

In relation to the authority proceedings initiated in response to the application submitted by the client **Biokál Internationál Kft. (H-7570 Barcs, Széchenyi köz 2.)** for the issuance of marketing and use authorization of the **Natur Biokál product family**, the National Food Chain Safety Office as the authority responsible for food chain surveillance (hereinafter: the “Competent Authority”) has made the following

RESOLUTION

The Competent Authority issues marketing and use authorization for the **Natur Biokál product family** as per the following:

1. Commercial name of the products: - **Natur Biokál 01**
- **Natur Biokál 02**

2. Type of the product: plant conditioner

3. Manufacturer: Biokál Internationál Kft.

H-7570 Barcs, Széchenyi köz 2.

Statistical code: 11223360214-5190-113-14

Authorization holder: **Biokál Internationál Kft.**

H-7570 Barcs, Széchenyi köz 2.

Statistical code: 11223360214-5190-113-14

4. Raw materials, prescribed quality conditions:

Raw materials:

Natur Biokál 01:

aqueous extract of herbs, aqueous extract of biohumus, essential oils, eucalyptus oil, mineral salts

Natur Biokál 02:

aqueous extract of herbs, aqueous extract of biohumus, aqueous extract of wood ash, eucalyptus oil, mineral salts

Prescribed quality conditions

Natur Biokál 01

appearance: light brown liquid with a characteristic odor

dry matter content (m/m%) min. 0.8

density (kg/dm³) 1.0 ± 0.1

pH (in original solution) 8.18 ± 0.5

Natur Biokál 02

appearance: light brown liquid with a characteristic odor

| | |
|------------------------------------|------------|
| dry matter content (m/m%) | min. 0.8 |
| density (kg/dm ³) | 1.0 ± 0.1 |
| pH (in original solution) | 8.45 ± 0.5 |
| organic matter content (m/m%) d.m. | min. 37.2 |
| Total N content (m/V %) | min. 2.14 |

Requirements pertaining to each product of the range

| | |
|---|------------|
| As content (mg/l) | max. 10.0 |
| Cd content (mg/l) | max. 2.0 |
| Co content (mg/l) | max. 50.0 |
| Cr content (mg/l) | max. 100.0 |
| Cu content (mg/l) | max. 100.0 |
| Hg content (mg/l) | max. 1.0 |
| Ni content (mg/l) | max. 50.0 |
| Pb content (mg/l) | max. 100.0 |
| Se content (mg/l) | max. 5.0 |
| Fecal coliform (unit/ml) | max. 10 |
| Fecal streptococcus (unit/ml) | max. 10 |
| Pseudomonas aeruginosa (unit/ml) | max. 10 |
| Salmonella sp. (unit/2 x 10 ml) | max. 0 |
| Human parasitic helminth eggs (unit/100 ml) | max. 0 |

5. Application:

- for the leaf treatment of field crops in the quantity of 10–20 l/ha, on 2–4 occasions during the growing season, applied at a concentration of 8–10%,
- for the leaf treatment of vegetables in the quantity of 10–15 l/ha, on 4 occasions during the growing season, applied at a concentration of 5–6%,
- for fruit cultures:
for apple in the quantity of 15–20 l/ha, for blackberry in the quantity of 10 l/ha, for grape in the quantity of 15–30 l/ha on 3–4 occasions during the growing season, applied at a concentration of 7–10%,

To protect bees and other pollinating insects, it cannot be applied in the flowering period. It cannot be applied in the presence of blooming weeds.

Mixing test should be carried out before simultaneous application with plant protective products and other materials increasing the yield.

6. Hazard classification as per Regulation (EC) 1272/2008**6.1. GHS pictogram -****6.2. Warning: -****6.3. Hazard H statements:** no marking is required *

*data not to be indicated on the label

6.4. P statements for caution:

| | |
|-------------|---|
| P102 | Keep it out of reach of children. |
| P264 | Wash hands thoroughly after handling. |
| P270 | Do not eat, drink or smoke when using this product. |

| | |
|-----------------------|---|
| P280 | Wear protective gloves/protective clothing/eye protection/face protection (3 types) |
| P302 + P352 | IF ON SKIN: Wash with plenty of water. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. |
| P362+P364 | Take off contaminated clothing, and wash it before reuse. |
| P501 | Dispose of contents/container to hazardous waste disposal site. |

6.5. Occupational health waiting time: 0 day

6.6. First-aid procedure:

In the event or with the suspicion of any infection or allergic disease, work has to be suspended instantly. After onsite first-aid services (see general procedure), medical, institutional care should be provided.

7. Environmental requirements:

It is forbidden to discharge or dispose the products, their unused residues or packaging materials contaminated with the products into rivers, still waters, other watercourses or reservoirs.

They may not be used in biosphere reserves, areas under strict protection. The products may be applied in areas of nature conservation, national parks and landscape protection areas solely with the prior permit of the competent nature conservation administrator.

For the protection of aquatic organisms and water quality, it is forbidden to store and apply the products in the 50-meter range from the shores of still waters and watercourses.

