



# **Draft Assessment Report (DAR)**

**- public version -**

**Initial risk assessment provided by the rapporteur Member State  
Hellas for the existing active substance**

## **HYDROLYSED PROTEINS**

**of the fourth stage of the review programme  
referred to in Article 8(2) of Council Directive 91/414/EEC**

**Volume 3, Annex B, part 4, B.8**

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## **B.8 ENVIRONMENTAL FATE AND BEHAVIOUR**

Hydrolysed Protein notified by three applicants seeking the inclusion of hydrolysed proteins in Annex I of Directive 91/414/EEC.

The three applicants are:

- 1) BIOIBERICA, S.A. (Ref. Code: BIO)
- 2) "PHYTOPHYL"-N.G.STAVRAKIS (Ref. Code: PHY)
- 3) SICIT 2000 S.p.A. (Ref. Code: SIC)

Today it is generally accepted that the term "Hydrolysed Protein" and its synonym "Protein Hydrolysate", are vague terms and are not suitable to determine the identity of an active substance seeking to be included in Annex I of 91/414. The term Protein Hydrolysate is a multi meaning and not a single meaning term. After understanding with the Rapporteur Member State the three applicants agreed to submit a common dossier with three different sections.

### **A) Animal tissue Hydrolysate (Ref. Code: BIO)**

According to the Notifier, the 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.

The hydrolysed proteins are biodegradable, so their persistence in the environment is very short, without any tendency for 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, according to the Notifier, it is not necessary to carry out the evaluation of the fate and behaviour in the environment of Hydrolysed proteins.

### **B) Beet molasses-Urea Hydrolysate (Ref. Code: PHY)**

Although there are no literature data about the Fate and behavior for BMU Hydrolysate, it is sure, according to the Notifier, that Beet Molasses-Urea Hydrolysate is totally biodegradable and according the points referred on sections "Toxicological and Toxicokinetic Studies on the Active Substance" and "Residues in or on Treated Products, Food and Feed", there is no doubt that Beet Molasses-Urea Hydrolysate is an active substance with minimum risk for the environment.

### **C) Collagen Protein Hydrolysate (Ref. Code: SIC)**

According to the Notifier, the product does not cause negative transformations in the environment if it is used following the suggested dosages and the suggested conditions. The product is completely degradable but if present in copious quantities can pollute ground and surface water: it is necessary to prevent concentrated product from penetrating into ground and surface waters. The product is constituted by natural substances and consequently is completely biodegradable. Reasonably there are not negative effects on the environment.

#### **B.8.1 ROUTE AND RATE OF DEGRADATION IN SOIL (ANNEX IIA 7.1.1; ANNEX IIIA 9.1.1)**

##### **A) Animal tissue Hydrolysate (Ref. Code: BIO)**

No study submitted.

##### **B) Beet molasses-Urea Hydrolysate (Ref. Code: PHY)**

No study submitted.

##### **C) Collagen Protein Hydrolysate (Ref. Code: SIC)**

No study submitted.

#### **B.8.1.1 Route of degradation**

##### **B.8.1.1.1 Aerobic degradation**

No study submitted.

##### **B.8.1.1.2 Anaerobic Degradation**

No study submitted.

##### **B.8.1.1.3 Photolysis in soil**

No study submitted.

#### **B.8.1.2 Rate of degradation**

##### **B.8.1.2.1 Laboratory studies**

###### **B.8.1.2.1.1. Aerobic degradation at 20 °C**

No study submitted.

###### **B.8.1.2.1.2. Aerobic degradation at 10 °C**

No study submitted.

###### **B.8.1.2.1.3. Anaerobic degradation**

No study submitted.

##### **B.8.1.2.2 Field Studies.**

No study submitted.

###### **B.8.1.2.2.1. Soil Dissipation studies**

No study submitted.

###### **B.8.1.2.2.2. Soil residue studies**

No study submitted.

**B.8.1.2.2.3. Soil accumulation studies**

No study submitted.

**B.8.2 ADSORPTION AND DESORPTION AND MOBILITY IN SOIL (Annex IIA 7.1.2 and 7.1.3; Annex IIIA 9.1.2)****A) Animal tissue Hydrolysate (Ref. Code: BIO)**

No study submitted.

