 1.5 L/ha ensured satisfactory protection of Olive in presence of very favourable conditions for natural infestation.
- Karate Zeon 1.5 at rate 0.125 L/ha and Flyral at rate 1.25 L/ha ensured satisfactory protection of Olive in presence of very favourable conditions for natural infestation.
- All the products have effectively contained the infestation.

The test substances were dispersed in water without any problem and solubility was perfect. The water used as carrier was tap water taken from the farm. No problem was observed during handling of the test materials. The weather conditions in field were favourable for the development of the infestation.

3.2 Summary of information on the development of resistance

No resistance development was observed after the application of BIOCEBO in any of the efficacy trials submitted.

3.3 Summary of adverse effects on treated crops

No adverse effects were observed after the application of BIOCEBO in any of the efficacy trials submitted.

3.4 Summary of observations on other undesirable or unintended side-effects

No undesirable or unintended side-effects were observed after the application of BIOCEBO in any of the efficacy trials submitted.

4 FURTHER INFORMATION

4.1 Summary of methods and precautions concerning handling, storage, transport or fire

Warehouse Storage: The original closed and sealed containers should be stored in a cool dry place, far from a heat source, and at room temperature.

User Storage: As it is usual in the use and manipulation of any plant protection product, the staff in charge of manipulating the product should take the proper precautions during transport, load and unload and manipulation of the product in order to avoid that the product comes into contact with skin, eyes or other parts of the body.

Transport: Follow the precautions indicated in the Handling and Storage section of the SDS. Comply with any local regulations. Check that containers are sound and that labels are undamaged before dispatch.

Fire Fighting Measures:

Extinguishing media: SMALL FIRE: use DRY chemical powder

LARGE FIRE: use water spray, fog or foam. Do not use water jet.

Protective clothing and equipment proposed – nature: Use adequate protection medias to manipulate the plant protection products.

Protective clothing and equipment proposed – characteristics:

Hand protection: protective gloves for chemicals.

Eye protection: safety glasses.
Keep work area clean.
Avoid contact with product.
Keep working clothes separate from other clothing.
Wash hands before breaks and at the end of work.

Change badly soiled or soaked clothing.

Sufficient data to evaluate suitability and effectiveness of protective clothing and equipment under realistic conditions of use: No special data are available. However, it is obvious that splash goggles will effectively protect eyes and that protective gloves for chemicals will act as a barrier.

Procedures to minimize the generation of waste: Only purchase and store quantities of product required in the short term. Do not open larger containers than is necessary for immediate requirements. Do not a mix a volume of spray solution greater than is required for immediate use.

Information on combustion products likely to be generated in the event of fire: Owing to the nature of the active substance contained in the attractant BIOCEBO, there is no production of dangerous compounds in the event of fire or combustion.

Risk reduction during handling:

Handler safety:
For applications by patching, work clothes, chemical resistant gloves, and an FFP1 mask or mask with a P1 type filter or similar must be used during mixing/loading, application, cleaning and maintenance of equipment.
- During the application of the product, the operator must avoid contact with the wet leaves.
- Do not use this product if mechanical labour is planned that might damage the chemical resistant gloves.
- Category L3 containers (200 and 1000 l drums) will be used in closed transfer conditions, using an automatic pump.

Worker safety:
Work clothes and chemical resistant gloves must be used at all times.
Do not enter the crop area until the product is dry.
Work clothes consist of long sleeves, long trousers, and appropriate footwear.

4.2 Summary of procedures for destruction or decontamination

Neutralisation procedures

A neutralization procedure is not applicable for this type of product.

Controlled incineration

Package product wastes. Close and label waste receptacles. Dispose of them at a suitable waste incineration plant in accordance with the official regulations. Where large quantities are concerned, consult the supplier.

4.3 Summary of emergency measures in case of an accident

Detailed procedures for use in the event of an accident during transport, storage or use: Prevent entry into drains, waters or soil. Use adsorbent material to collect spillage (*e.g.* sawdust, peat, chemical binder). Place contaminated adsorbent in closable containers. Use a damp cloth to clean floors and other objects after removal of contaminated adsorbent. Also place used cleaning materials into closable receptacles.

5 METHODS OF ANALYSIS

5.1 Methods used for the generation of pre-authorisation data

5.1.1 Analysis of the active substance as manufactured

The determination of the content of hydrolysed proteins in samples is performed by the determination of the percentage of protein nature nitrogen.

The samples whose composition contains nitrogen of different nature (urea, nitric, ammonium, organic), the content of protein nitrogen is determined by the difference between the total nitrogen and the non-organic nitrogen by the following formula:

N organic= T – (N + A + U)

Being:

T = Total N
N = Nitric Nitrogen (Determination according to Robertson's method)
A = Ammonium Nitrogen (determination according to formaldehyde method)
U = Urea Nitrogen (determination according to urease method)

The content of amino nitrogen is calculated from the organic nitrogen by means of a conversion factor.

The method described below is the official method for the determination of the total nitrogen, published in the Spanish Royal Decree 1110/1991, Method 8.

Principle of the Method:

Transform the organic nitrogen into ammonium sulphate by boiling it with concentrated sulphuric acid. Previously, the nitric nitrogen has to be reduced to ammonium and distil all the ammonium nitrogen in alkaline medium with an acid of known titration.

Material and tools:

- Kjeldahl Flasks from 500 to 800 ml.
- Distillation plant

Reagents:

- Concentrated sulphuric acid
- Salicylic acid / sulphuric acid: dissolve 25 g of salicylic acid in one litre of concentrated sulphuric acid
- Thiosulphate of solid sodium
- Catalytic blending: Blend closely 80 g of potassium sulphate, 20 g of copper sulphate and 2 g of selenium.
- Solution of sodium hydroxide at 30%
- Solution of phenolphthalein at 1 % in ethanol
- Aqueous solution of boric acid at 2%
- Indicator. Dissolve 0,125 g of methyl red and 0.080 g of methylene blue in 100 ml of ethanol
- Sulphuric acid or hydrochloric acid 0,1 N

Procedure:

Compound from 0,2 to 2 g of the sample, put them into a Kjeldahl Flask and add 10 ml of the salicylic-sulphuric reactant, stir it in order to wet all the sample and leave it rest for 30 minutes; add 1 g of solid sodium thiosulphate and stir it; wait for 15 minutes and add between 10 and 15 ml of concentrated sulphuric acid and 5 g approximately of catalytic blending.

Place the flask in a heater blanket. Heat it slowly for 5 minutes until the white smokes disappear. Stir it softly by rotation and elevate the temperature as much as possible. Then continue the digestion until the solution becomes clear (it usually happens in 60 minutes).

Cool it and then add carefully 200 ml of water; cool it again, then add 2 or 3 drops of phenolphthalein and solution of NaOH at 30 % until getting the red colour.

Immediately after, connect the flask with the distillation plant always having the end of the adapter in a Erlenmeyer flask or un a glass that contains 20 ml of acid 0,1 N. The colour change goes from green into dark red.

Calculations:

Percentage N = V x 0,14 / W

Being:

V = volume, in ml, of acid 0,1 N consumed
W = weight, in grams, of the sample

Observations:

Some digestion equipment's with temperature regulation and equipment's of distillation with air entrainment or by water vapour with semiautomatic addition of reagents can be used.

5.1.2 Formulation analysis

The methods used for the determination of the active substance in the plant protection product are the following:

-AOAC Method 955.04 Nitrogen (total) in fertilizers – Kjeldahl method. Official methods of Analysis – Fifteen edition, 1990, vol.I pag.17.

-AOAC method 979.09 "Protein in grains". Official methods of Analysis – Fifteen edition, 1990, vol.II pag.788.