8. Fire and explosion protection class: no required marking.

9. Packaging, storage, shelf life

9.1 Packaging material, net weights: 1, 5, 20 liter polyethylene flask and can, 1000 liter plastic tank with metal structure

9.2 Data to be indicated on the packaging and accompanying document:

Date of manufacturing, number of the permit, Sections 1, 2, 3, 5, 6, 7, 8, 9, 10 and 12 of the permit, as well as the active ingredient content from Section 4.

9.3 Storage conditions: in original closed packaging, in a dry, cool, sheltered place protected from frost

9.4 Shelf life: 2 years

10. Customs tariff number specified by the applicant: 310100

11. Other requirements:

The products may not contain germination and growth inhibitors, the seeds or vegetative parts of quarantined weeds, macro- or microorganisms that are harmful, infectious in terms of human, animal and plant health, or toxic, contaminating and radioactive substances.

12. Validity of the authorization: 21 March 2029

The fee of the authorization procedure amounts to HUF 200,000, which has been paid by the client.

Administrative court proceedings may be initiated against this resolution by means of a statement of claim.

The statement of claim shall be submitted to the National Food Chain Safety Office (hereinafter

referred to as NÉBIH) as addressed to the Metropolitan Court of Public Administration and Labor of Budapest within 30 days following the notification on this resolution.

Any party acting with legal representative, as well as any business entity with registered seat in Hungary is required to submit their statement of claim by way of an electronic form (ANYK form) available at the website <http://anyk.nebih.gov.hu>.

The court of justice will judge the matter without holding any hearing, however upon the request of either party regular court proceedings shall be summoned. Such court proceedings may be requested by statement of claim, or in the absence of such request it may not be rectified.

REASONS

On 27 August 2018 *Biokál Internationál Kft. (H-7570 Barcs, Széchenyi köz 2.) as client* submitted an application to the Competent Authority requesting the issuance of marketing and use authorization for the *Natur Biokál product family*. To the application, the client enclosed the relevant documentation specified in *Appendices 1 and 2 to Decree 36/2006 (V. 18.) of the Ministry of Regional Development on the licensing, storage, distribution and use of crop-boosting materials (hereinafter: D.)*

In terms of nutrition and soil hygiene, the product cannot be objected to, and in terms of human-toxicology it only poses acceptable risk on condition that good agricultural practices are observed, and the product is used with appropriate application technology for its intended purposes. The product does not contain any hazardous ingredient, hazardous waste, dangerous substances in concentration that exceeds the limit values specified in *Appendix 3 to the D.*

In view of the foregoing, the competent authority ascertained that the conditions of the issuance of the authorization as specified under *Section (1) of Article 7 of the D.* are met, and therefore it has made a resolution as described in the operative part.

The amount of the fee of the authorization procedure is determined in line with *Section 8.18.2.1 of Appendix I to Decree 63/2012 (July 2) of the Ministry of Rural Development on the amount of the administrative service fee to be paid in procedures initiated at the National Food Chain Safety Office, and at the specialized bodies of agricultural administration of the county government offices, as well as on the payment thereof.*

The competent authority has made its resolution acting under the authority provided by *Section (1) of Article 3 of Government Decree 22/2012 (Feb. 29) on the National Food Chain Safety Office*, in compliance with *Section (1) of Article 80 and Section (1) of Article 81 of Act CL of 2016 on general public administration procedures (hereinafter: Public Administration Procedures Act).*

The option to institute an appeal against this Resolution is available pursuant to *Section (1) of Article 114 of the Public Administration Procedures Act, Section (1) of Article 12, Sections (1)-(3) of Article 13, Section (1) of Article 29, Section (1) of Article 39, Sections (1)-(2) of Article 77 of Act I of 2017 on the code of administrative court procedure, furthermore, to Article 608 of Act CXXX of 2016 on the code of civil procedure, and to Paragraph d) of Section 17 of Article 1, Subparagraph aa) of Paragraph a) and Paragraph b) of Section (1) Article 9 of Act CCXXII of 2015 on the general rules of electronic administration and trust services.*

Budapest, 21 March 2019

Dr. Márton Oravecz
chairman
in his name, under duly provided
authorization:

László Jordán
director

l.s.

To:

1. Client
2. Archives



National Food Chain Safety Office
Directorate for Plant Protection,
Soil Conservation and Agri-Environment Protection
✉ H-1118 Budapest, Budaörsi út 141-145.
☎ +36 (1) 309 1000
E-mail: tea.registration@nebih.gov.hu
portal.nebih.gov.hu

Number of the authorization document: 6300/1003-1/2019 NÉBIH

MARKETING AND USE AUTHORIZATION DOCUMENT

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- *Natur Biokál 02*

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| Hg content (mg/l) | max. 1.0 |
| Ni content (mg/l) | max. 50.0 |
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Budapest, 21 March 2019

Dr. Márton Oravecz
chairman

in his name, under duly provided authorization:

László Jordán
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