

EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **DIFTOSEC CT**

MEMBER STATE SPECIFIC INFORMATION

Batch number of finished product: L419507

Release date of finished product: 23-Mar-2015

Marketing authorisation number: 2409/1/08 MgSzH ATI

Issued by: hungary

Target species: avian

Total number of containers in this batch: 100 boxes of 10 units

Number of containers the release is applied for: 100 boxes of 10 units

Number of doses per container: Bottle of 1000 doses

Number of samples for the competent authority: Available upon request

Date of expiry: 28-Aug-2016

Name and Address of Marketing Authorisation Holder:

MERIAL
29, avenue Tony Garnier
69007 LYON
France

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name: DIFTOSEC CT

INN / PE name / common name of product: Fowl-pox (live) vaccine

Batch number of:

| Finished product: | Final batch: | Final bulk: |
|-------------------|--------------|-------------|
| L419507 | 4SGD0831 | 4SGD0830 |
| L419507 | 4DCC3031 | 4DCC0030 |

Pharmaceutical form of finished product: Lyophilisate and solvent for suspension for injection

Type of final container: Bottle of glass

Date of start of period of validity: 28-Nov-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

CERTIFICATION BY THE MANUFACTURER

I herewith certify that batch DIFTOSEC CT n° L419507 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: 24-Mar-2015

Signature

Dr Olivier MONTET
Pharmacien Adjoint
MERIAL Lyon Porte des Alpes