5.1.3 Methods for Risk Assessment

Hydrolysed proteins are natural compounds of degradation from the hydrolysis of living organism's tissues, that can have vegetable or animal origin. Proteins are the most abundant organic molecules in cells, constitute the 50% of the dry weight of cells or even more. They can be found in every single cell, since they are fundamental in all aspects of the cell structure and function (Lehninger, 1983).

The biotic degradation of the hydrolysed proteins results in more simple metabolites called amino acids. These compounds are present in live cells; consequently, they are not considered real waste, since they can be used again by the same live cells in the protein synthesis.

The metabolites that come from the degradation of the formulated product are identical to those that exist in cells in a natural way. Therefore, any analysis of waste would not be capable of distinguishing them.

Effects of the industrial and/or domestic transformation on nature and magnitude of waste

Hydrolysed proteins are completely biodegradable, so waste is not expected to be found in harvested vegetable products treated with formulated products containing hydrolysed proteins.

Alterations in smell, taste or other quality aspects due to the presence of waste

Hydrolysed proteins do not modify the organoleptic characteristics of the treated crops or their fruits.

Waste estimation in animal products, if appropriate

In treated vegetables Hydrolysed proteins are degraded without any waste accumulation, waste estimation in animal products is thus not necessary.

Furthermore, it would not be possible to distinguish the proteins brought in an artificial way from the ones already existing in the same animal tissues.

Waste data in crop rotations

Hydrolysed proteins are quickly degraded being soluble in water. Therefore, once the substance has been degraded, it is not probable that it has an effect on next crops, in case waste could be quantified.

Methods in plants, food, soil, water and air

Not required, see above explanation.

5.2 Methods for post-authorisation control and monitoring purposes

As stated in the Draft Assessment Report submitted by Greece to EFSA and still valid, there is no MRL's stablished for hydrolysed proteins at the community or member State level. The argumentation was based on these two points:

a) A residue definition of hydrolysed protein for plants is not considered relevant for the uses intended in EU.

b) No supervised trials were conducted since hydrolysed proteins is exempted from the requirements of data residues.

By default, a MRL of 0.01 mg/kg was set according to Article 18 (1) (b) of the Regulation 396/2005.

6 IMPACT ON HUMAN AND ANIMAL HEALTH

6.1 Effects Having Relevance to Human and Animal Health

6.1.1 Summary of adsorption, distribution, metabolism and excretion

Hydrolysed proteins are natural compounds of degradation from the hydrolysis of living organisms tissues, that can have vegetable or animal origin. Proteins are the most abundant organic molecules in cells. They constitute the 50% of the dry weight of cells, or even more. They can be found in every single cell, since they are fundamental in all aspects of the cell structure and function (Lehninger, 1983).
The Animal and Vegetable cells are formed mainly by proteins, which constitute more than the half of the dry weight of the cell. Proteins determine the shape and structure of the cell and also function as an instrument of molecular recognition and of catalysis (Alberts, 1986).

Proteins have many different biological functions. The widest group of proteins are the enzymes whose function is about catalysing the biochemical processes that take place in the living organisms. Moreover, there are proteins of reservation of amino acids such as plant nutrients; transport proteins of specific molecules; proteins that work as essential elements of the motile and contractile systems; protective proteins that are present in the blood of the vertebrates such as antibodies; proteins that function as hormones and, finally, structural proteins (Lehninger, 1983).

The proteins that are found in food and eaten by human beings and mammals are normally degraded metabolically by means of enzymatic processes to give rise to more simple metabolites (peptides and amino acids) that are used by the living cells for the biosynthesis of new specific proteins. Therefore, they do not cause any danger to human beings and mammals in general. As it has been explained before, proteins appear in all biochemical processes that take place in every cell being, this way, essential compounds for human life.

Furthermore, hydrolysed proteins are authorized by the EU in order to be used as attractant in the elaboration of baits in combination with appropriate insecticides of the Organic Farming (Regulation **EC 889/2008 annex 2**). This shows the innocuousness of these compounds, since the practice of this kind of agriculture is very demanding with the use of products that can be harmful to human beings.

