



**Certificat d'analyse / Analysis certificate**  
**Certificat de libération / Release certificate**

PRODUIT / PRODUCT : DELNANIL FLEXIBAG 2,5L VBI  
 Code produit / Code product : 308702  
 Date de fabrication / Manufacturing date : July 2019

LOT N° / BATCH N° : 7EM3  
 Quantité / Quantity : 354 P  
 Date de validité / Expiry date : June 2024

Lot Informatique / IT batch number 2498263

Date d'édition / printed on :  
 July 30, 2019

| ANALYSES / ANALYSIS            | RESULTATS / RESULTS | NORMES / STANDARDS   |
|--------------------------------|---------------------|--|
| <b>CHARACTERS</b>              |                     |  |
| Appearance of product          | Passed              | Slightly yellowish clear oily solution   |
| Appearance of packaging        | Passed              | aluminium-coloured flexible pouches 2,5L equipped by a screw cap and a transfer device |
| Density                        | 0.949 g/ml          | 0.940 to 0.960 g/ml  |
| Water content                  | 0 %                 | Max. 1 %   |
| Extractable volume for pouches | Passed              | Min 2500 ml  |
| <b>IDENTIFICATIONS</b>         |                     |  |
| Deltamethrin (HPLC/UV)         | Passed              | RT and UV identical to reference   |
| <b>TESTS</b>                   |                     |  |
| TMAC                           | <10                 | Max 100 CFU/g  |
| TYMC                           | <10                 | Max 10 CFU/g   |
| Pseudomonas aeruginosa         | Passed              | Absence/1g   |
| Staphylococcus aureus          | Passed              | Absence/1g   |
| <b>ASSAYS</b>                  |                     |  |
| Deltamethrin (HPLC)            | 0.98 g/100ml        | 0.95 to 1.05 g/100ml   |

Je certifie que ces informations sont exactes et authentiques. Ce lot a été fabriqué, y compris l'emballage / étiquetage et le contrôle qualité, en conformité avec les BPF en vigueur. Dans le cas d'un produit avec une autorisation de mise sur le marché, je certifie que toutes les étapes de fabrication de ce lot sont conformes aux spécifications de l'AMM du (ou des) pays de destination.

I hereby certify that all this information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control in full compliance with the applicable GMP requirements. In case of product with marketing authorization, I certify that all manufacturing steps of this batch are in compliance with the marketing authorization specifications of the importing country(ies).

Date de libération/Release date

Personne qualifiée/Qualified person

Signature

30 JUL. 2019

PA. MAGNIN

Virbac

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Siège social - 1<sup>er</sup> avenue 2065 m - LID - 06516 Carros - société anonyme à directoire et conseil de surveillance au capital de 10.572.500 euros - 417 350 311 RCS Grasse

Meoszám:190800024MBT

5.pld. Kiadva: 19/08/27

MEDIMPEX GYÓGYSZER ZRT.  
 1158 Bp., Rákospalotai határút 2.  
 Nagyné Káti Éva  
 Minőségbiztosító szakasszisztens  
 Csak a piros szín hiteles

**Virbac**

### BATCH RELEASE CERTIFICATE

|                |          |
|----------------|----------|
| CODE           | 308702   |
| QUANTITY       | 354 P    |
| FINAL DECISION | Accepted |

|   |  |
|---|--|
| NAME OF PRODUCT   | DELTANIL POUR ON 2,5L VBI  |
| COUNTRIES FOR WHICH THE PRODUCT HAS A MARKETING AUTHORIZATION | Austria-Belgium-Germany-Netherlands-Denmark                          |
| MARKETING AUTHORISATION NUMBER                                | Zul. Nr :835334-BE-V486222-401662.00.00-<br>REG NL 111025-MTnr.49900 |
| STRENGTH/POTENCY  | Cf CoA   |
| PHARMACEUTICAL FORM   | Liquid preparations for cutaneous application                        |
| PACKAGE SIZE / TYPE   | Cf CoA   |
| BATCH NUMBER  | 7EM3   |
| DATE OF MANUFACTURE   | 07 / 2019  |
| EXPIRY DATE   | 06 / 2024  |
| ALL MANUFACTURING & QUALITY CONTROL SITES                     | VIRBAC 1 <sup>ère</sup> avenue - 2065 m<br>06516 CARROS CEDEX (FR)   |
| CERTIFICATE OF GMP COMPLIANCE OF ALL SITES LISTED UNDER 10    | V 0296/79  |
| RESULTS OF ANALYSIS   | Cf CoA   |
| COMMENTS / REMARKS  |  |

Printed on : 30/07/19

#### 14. CERTIFICATION STATEMENT

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control, at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging, and analysis records have been reviewed and found to be in compliance with GMP.

Release date

Qualified person

Signature

30 JUL. 2019

PA. MAGNIN



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