Signed digitally by
Dr Szilvia Deim
2025.07.23. 16:09:58

NATIONAL PUBLIC HEALTH & PHARMACEUTICAL CENTER

Division for Chemical Safety and Competent Authority Matters.
Department for Biocidal Competent Authority Matters

File No.: NNGYK/30783-17/2025
Official in charge: Dr Dóra Helmle
Phone: +36 30 433 1503

Re: Authorization of the making available on the market of **Mosquito Control Liquid Deltasect PR 1.2 ULV**
Ref. No.: ---
Your contact: ---
Attachment: Annex 1 – Summary of Product Characteristics for a Biocidal Product (6 pages)

RESOLUTION

In a procedure initiated towards transitory authorization of a biocidal product known as **Mosquito Control Liquid Deltasect PR 1.2 ULV** (hereinafter 'the Product'), initiated upon application by **Dr László Kondár** (hereinafter 'Applicant') acting for and on behalf of **Sharda Hungary Kft** (Öv utca 182/B, H-1147 Budapest) (hereinafter 'Authorization Holder'), I herewith

authorize

the making available on the market and use of the Product in Hungary in Product Type 18 under Authorization No. **NNGYK/30783/2025**, subject to provisions as written below:

1 **A summary of characteristics relating to said biocidal product** is given in Annex 1 to this Resolution.

2 As long as the Product is made available on the market and used, all requirements as specified in document *'Summary of Product Characteristics for a Biocidal Product'* annexed to this Resolution shall be met continuously.

3 Any stocks of the Product as may be made available for sales shall have a formula and quality agreeing with the product specifications in the technical documents submitted in the authorization procedure, and meet relevant provisions in Government Decree 316/2013 (VIII.28.) *on certain rules for the authorization and marketing of biocidal products* (hereinafter 'Gov. Decree').

4 The Product shall not be made available on the market unless supplied with a label containing all mandatory content items based on document *'Summary of Product Characteristics for a Biocidal Product'* annexed to this Resolution, including its Authorization Number.

Authorization Holder has made payment of statutory administration service fees to amounts of HUF 129,600 and HUF 506,500.

Annex *'Summary of Product Characteristics for a Biocidal Product'* forms an integral part of this Resolution.

This Resolution will become final when communicated.

On the grounds of actionable injury, a client having a grievance against this Resolution may file an administrative lawsuit through a statement of claim addressed to Metropolitan Court of Budapest, but submitted to National Public Health & Pharmaceutical Center (hereinafter 'NNGYK'), in 30 days upon the issue of this Resolution. Any party acting through its legal representative or any business organization shall always submit its statement of claim via electronic channels.

If establishing a violation of law except for any procedural offence as may not have a material impact on judgement on the merits of the case, the Court will revise, set aside or invalidate the final resolution as requested by the client, and may, if need be, instruct the authority to conduct a new procedure. Finding no violation, the Court will reject the claim.

Filing a statement of claim will not have any suspensive effect on the going into effect of this Resolution.

The Court will pass its judgement on the claim out of court, but may have a hearing in the case upon request made by any of the parties concerned. A hearing can be requested via the claim, and in default of so doing there will be no room for an excuse. Court proceedings are subject to fees payable in accordance with the decision of the Court.

R E A S O N S

Via an application submitted to NNGYK on 2nd April, 2025, Applicant requested issue of an authorization certificate for the making available on the market of the Product in Hungary in Product Type 18.

Containing an existing active substance affected by the review programme, the Product has been authorized according to national rules pursuant to Article 89(2) of Regulation (EU) 528/2012 *concerning the making available on the market and use of biocidal products* (hereinafter 'EU Regulation').

Fees to amounts of HUF 129,600 and HUF 506,500, totalling HUF 636,100, shall be payable pursuant to Item VI.32 ('Authorization of the making available on the market of an insecticide, rodenticide or repellent') and Item VI.33.1 ('Expert opinion on an insecticide'), respectively, in Annex 1 to Decree 1/2009 (I.30.) (EüM) *on charges payable for certain administrative procedures and services delivered by the National Public Health & Medical Officers Service* (hereinafter 'EüM Decree').

Said administrative service fees payable for this procedure were paid by Authorization Holder on Treasury days 2nd April, 30th April, and 5th June, 2025.

Through its Order No. NNGYK/30783-2/2025 of 8th April 2025 (hereinafter 'the additional submission order'), NNGYK called Applicant for additional submission of missing data within a time limit of 8 days upon receipt of such Order, pursuant to § 24/A of Government Decree 316/2013 (VIII.28.) *on certain rules for the authorization and marketing of biocidal products* (hereinafter 'Gov. Decree'), § 44 of Act CL of 2016 *on the General Administrative Procedural Code* (hereinafter 'GAdP'), and Items VI.32 and VI.33.1 in Annex 1 to EüM Decree.

Applicant received the additional submission order in a verifiable manner on 25th April, 2025.

Via a letter of request received by NNGYK on 3rd May, 2025, Applicant requested suspension of the procedure, and, acceding to such request, I made a decision on suspension of the procedure as from 3rd May 2025 in accordance with §49(1) of GAdP.

During the suspension period, Applicant submitted additional documents on 3rd June, 2025, with a letter of notice No. NNGYK/30786-6/2025 of 4th June 2025 sent by NNGYK in reply.

Applicant made its additional submission of missing data called for on 25th June, 2025, requesting resumption of the procedure.

Through its Order No. NNGYK/30786-9/2025, NNGYK resumed the procedure as from 25th June, 2025, in accordance with §49(2) of GAdP.

Having reviewed the documents submitted, NNGYK found that corrections of the documents were needed to clear up the facts of the case, and used its Order No. NNGYK/30786-12/2025 of 3rd July 2025 to summon Applicant to make a statement in accordance with §63 of GAdP.

Applicant submitted its statement in reply on 14th July, 2025.

Having reviewed the statement submitted, NNGYK found that further corrections of the documents were needed to clear up the facts of the case, and used its Order No. NNGYK/30786-14/2025 of 15th July 2025 to summon Applicant to make a statement in accordance with §63 of GAdP.

Applicant submitted its statements in reply on 15th and 17th July, 2025.

Based on all documents submitted, the Product was found to be adequately efficient, and not to imply unacceptable risks, when used in compliance with the requirements in the annex to this Resolution.

In light of the foregoing, decisions as written in the operative part of this Resolution have been made.

This is to call Authorization Holder's attention to its obligation to keep track of any regulations or changes thereto as may be relevant to the Product. If Authorization Holder makes any changes to the formula, ingredients or manufacture of the Product, Authorization Holder shall have the Product authorized again.

This Resolution has been passed within power and authority as granted in § 24/A of Gov. Decree, acting on the basis of national competence and jurisdiction as granted in § 13(3) of Government Decree 385/2016 (XII.2.) *on delivery of public health duties by metropolitan and county-level government offices and district-level (or metropolitan district-level) offices, and appointment of a medical administrative body*.

This Resolution will become final when communicated pursuant to §82(1) of GAdP.

Options of legal remedy are ensured pursuant to § 114(1) of GAdP, and rules thereof are laid down in Act I of 2017 *on the Code of Administrative Procedure* (hereinafter 'CAP'). The competence and jurisdiction of the Metropolitan Court of Budapest have been determined on the basis of provisions in Annex 4 to Act CLXXXIV of 2010 *on the description and seat, and defining the scope of jurisdiction, of courts*.

The rate of duties payable is regulated in § 45/A(1) of Act XCIII of 1990 *on duties*, and § 62(1)h of the same Act contains provisions relevant to the right of prenotation of duties.

In Budapest, at the time and date as indicated by the timestamp

Dr Szilvia Deim
Head of Division

for and on behalf of

Dr Orsolya Surján
National Chief Medical Officer

Served on:

1 **Dr László Kondár**, via Office Gateway
2 National Agency for the Safety of Food Chain, via Office Gateway
3 Division for Microbiological Reference Laboratories, mrlf@nngyk.gov.hu
4 Files

Summary of Product Characteristics for a Biocidal Product

1. ADMINISTRATIVE INFORMATION

1.1 Trade name(s) of the product

Trade name	**Mosquito Control Liquid Deltasect PR 1.2 ULV**

1.2 Authorisation holder

Name and address of the authorisation holder	Name	Sharda Hungary Kft
	Address	Öv utca 182/B, H-1147 Budapest
NNK expert opinion number	NNGYK/30783-16/2025	
Authorisation number	**NNGYK/30783/2025**	

1.3 Manufacturer(s) of the product

Name of the manufacturer	Sharda Cropchem Ltd.
Address of the manufacturer	400056 Mumbai, 2nd floor, Prime Business Park, Vile Parle (West), India
Location of manufacturing sites	400056 Mumbai, 2nd floor, Prime Business Park, Vile Parle (West), India

Name of the manufacturer	Corax – Bioner Biotechnológiai Zrt
Address of the manufacturer	Gyár u. 2., H-2040 Budaörs, Hungary
Location of manufacturing sites	Gyár u. 2., H-2040 Budaörs, Hungary

1.4 Manufacturer(s) of the active substance(s)

Active substance	**deltamethrin**
Name of the manufacturer	Sharda Europe B.V.B.A. (Acting for Sharda Cropchem Limited (India))
Address of the manufacturer	Jozef Mertensstraat 142 1702 Dilbeek, Belgium
Location of manufacturing sites	2nd floor, Prime Business Park, Vile Parle (West), 400056 Mumbai, India

Active substance	**prallethrin**
Name of the manufacturer	Endura S.p.A.
Address of the manufacturer	Vile Pietro Pietramellara 5, 40121 Bologna, Italy
Location of manufacturing sites	Vile Pietro Pietramellara 5, 40121 Bologna, Italy

2. PRODUCT COMPOSITION AND FORMULATION

2.1 Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (m/m%)
Deltamethrin	**[(S)-Cyano(3-phenoxyohenyl) methyl]-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl cyclopropane-1-carboxylate**	**Active substance**	**52918-63-5**	**258-256-6**	**0.135**
Prallethrin	**(S)-2-methyl-4-oxo-3-prop-2-yn-1-ylcyclopent-2-en-1-yl(1R)-cis,trans-2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate**	**Active substance**	**23031-36-9**	**245-387-9**	**0.013**
Cyclohexanone	Cyclohexanone	Non-active substance	108-94-1	203-631-1	1.5
BHT	2,6-Di-tert-butyl-p-cresol	Non-active substance	128-37-0	204-991-4	< 0.001
Purified mineral oil (white oil)	Paraffin oil	Non-active substance	8042-47-5	232-455-8	98.3511

2.2 Type of formulation: liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	**H304** – May be fatal if swallowed and enters airways. **H410** – Very toxic to aquatic life with long lasting effects.
Precautionary statements	**P101** – If medical advice is needed, have product container or label at hand. **P261** – Avoid breathing vapours or spray. **P280** – Wear protective gloves, protective clothing, eye protection / face protection. **P301 + P310 + P331** – IF SWALLOWED: Immediately call a POISON CENTER or doctor / physician. Do NOT induce vomiting. **P405** – Store locked up. **P501** – Dispose of contents / container to a hazardous wastes dump site.

4. AUTHORISED USE(S)

4.1 Use description

Table 1 – #1 – Mosquito Control Liquid Deltasect Plus 1.2 ULV

Product type	Product type 18 – Insecticides, acaricides and products to control other arthropods (Pest control products)
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	Scientific name: *Aedes spp* Common name: Mosquitoes Development stage: Adults Scientific name: *Culex spp* Common name: Mosquitoes Development stage: Adults Scientific name: *Culicidae sp* Common name: Mosquitoes Development stage: Adults
Field(s) of use	outdoors
Application method(s)	A pesticide for handheld or ground application by thermal fogging, and handheld or ground application by ULV technique.
Application rate(s) and frequencies	**Application rates:** 0.6-0.8 L/ha depending on actual degrees of land coverage with vegetation. Choose the lower rate to treat rather open lands, or the upper rate to treat areas covered with vegetation partly or built up rather densely. Keep a 1-week interval at least between any two treatments. Apply 5 treatments at the maximum to any particular area, and have a 4-week break afterwards.
Category(ies) of users	Skilled professionals
Pack sizes and packaging material	Made available on the market with a fill volume of 20L in plastic (PE) cans; fill volume of 200L in metal barrels; fill volume of 1000L in IBC containers.

4.1.1 Use-specific instructions for use

4.1.2 Use-specific risk mitigation measures

4.1.3 Where specific to the use, particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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4.1.4 Where specific to the use, instructions for safe disposal of the product and its packaging

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4.1.5 Where specific to the use, conditions of storage and shelf-life of the product under normal conditions of storage

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5. GENERAL DIRECTIONS FOR USE[1]

5.1 Instructions for use

Ground applications using the ULV technique:
This kind of application is specifically recommended in open lands or those only partly covered with vegetation. Prior to treatment, calibrate your spray applicator, and adjust nozzles and pressure, to ensure that at least 90 % of spray droplets formed fall within the size range of 15 to 40 μm.
Pour undiluted product into the tank of your ULV applicator, and carry out a spraying test to determine the direction and velocity of air currents prevailing at the site.