The active ingredient Hydrolysed proteins means polypeptides, peptides and amino acids and mixtures thereof obtained by hydrolysis of animal by-products. The main health hazard of concern with hydrolysed proteins derived from animal by-products is the risk of BSE/TSE (Bovine spongiform encephalopathy/transmissible spongiform encephalopathy) contamination or of microbial human pathogens contamination. In order to exclude the risk of contamination of the raw animal material, the manufacturing process and the plant facilities are in accordance to the requirements of the Regulation 1069/2009, laying down health rules concerning animal by-products not intended for human consumption.

The Draft Assessment Report of Greece stated in 2008 that RMS accepted the argumentation that the active substance hydrolysed proteins derived from hydrolysis of animal tissues do not have any significant toxicity potential.

6.1.2 Summary of acute toxicity

Not applicable. However, acute toxicity in aquatic organisms available. See section 8.2 of this dossier.

6.1.3 Summary of short-term toxicity

Not applicable

6.1.4 Summary of genotoxicity

Not applicable

6.1.5 Summary of long-term toxicity and carcinogenicity

Not applicable

6.1.6 Summary of reproductive toxicity

Not applicable

6.1.7 Summary of neurotoxicity

Not applicable

6.1.8 Summary of further toxicological studies on the active substance

Not applicable

6.1.9 Summary of toxicological data on impurities and metabolites

Not applicable

6.1.10 Summary of medical data and information

Not applicable

6.2 Toxicological end point for assessment of risk following long-term dietary exposure – ADI

Not applicable

6.3 Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

Not applicable

6.4 Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

Not applicable

6.5 Summary of product exposure and risk assessment

In the EFSA Report (Peer Review of the pesticide risk assessment of the active substance hydrolyzed proteins (EFSA Journal 2012:10(2):2545) it is stated that hydrolyzed proteins are considered as a toxicological low risk (always if animal origin hydrolyzed proteins are free of pathogens). Due to this, it is not expected that hydrolyzed proteins suppose a risk for the human health.

6.5.1 Operators

Not applicable

6.5.2 Bystander and resident exposure

Not applicable

6.5.3 Workers

Not applicable

7 RESIDUES

In the initial application dossier, BIOIBERICA requested the exemption of hydrolysed proteins from animal origin of the requirement of residue data based upon the consideration that the biotic degradation of the hydrolysed proteins results in more simple metabolites like peptides and amino acids. These compounds have no insecticide activity, they are only superficial and they disappear easily with a quick wash or by the rainfall action. Peptides and amino acids are present in living cells, and consequently, they are not considered real waste, since they can be used again by the same living cells in the protein synthesis.

The metabolites that come from the degradation of the formulated product are identical to those that exist in cells in a natural way. Therefore, any analysis of residues would not be capable of determining them. These arguments were found acceptable and no residue data was deemed necessary, as stated in the Draft Assessment Report made by Greece.

The presented rationale was accepted by EFSA and no residue data was considered necessary. No plant metabolism or residues studies were performed during the process of inclusion in Annex I and no definition of residues were established for either monitoring and control, or risk assessment purposes.

No trials were presented either in support of the requested uses, taking into consideration:

- Hydrolysed proteins mainly originate from the hydrolysis of natural proteins, and mostly consist of amino acids and small peptides, undistinguishable from those present naturally in the crop, whether originating in the actual plant or having an exogenous origin in other organisms.
- They are used as attractant substance and have no insecticide capacity per se
- Hydrolysed Proteins derive from hydrolytic cleavage of natural proteins, and are mainly composed by amino acids and small peptides. Because of that, there is no way to distinguish between the hydrolysed proteins coming from the active substance and those formed by field degradation of proteins from living organisms.
- Hydrolysed Proteins are used as an attractant substance. It doesn’t have any pesticide effect by itself, thus, it has to be mixed with properly authorized insecticides.

In addition, in the Peer Review (EFSA Journal 2012; 10 (2): 2545) it was noted that hydrolysed proteins are of low toxicity (following pages).

