

HUNGARY
22016915



Site de Lyon-Porte-des-Alpes
Rue de l'Aviation
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Tél.: +33 (0) 4 72 72 30 00
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EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **RUVAX**

MEMBER STATE SPECIFIC INFORMATION

Batch number of finished product: L418428

Release date of finished product: 17-Jan-2015

Marketing authorisation number: 2977/4/11

Issued by: HUNGARY

Target species: PIGS

Total number of containers in this batch: 250

Number of containers the release is applied for: 250

Number of doses per container: Bottle of 250 mL

Number of samples for the competent authority: Available upon request

Date of expiry: 29-Apr-2016

Name and Address of Marketing Authorisation Holder:

MERIAL
29, avenue Tony Garnier
69007 LYON
France

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SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name: RUVAX

INN / PE name / common name of product: Swine Erysipelas (inactivated, adjuvanted) vaccine

Batch number of:

| Finished product: | Final batch: | Final bulk: |
|-------------------|--------------|-------------|
| L418428 | 4RVX0541 | 4RVX0540 |

Pharmaceutical form of finished product: Suspension for injection

Type of final container: Bottle of polypropylene

Date of start of period of validity: 29-Apr-2014

Storage: 2°C-8°C

Name and address of manufacturer:

MERIAL
Lentilly
1, chemin de Cruzols
69210 Lentilly
FRANCE

Name and address of the batch release site :

MERIAL
Lyon Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
FRANCE


COMMENT: 4RVX0541- The expiry date is calculated using the formulation date.

CERTIFICATION BY THE MANUFACTURER

I herewith certify that batch RUVAX n° L418428 was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirement and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended by Directive 2004/28/EC.

Date: 23-Jan-2015

Signature


Dr Marc TEICHNER
Deputy Qualified Person
MERIAL LYON

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