

SWATI SPENTOSE PVT. LTD. UNIT-I

Manufacturing Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India

DATE:

25/04/2019

TO WHOMEVER IT MAY CONCERN

Transmitting Animal Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE) Declaration

PRODUCT: Prilocaine Hydrochloride

CAS No.: 1786-81-8

We Swati Spentose Pvt. Ltd Unit-I declare and certify, that manufacturing of the above product here at the site A-1/2102 & 2103, Phase-III, G.I.D.C., Vapi- 396195, Gujarat. India contains no ingredients of animal origin and no materials derived from, or exposed to animals affected by, or under quarantine for Transmitting Animal Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE). This is conformed under guidance of "EMA/410/01/rev03" expression in the TSE BSE docs.

Above product is produced in a facility where no animal, animal products, animal by-products, veterinary vaccines or animal pathogens are maintained. The above product is packed in a packaging that can be identified as to the nature of the product and the country of origin.

The validity of this certificate is 3 years from the date of issue.

For, Swati Spentose Private Limited Unit-I.

Authorized Signature

Mr. S. K. Srivastava

Corporate Head (QA & QC)

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