7.1 Summary of storage stability of residues

Not applicable

7.2 Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

Not applicable

7.3 Definition of the residue

Not applicable

7.4 Summary of residue trials in plants and identification of critical GAP

Not applicable

7.5 Summary of feeding studies in poultry, ruminants, pigs and fish

Not applicable

7.6 Summary of effects of processing

Not applicable

7.7 Summary of residues in rotational crops

Not applicable

7.8 Summary of other studies

Not applicable

7.9 Estimation of the potential and actual exposure through diet and other sources

Not applicable

7.10 Proposed MRLs and compliance with existing MRLs

Not applicable

7.11 Proposed import tolerances and compliance with existing import tolerances

Not applicable

8 FATE AND BEHAVIOUR IN THE ENVIRONMENT

The hydrolysed proteins are biodegradable, so their persistence in the environment is very short, without existing any tendency to bioaccumulation.

Due to the nature of the hydrolysed proteins and its characteristics regarding its fate and behaviour in the Environment, it could be considered very unlikely the existence of relevant residues of hydrolysed proteins in the soil derived from the application of formulated products containing hydrolysed proteins. In addition, it is unlikely that leaching of hydrolysed proteins can occur or that residues can reach groundwater under the proposed conditions of use.

For this reason, it was required the exemption of carrying out the evaluation of the fate and behaviour in the environment of Hydrolysed proteins and it was accepted; the overall conclusion from the draft assessment report, the recommendations by the rapporteur Member State and the result of the examination in accordance with the provisions of Article 24a of Regulation 2229/2004 is that there are clear indications that it may be expected that hydrolysed proteins does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex VI of regulation (EC) 2229/2004 as last amended by Regulation (EC) 1095/2007.

8.1 Summary of fate and behaviour in soil

Not applicable

8.2 Summary of fate and behaviour in water and sediment

Not applicable

8.3 Summary of fate and behaviour in air

Not applicable

8.4 Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

Not applicable

8.5 Definition of the residues in the environment requiring further assessment

Not applicable

8.6 Summary of exposure calculations and product assessment

Not applicable

9 EFFECTS ON NON-TARGET SPECIES

The SANCO report for Hydrolysed proteins (SANCO/2615/08 rev 3) is considered to provide the relevant review information or a reference to where such information can be found. The overall conclusions included there, in point 3, states: ...*"there are clear indications that it may be expected that hydrolysed proteins does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex VI of regulation (EC) 2229/2004 as last amended by Regulation (EC) 1095/2007"*.

Thus, we can conclude that no additional information needs to be provided to prove that the hydrolyzed proteins, when properly used will be devoid of any ecotoxicological risk or impact.

According to this, it is not expected that hydrolyzed proteins, when used under proper conditions, could have any potential risk for:

- birds,
- aquatic organisms (fish, invertebrates, algae, etc.),
- arthropods,
- earthworms and other non-target soil macro-organisms,
- non-target plants, and / or
- non-target species (Flora and Fauna).

9.1 Summary of effects on birds and other terrestrial vertebrates

there is no potential risk

9.2 Summary of effects on aquatic organisms

Regulation 571/2012, amending Regulation (EU) No 540/2011 as regards to the conditions of approval of the active substances aluminium silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine), establishes that for the hydrolyzed proteins some additional information is required regarding the risk for aquatic organisms.

In this mentioned Regulation, it is also stated that applicants shall submit the information requested to the European Commission through the Rapporteur European Member State (Greece in this case), by 1st of November 2013. BIOIBERICA S.A.U., as one of the applicants for the inclusion of Hydrolyzed proteins in Annex I of the derogated Directive 91/414, concerning the placing of plant protection products on the market, has accordingly prepared two acute toxicity studies on *Daphnia sp* and on *Brachydanio rerio* (fish). Both studies were performed in a GLP complying laboratory (Eurofins Biolab S.r.l., located in Italy) and tested the active substance called "BIOCEBO" (35 % w/w hydrolyzed proteins). Results showed that BIOCEBO (which in this case

is not the PPP), supposes no risk for aquatic organisms such as *Daphnia* or *Brachydanio rerio* in acute toxicity tests such as acute Immobilisation Test and Limit Test (equilibrium loss, irregular swimming, difficulties in respiratory functions and variation of pigmentation), respectively.

Moreover, BIOIBERICA, S.A.U. together with the other two applicants, requested to IRTA (Institute for Food and Agricultural Research and Technology) a bibliographical analysis of the effects of hydrolysed proteins on aquatic organisms. The results of this analysis concluded that there is no evidence for any effects of hydrolysed proteins on aquatic ecosystems in general and on aquatic organisms in particular.

The next pages present the results of these three studies.

STUDY NUMBER 1. Acute toxicity on aquatic organisms (Daphnia sp): EC50 TEST ON "BIOCEBO"

Introduction:

The aim of this study was to determine the ecotoxicological effects "BIOCEBO" (hydrolyzed proteins ≥35 % w/w), on biotic systems putting as a model the aquatic organism *Daphnia magna* as a test system to perform the EC_{50} test.

This acute immobilization test was evalutated according to the OECD guideline N.202.

Report:	S-2013-01827 AM
Title:	Acute toxicity on aquatic organisms (Daphnia sp): EC50 TEST ON "BIOCEBO"
Test facilities:	Eurofins Biolab S.r.l. of Vimodrome (MI)-via B. Buozzi n.2 (Italy)
Guidelines:	OECD Guidelines for the testing of Chemicals/Section 2: Effects on Biotic Systems Test Nº. 202: Daphnia sp. Acute Immobilisation Test 2004
GLP	Yes

Material and Methods:

The organisms were exposed to 5 different solutions of BIOCEBO for a total period of 48 hours, the number of immobilized organisms and/or possible abnormal behaviors were observed.

120 Daphnia were used, 100 of them treated with different concentrations and 20 as a control (no Biocebo addition). 4 replications for every condition were prepared, afterwards Daphnia was added to the vessels of the assay sample.

Dissolved oxygen, pH and temperature of the assay were measure at the beginning and at the end of the test.

Validity criteria:

- The immobilization of control animals must not be higher than 10% at the end of the test.
- pH values must not change for more than 1.5 units
- The concentration of dissolved oxygen in the vessels must not go below 2 mg/l.

Findings:

- pH values were not significantly different between the two treatment conditions.
- Dissolved oxygen was lower at the end of the test with the highest concentration of BIOCEBO but validity criteria was satisfied.
- Temperature did not change during the test.
- The obtained results showed that the *Daphnia magna* EC_{50} after 48 hours at the concentration of 100 mg/l of the test item "BIOCEBO" is higher than 1.00 g/l.
- All the test parameters satisfied the validity criteria.

Conclusion/endpoint:

Results showed that BIOCEBO supposes no risk for aquatic organisms such as *Daphnia*.

STUDY NUMBER 2. *Brachydanio rerio*, acute toxicity test-limit test: on "BIOCEBO".

Introduction:

The aim of this study was to determine the ecotoxicological effects "BIOCEBO" (hydrolyzed proteins ≥35 % w/w), on biotic systems putting as a model the aquatic organism *Brachydanio rerio* as a test system to perform a limit test.

This acute immobilization test was evaluated according to the OECD guideline N.203.

Report:	S-2013-01828 AM
Title:	Brachydanio rerio, ACUTE TOXICITY TEST-LIMIT TEST: ON "BIOCEBO".
Test facilities:	Eurofins Biolab S.r.l. of Vimodrome (MI)-via B. Buozzi n.2 (Italy)
Guidelines:	OECD Guidelines for the testing of Chemicals/Section 2: Effects on Biotic Systems Test Nº. 203: Fish, Acute Toxicity Test 1992
GLP	Yes

Material and Methods:

The organisms were exposed to 100 mg/l of BIOCEBO or control solutions for a total period of 96 hours. All visible abnormalities such as equilibrium loss, irregular swimming, difficulties in respiratory functions and variation of pigmentation were measured.