**B) Beet molasses-Urea Hydrolysate (Ref. Code: PHY)**

No study submitted.

**C) Collagen Protein Hydrolysate (Ref. Code: SIC)**

No study submitted.

**B.8.2.1 Adsorption, desorption****B.8.2.2. Mobility in the soil****B.8.2.2.1. Column leaching studies**

No study submitted.

**B.8.2.2.2. Aged residue column leaching**

No study submitted.

**B.8.2.2.3. Lysimeter studies or field leaching studies**

No study submitted.

**B.8.3 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC<sub>s</sub>) (Annex IIIA.9.1.3)****A) Animal tissue Hydrolysate (Ref. Code: BIO)**

No study submitted. The following statement was made by the Notifier:

The Hydrolysed proteins, which are the components of BIOCEBO, 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.

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 active substance (hydrolysed proteins), the type of use of BIOCEBO and the characteristics of the active substance regarding its fate and behaviour in the Environment, it could be considered very unlikely the existence of relevant residues of the active substance in the soil derived from the application of BIOCEBO. In addition, it is unlikely that leaching of the active substance can occur or that residues can reach groundwater under the proposed conditions of use. For this reason, it is not necessary to carry out the evaluation of the fate and behaviour in the environment of BIOCEBO.

Comment by the RMS: **The Notifier proposes areal application of BIOCEBO, which is not a way of application that can be accepted by the RMS, especially when no relevant data has been submitted.**

**B) Beet molasses-Urea Hydrolysate (Ref. Code:PHY)**

No study submitted. The following statement was made by the Notifier:

**Although there are no data about**

- Fate and behavior for DACONA (BMU-Hydrolysate).

It is sure that Beet Molasses-Urea Hydrolysate is totally biodegradable and according the points referred on *"Toxicological studies and exposure data and information &. Metabolism and residues data"* there is no doubt that Beet Molasses-Urea Hydrolysate is an active substance with minimum risk for the environment.

Comment by the RMS: **The Notifier proposes areal application of DACONA, which is not a way of application that can be accepted by the RMS, especially when no relevant data has been submitted.**

**C) Collagen Protein Hydrolysate (Ref. Code: SIC)**

No study submitted. The following statement was made by the Notifier:

The product is constituted by natural substances and consequently is completely degradable.

Reasonably there are not negative effects on the environment, but if present in copious quantities can pollute ground and surface water: it is necessary to prevent concentrated product from penetrating into ground and surface waters.

**B.8.4 FATE AND BEHAVIOUR IN WATER**

**A) Animal tissue Hydrolysate (Ref. Code:BIO)**

No study submitted.

**B) Beet molasses-Urea Hydrolysate (Ref. Code:PHY)**

No study submitted.

**C) Collagen Protein Hydrolysate (Ref. Code: SIC)**

No study submitted.

**B.8.4.1 Hydrolytic degradation**

No study submitted.

**B.8.4.2. Photolytic degradation**

No study submitted.

**B.8.4.3. Biological degradation**

**B.8.4.3.1. Ready biodegradability**

No study submitted.

#### **B.8.4.3.2. Water/sediment study**

No study submitted.

### **B.8.6 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND IN GROUND WATER (PEC<sub>SW</sub>, PEC<sub>GW</sub>)**

#### **A) Animal tissue Hydrolysate (Ref. Code: BIO)**

No study submitted. The following statement was made by the Notifier:

The Hydrolysed proteins, which are the components of BIOCEBO, 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.

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 active substance (hydrolysed proteins), the type of use of BIOCEBO and the characteristics of the active substance regarding its fate and behaviour in the Environment, it could be considered very unlikely the existence of relevant residues of the active substance in the soil derived from the application of BIOCEBO. In addition, it is unlikely that leaching of the active substance can occur or that residues can reach groundwater under the proposed conditions of use. For this reason, it is not necessary to carry out the evaluation of the fate and behaviour in the environment of BIOCEBO.