Application rates:
0.6-0.8 L/ha depending on actual degrees of land coverage with vegetation. Choose the lower rate to treat rather open lands, or the upper rate to treat areas covered with vegetation or built up rather densely, respectively.

Application equipment:
Do not use anything for application of the product but an ULV machine specifically recommended by its manufacturer for outdoor mosquito control. Always use a regularly serviced ULV machine in good technical condition that is properly equipped for mosquito control projects. Prefer to choose units meeting European standards, bearing their factory-attached data plates.

Ground applications using the thermal fogging technique:
This kind of application is specifically recommended in areas thickly covered with vegetation.
Pour undiluted product into the tank of your thermal fogging machine, and carry out a spraying test to determine the direction and velocity of air currents prevailing at the site.

Application rates:
0.6-0.8 L/ha depending on actual degrees of land coverage with vegetation. Choose the lower rate to treat rather open lands, or the upper rate to treat areas covered with vegetation or built up rather densely, respectively.

Application equipment:
The product being oil-based, make sure, before starting to work, that your thermal mist generator is suitable for applying this type of chemicals. Do not use anything for application of the product but a thermal fogging machine specifically recommended by its manufacturer for outdoor mosquito control. Always use a regularly serviced thermal mist generator in good technical condition that is properly equipped for mosquito control projects. Prefer to choose units meeting European standards, bearing their factory-attached data plates.

Whenever applying Mosquito Control Liquid Deltasect PR 1.2 ULV, observe the following considerations:

- Except in epidemiological emergencies or in the event of a mosquito attack arising from floods, any treatment of continuous areas in excess of 10 hectares shall be governed by an IPM (Integrated Pest Management) program covering, among others, frequency of treatments and resistance management. Always consider treatment of mosquito breeding sites using biological methods.
- Prior to any application, carry out a survey for mosquito population densities in accordance with Chapter 7.4 of the guidance document titled ‘Information on authorized pesticides and technical guidelines of health pest control’, or using another objective measurement method, to justify your treatment project.
- Carry out thermal fogging or ULV applications in rainless and windless weather, and complete the job across the pre-determined area within a period from sunset to daybreak, taking daily activity peaks of harmful mosquito species into consideration. Do not apply any treatment at air temperatures below 15°C or with a side-wind velocity exceeding 2m/sec or when it is raining.
- If there are apiaries within the area to be treated, commence your mosquito control project one hour before astronomical sunset at the earliest, and finish one hour before astronomical sunrise at the latest.
- The vehicle carrying the applicator should travel at a speed of 15 to 20 km/h.
- Depending on the type of your applicator, the total area that can be treated hourly is 20 to 100 ha at the maximum via ULV application, or 100 ha at the maximum via thermal fogging application, respectively.
- Make sure that areas covered with trees and shrubbery remain befogged for 10 to 15 minutes at least to let the product keep in contact with mosquitoes for a sufficiently long time.
- Under optimal conditions, the mist formed will spread in the air at a width of about 25 metres on either side along the line of travel, consequently a treatment strip about 50 metres wide can be reckoned with. Actual spread sizes will, however, be largely dependent upon prevailing conditions of the application.
- While treating a large continuous area, monitor for actual per hectare consumption of the product (by calculation from quantities used up) during the application and, if need be, select application routes closer to one another for

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorized uses.

correction. Such monitoring is especially reasonable where a small-size machine with nominal outputs of 50-70 L/hour is used.

- To protect bees, the municipal notary of the competent local government shall be notified in writing, with such notification containing all data as required, of any outdoor insect control project to be performed across an area exceeding 1 hectare, before 9am on the workday preceding the date of application, pursuant to § 17, Clause (1), of Decree 16/2017 (VIII.7.) (EMMI) on rules of activities using public health pesticides or fumigants.
- The competent district office shall be notified, with such notification containing all data as required, of any mosquito control project to be performed using a ground vehicle, before 9am on the workday preceding the date of application, pursuant to § 16, Clause (9), of Decree 16/2017 (VIII.7.) (EMMI) on rules of activities using public health pesticides or fumigants.
- Applying the product, respect a buffer zone of 50 metres to the coast of still waters and watercourses (calculated as a safety zone of 25 metres + an optimum lateral mist spread size of 25 metres). Accordingly, the vehicle carrying the applicator must not travel closer than 50 metres to such a coastline (i.e. the land-to-water interface).