14 fishes were used, 7 of them treated with the BIOCEBO with a concentration of 100 mg/l and other 7 were used as control, in the same assay conditions than without adding BIOCEBO.

At the different observations intervals pH, dissolved oxygen and assay water temperature were measured.

Validity criteria:

- The mortality in the control animals should not exceed one fish at the end of the test.
- The dissolved oxygen concentration must have been at least 60 percent of the air saturation value throughout the test.

Findings:

- pH values remained within the required limits (6,0-8,5).
- The percentage of saturation has remained for the whole length of the assay above 60% both in control and in treated conditions.
- Temperature remained in the interval required for the species.
- The obtained results showed that no case of mortality was declared in treated animals and in control ones. No toxic symptom was detected neither.
- All the test parameters satisfied the validity criteria.

Conclusion/endpoint:

The obtained results, in compliance with assay validity criteria, showed that no dead fishes at 100 mg/l of BIOCEBO after 96 hours were observed.
Results showed that BIOCEBO supposes no risk for aquatic organisms such as Brachydanio.

STUDY NUMBER 3. Bibliographical analysis of the effects of hydrolysed proteins on aquatic organisms

Introduction:

The objective and scope of this study was to make a complete and systematic technical and scientific bibliographical review of the effects that the use of protein hydrolysate baits may have on the aquatic organisms.

Report:	-
Title:	Bibliographical analysis of the effects of hydrolysed proteins on aquatic organisms.
Test facilities:	IRTA: Institute for Food and Agricultural Research and Technology
Guidelines:	Not applicable
GLP	Not applicable

Material and Methods:

To do so, the following database and open access search engine and repositories have been consulted: Web of Knowledge, Google Scholar, AGRIS, Aquatic Commons, OceanDocs, OAister WorldCat and OpenDOAR.

The search strategy consisted on different key words used such as “hydrolysed protein” and “aquatic organisms” and the Boolean operators applied to combine them.

Results:

- Through the different searches, several records were found but none of them was relevant to the subject.

Conclusion/endpoint:

The obtained results of the systematical bibliographical search showed no effects of any kind of the use of hydrolysed protein baits on aquatic organisms.

Therefore, there is no evidence for any adverse effects of hydrolysed proteins on aquatic ecosystems in general and on aquatic organisms in particular.

9.3 Summary of effects on arthropods

there is no potential risk

9.4 Summary of effects on non-target soil meso- and macrofaunal

there is no potential risk

9.5 Summary of effects on soil nitrogen transformation

there is no potential risk

9.6 Summary of effects on terrestrial non-target higher plants

there is no potential risk

9.7 Summary of effects on other terrestrial organisms (flora and fauna)

there is no potential risk

9.8 Summary of effects on biological methods for sewage treatment

there is no potential risk

9.9 Summary of product exposure and risk assessment

Next pages review the eco-toxicological studies for the product BIOCEBO, containing as active substance Hydrolysed proteins, which was included into Annex I of Directive 91/414/EEC (2009/153/EC). This document refers to the conclusions of the EU review of the Hydrolysed proteins, because the active substance data is relied upon in the risk assessment of the formulation. The SANCO report for Hydrolysed proteins (SANCO/2615/08 rev 3) is considered to provide the relevant review information or a reference to where such information can be found. The overall conclusions included there, in point 3, states: ...“*there are clear indications that it may be expected that hydrolysed proteins does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex VI of regulation (EC) 2229/2004 as last amended by Regulation (EC) 1095/2007”*.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on hydrolysed proteins (SANCO/2615/08 - rev 3) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health were taken into account. These concerns were addressed when the Annex III dossier for BIOCEBO was submitted to Spanish Authorities.

This section summarises the ecotoxicological effects of the formulation and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms.

