



CVMP PUBLIC STATEMENT

ON

CPMP PUBLIC STATEMENT

"LACTOSE PREPARED USING CALF RENNET: RISK ASSESSMENT IN RELATIONSHIP TO BOVINE SPONGIFORM ENCEPHALOPATHIES (BSE)"

The CVMP endorses the Public Statement by the CPMP 'Lactose prepared using calf rennet: risk assessment in relationship to bovine spongiform encephalopathies (BSE)'.

The CVMP clarifies that:

- i. The risk assessment applies only to pharmaceutical grade lactose prepared using calf rennet¹.
- ii. A full risk assessment would still be required for lactose produced using any other materials of ruminant origin that fall within the scope of the Note for Guidance EMEA/410/01-Rev.1².

¹ When produced from milk sourced from healthy animals in the same conditions as milk collected for human consumption.

² Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01-Rev.1)
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