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## EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **BTVPUR (serotype 4)**

### MEMBER STATE SPECIFIC INFORMATION

**Batch number of finished product:** L443850

**Release date of finished product:** 03-Apr-2017

**Marketing authorisation number:** EU/2/10/113/028

**Issued by:** EMEA LONDON UK

**Target species:** CATTLE/SHEEP

**Total number of containers in this batch:** 22133 boxes of 1 unit

**Number of containers the release is applied for:** 22133 boxes of 1 unit

**Number of doses per container:** Bottle of 50 doses

**Number of samples for the competent authority:** Available upon request

**Date of expiry:** 27-Jul-2018

**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:** BTVPUR (serotype 4)

**INN / PE name / common name of product:** Bluetongue virus (inactivated, adjuvanted) vaccine

**Batch number of:**

Finished product:	Final batch:	Final bulk:
L443850	17BR40A11	17BR40A10

**Pharmaceutical form of finished product:** Suspension for injection

**Type of final container:** Bottle of polypropylene

**Date of start of period of validity:** 27-Jan-2017

**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 BTVPUR (serotype 4) n° L443850 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: 13-Apr-2017

Signature:

Dr Magali BENABEN  
Substitute Deputy Qualified Person  
Merial Lyon