The Assessment Report for Hydrolysed proteins concludes as follows:

"*Regarding to ecotoxicology section, no risk is anticipated due to the use of hydrolyzed proteins to environmental organisms. In our opinion there is no additional data needed concerning the risk to birds and mammals, aquatic organisms, pollinators or non-target arthropods, earthworms, other soil non-target macro-organisms and micro-organisms, other non-target plants and sewage treatment plants of hydrolyzed proteins.*

We can conclude that no additional information needs to be provided to prove that BIOCEBO, when properly used will be devoid of any ecotoxicological risk or impact.

According to this, it is not expected that BIOCEBO, when used under proper conditions, could have any potential risk for:

- *birds,*
- *aquatic organisms (fish, invertebrates, algae, etc.),*
- *terrestrial vertebrates other than birds,*
- *bees,*
- *arthropods other than bees,*
- *earthworms and other non-target soil macro-organisms,*
- *non-target plants, and / or*
- *non-target species (Flora and Fauna).*

Moreover, in Ecotoxicological Expert Panel concluded in the Ecotoxicological area of the Spanish Registration Reports of BIOCEBO, reviewed under Uniform Principles, accepted the conclusions of the Final addendum to the DAR regarding the evaluation of the risk of the active substance Hydrolysed proteins:

Hydrolysed proteins degrade rapidly into simple metabolites which also have no insecticide activity. Residues are only superficial and disappear easily by straightforward washing or with rain. Their persistence in the environment is very short, and there is no bioaccumulation potential.

Biotic degradation of hydrolysed proteins results in simple metabolites called amino acids. These compounds are present in living cells and are not therefore considered residues because they may be used by cells in protein synthesis.

Plants and animals are mainly made up of proteins, which accounts for more than half the dry weight of a cell. Hydrolysed proteins come from the enzymatic hydrolysis of animal tissues, and they therefore pose no danger whatsoever to humans or animals in general.

Hydrolysed proteins were authorised by the EU to be used as an attractant in the production of baits combined with appropriate insecticides in ecological agriculture. This proves that these compounds are innocuous. The use of hydrolysed proteins is considered of low risk to terrestrial and aquatic life to ecosystems in general.

10 CLASSIFICATION AND LABELLING

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures:

1. CLASSIFICATION AND LABELLING

Classification based on health effects and physical and chemical properties

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Signal word

Symbols

Hazard statements

Precautionary statements

P261: Avoid inhaling the spray.
P262: Avoid contact with the eyes, skin, and clothes.
P280: Wear gloves and protective clothing.
P102: Keep out of reach of children.
P270: When using, do not eat, drink or smoke.

2. CLASSIFICATION AND LABELLING

Other components in addition to the technical-grade active ingredient

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Other phrases and statements

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

Recommendations in cases of intoxication or accident.

First-aid measures:

- *If in eye, rinse with plenty of water for at least 15 minutes. Do not forget to remove contact lenses.*
- *If on skin, rinse with plenty of water and soap, but do not scrub*
- *If necessary transfer the casualty to a medical centre and take the label or the container with you.*

DO NOT LEAVE THE AFFECTED PERSON ALONE UNDER ANY CIRCUMSTANCES.

Therapeutic information for doctors and healthcare personnel:

- *Symptomatic treatment*

IN CASE OF ACCIDENT OR ILLNESS, CALL THE NATIONAL POISON CENTRE. TELEPHONE 91-562.04.20. In both cases, have the container or the label at hand.

User category

Professional use

3. TYPES OF CONTAINER

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11 RELEVANCE OF METABOLITES IN GROUNDWATER

Not applicable, see justification in section 7 and 8 of this dossier.

11.1 Summary

11.2 Conclusion

Not applicable due to the nature of hydrolyzed proteins as a natural substance present in the environment.

12 CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT

Not applicable

12.1 Summary

12.2 Conclusion

Appendix 1: Metabolites formed from Active Substance and their occurrence

Code Number	Description	• Compound found in	Structure
		•	
		•	

Appendix 2: Proposed Metabolic Pathway