5.2 Risk mitigation measures

- Use only for insect control in accordance with its directions for use.
- Use personal protective equipment when applying the pesticide. After handling the product, wash hands thoroughly with soap and hot water.
- Call a doctor / physician if you feel unwell. If swallowed, show the container and label to the doctor / physician. Storage and use of the product shall comply with relevant provisions in Decree 16/2017 (VIII.7.) (EMMI).
- Prior to commencement of an application, the community of the area affected shall be informed. The competent local municipality that has ordered treatment or governs the area to be treated will be responsible to inform the local community. The person in charge of pesticide applications will be responsible to notify the competent municipality of their obligation to inform the community. Information channels available for use include printed, broadcast and on-line communications, and efforts must be made to ensure that the broadest possible range of inhabitants is reached. Information communicated shall include:
  - exact time and date of the application,
  - village / town, or area within, affected by the application,
  - name of the pesticide and description of the application technique used,
  - recommended measures to be taken by the community as follows: *'Remove or cover children's toys, foods, cutlery, and laundry stored or dried outdoors on the day of the application. Keep windows and doors closed, and inactivate artificial ventilation equipment using outdoor air, for the duration of the application + 1 more hour afterwards. Prior to consumption or processing, wash vegetables and fruits grown within the area treated. Never stay in the immediate vicinity of the vehicle carrying the applicator. Mosquito larvae can grow in uncovered cisterns, or any other outdoor objects as may catch rainwater, in a matter of a week. To amplify mosquito control projects, real estate owners are recommended to eliminate, regularly empty or cover any stagnant waters as may accumulate around their buildings.'*
- Prior to the commencement of a treatment project, the person in charge of pesticide applications shall obtain a statement from the competent local municipality to the effect that the community has been informed as specified above.

5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

General first-aid instructions:
NEVER leave a poisoned person alone!
Should medical attention be needed, keep the product label or container at hand, and call a poison center.

Upon skin contact: Immediately remove / take off contaminated clothing, and wash affected skin with soap and plenty of water without rubbing.
Upon eye contact: Rinse the eyes cautiously with plenty of water. Remove contact lenses if present and easy to do. Continue rinsing with an eye wash or water. If eye irritation persists, seek medical attention.
If swallowed: Rinse mouth with water. Let the victim drink much water. Call a poison center or doctor / physician if you feel unwell. Do NOT induce vomiting.
If inhaled: Remove the victim to fresh air and keep at rest in a position comfortable for breathing. Call a doctor / physician if the symptoms grow worse or persist.

Environmental precautions:
Prevent any release of the product or its unused leftovers or container into live waters, soil or public sewers.

When pouring the product or cleaning the applicator, take care to prevent any release of the pesticide into the soil or surface waters. To this end, always carry out pouring or cleaning operations in a paved area or one covered with a waterproof canvas, and collect any spills and water contaminated with the pesticide.

5.4 Instructions for safe disposal of the product and its packaging

Any redundant pesticide or that with its shelf-life expired shall be kept in its original container until disposal. Leftovers and containers of the product and any other wastes contaminated with the pesticide shall be disposed of as hazardous wastes, and users will be responsible to have such wastes treated in accordance with relevant provisions in Government Decree 225/2015 (VIII.7.).

5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Store the product in its original closed container in a dry, cool, and well-ventilated place protected against frost and light, away from food and feeding stuffs. Keep out of the reach of children and animals / pets. Shelf-life: 2 years from the date of manufacture. (Such information as batch number or symbol and shelf-life under normal storage conditions shall be indicated on each individual pack.)

6. OTHER INFORMATION

The label shall cover the following details:

Mosquito Control Liquid Deltasect PR 1.2 ULV
A pesticide with Marketing Category II
Active substances: Deltamethrin 0.135% + prallethrin 0.013 %
Authorization holder: Sharda Hungary Kft., Öv utca 182/B, H-1147 Budapest
Biocidal products authorization number: NNGYK/30783/2025
and sections of this document as listed below:
3, 4 (except for passages on pack sizes and packaging material), 5.