



BSE / TSE Declaration Template

TO WHOM IT MAY CONCERN

TSE COMPLIANCE STATEMENT

Sodium Hydroxide 10N Solution, Bio Pharma Grade, product code NAHY-4150 has been assessed in respect to materials identified in the “Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01 Rev 3)”.

No risk materials identified in this guidance are:

- Used as reagents or starting materials, or media used to prepare cell banks
- Used as cleaning agents, lubricants, and softeners that are product contact
- Used as culture media in media fill exercises
- Used in product contact packaging
- Used in the same equipment, or part of the manufacture of another material manufactured in the same equipment
- Used in another product within the same facility and have a potential to cross contaminate the material in question

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