

## MINIMIZING THE RISK OF TSE IN ANIMAL DERIVATIVES

See the “Note for Guidance of Minimising the Risk of Transmissible Animal Spongiform Encephalopathy Agent – TSE - via medicinal products” European Agency for Evaluation of Medicinal Products.

NAME OF THE PRODUCT: **COLUMBIA AGAR BASE**

VWR reference number **84621.0500**

### DESCRIPTION OF THE MATERIAL

Columbia agar base is a mixture of peptones, organic and inorganic compounds to achieve a culture medium suitable for general purposes in microbiology.

### TRACEABILITY

The traceability of production and distribution activities are described by SOPs n° PAQ02 and ILPR01. The traceability of raw materials and finished products is subject to audit under ISO 9001/ ISO 13485 certifications.

### MANUFACTURING

The Typical formula of COLUMBIA AGAR BASE includes the following peptones of animal origin:

INGREDIENT / REF	TISSUE (AS DECLARED BY THE MANUFACTURER)	COUNTRY OF ORIGIN OF ANIMALS (AS DECLARED BY THE MANUFACTURER)	CATEGORY	NOTES N°
<b>Meat peptone</b> BL2BEP039	Beef lung	New Zealand	IB * / III**	1
<b>Casein peptone</b> BL2BEP010	Bovine Milk	Australia/New Zealand	IV**	12A
<b>Brian Heart Infusion Pork</b> BL2BEP005P	Pork brain and heart	Brazil		20

\*as defined in EMEA/410/01 rev 3

\*\* as defined according to WHO/EMC/ZOO097.3

#### Note 1

**Meat Peptone** has been certified by Directorate for Quality Medicines (Certification of suitability of monographs of the European Pharmacopoeia n° RO-CEP 2001-291-Rev 01). Each batch is supplied with the Sanitary Certificate.

Each batch is supplied with a Manufacturer's certificate declaring that:

The product has been heated to a minimum of 80°C for a minimum of 1 hour including a minimum of 30 minutes at a minimum of 105°C

During processing no commingling or in any manner mixing with any animal material does occur

The product was dried at a minimum of 140°C

Before, during and after completion of drying process every precaution was taken to prevent contamination of the product

Country of origin of animals: New Zealand

Country of born, raised and slaughtered: New Zealand

Country of manufacture of finished product: Mexico

Enzyme animal species: porcine (derived from pancreas/stomach); country of origin: USA

**Note 12A**

**Casein peptone.** Each batch is supplied with the Sanitary Certificate declaring that:

Among the raw materials and auxiliaries used in its preparation, the milk casein is of bovine origin. It is sourced in New Zealand and Australia, under veterinary control.

Pancreatin used is issued from pigs pancreas coming from France. Enzyme is issued from pigs coming from holdings free from foot-and-mouth disease and not subjected to sanitary restrictions linked to infectious diseases of the species.

Furthermore, the manufacturing process includes boiling at 100°C for a minimum of 5 minutes and instantaneous heating at 150°C on spray drying

**Note 20**

**Brian Heart Infusion Pork** Each batch is supplied with the Sanitary Certificate declaring that:

The mentioned product doesn't contain and is not derived from specific risk material defined in Commission Decision 2000/418/EC

The raw materials were collected in Brazil and come from abattoirs controlled by Brazilian Agriculture Ministry.

The raw materials were obtained from animals not showing, during ante and post mortem inspection at slaughter, signs or evidence of diseases communicable to humans.

The manufacturing process includes at least 30 minutes heat treatment at  $95 \pm 5$  °C

The enzymes used during manufacturing process are obtained from non-animal origin sources.

**PROCESS VALIDATION**

VWR has no information regarding prion inactivation studies. However origin materials come from countries with no endemic cases of BSE.

The information here enclosed are confidential and should be used only for regulatory purposes.

Name: **Leen Van Nerum**

Position: **QA Private Label Chemicals**

Rev. 0 - Date 20-06-2016

Signature