Comment by the RMS: **The Notifier proposes areal application of BIOCEBO, which is not a way of application that can be accepted by the RMS, especially when no relevant data has been submitted.**

#### **B) Beet molasses-Urea Hydrolysate (Ref. Code: PHY)**

No study submitted. The following statement was made by the Notifier:

##### **Although there are no data about**

- Fate and behavior for DACONA (BMU-Hydrolysate).

It is sure that Beet Molasses-Urea Hydrolysate is totally biodegradable and according the points referred on *"Toxicological studies and exposure data and information & Metabolism and residues data"* there is no doubt that Beet Molasses-Urea Hydrolysate is an active substance with minimum risk for the environment.

Comment by the RMS: **The Notifier proposes areal application of DACONA, which is not a way of application that can be accepted by the RMS, especially when no relevant data has been submitted.**

**C) Collagen Protein Hydrolysate (Ref. Code: SIC)**

No study submitted. The following statement was made by the Notifier:

The product is constituted by natural substances and consequently is completely degradable.

Reasonably there are not negative effects on the environment, but if present in copious quantities can pollute ground and surface water: it is necessary to prevent concentrated product from penetrating into ground and surface waters.

**B.8.6.1 Predicted Environmental Concentrations in Surface Water & Sediment**

No study submitted.

**B.8.6.2 Predicted Environmental Concentrations in Ground Water****B.8.7 FATE AND BEHAVIOUR IN AIR****A) Animal tissue Hydrolysate (Ref. Code: BIO)**

No study submitted.

**B) Beet molasses-Urea Hydrolysate (Ref. Code: PHY)**

No study submitted.

**C) Collagen Protein Hydrolysate (Ref. Code: SIC)**

No study submitted.

**B.8.8 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN AIR (PECair)****A) Animal tissue Hydrolysate (Ref. Code: BIO)**

No study submitted. The following statement was made by the Notifier:

The Hydrolysed proteins, which are the components of BIOCEBO, 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.

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 active substance (hydrolysed proteins), the type of use of BIOCEBO and the characteristics of the active substance regarding its fate and behaviour in the Environment, it could be considered very unlikely the existence of relevant residues of the active substance in the soil derived from the application of BIOCEBO. In addition, it is unlikely that leaching of the active substance can occur or that residues can reach groundwater under the proposed conditions of use. For this reason, it is not necessary to carry out the evaluation of the fate and behaviour in the environment of BIOCEBO.

Comment by the RMS: **The Notifier proposes areal application of BIOCEBO, which is not a way of application that can be accepted by the RMS, especially when no relevant data has been submitted.**

#### **B) Beet molasses-Urea Hydrolysate (Ref. Code:PHY)**

No study submitted. The following statement was made by the Notifier:

##### **Although there are no data about**

- Fate and behavior for DACONA (BMU-Hydrolysate).

It is sure that Beet Molasses-Urea Hydrolysate is totally biodegradable and according the points referred on *"Toxicological studies and exposure data and information &. Metabolism and residues data"* there is no doubt that Beet Molasses-Urea Hydrolysate is an active substance with minimum risk for the environment.

Comment by the RMS: **The Notifier proposes areal application of DACONA, which is not a way of application that can be accepted by the RMS, especially when no relevant data has been submitted.**

#### **C) Collagen Protein Hydrolysate (Ref. Code: SIC)**

No study submitted. The following statement was made by the Notifier:

The product is constituted by natural substances and consequently is completely degradable.

Reasonably there are not negative effects on the environment, but if present in copious quantities can pollute ground and surface water: it is necessary to prevent concentrated product from penetrating into ground and surface waters.

### **B.8.9 DEFINITION OF THE RESIDUE**

Soil: Animal tissue Hydrolysate, Beet molasses-Urea Hydrolysate, Collagen Protein Hydrolysate

Groundwater: Animal tissue Hydrolysate, Beet molasses-Urea Hydrolysate, Collagen Protein Hydrolysate

Surface water/Sediment: Animal tissue Hydrolysate, Beet molasses-Urea Hydrolysate, Collagen Protein Hydrolysate

Air: Animal tissue Hydrolysate, Beet molasses-Urea Hydrolysate, Collagen Protein Hydrolysate

### **B.8.10 REFERENCES RELIED ON**

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner