

Specifications for teats for feeding IS 3565:2018

The teats are devices designed to fit on the neck of a feeding bottle, allowing controlled flow of liquid for infant feeding. They are typically made of natural rubber or silicone rubber.

Consumer expectations:

Teats must be **free from harmful substances** like lead, cadmium, and phthalates, which can pose health risks to infants. The material should be **easy to clean and sterilize**, preventing bacterial growth and should withstand repeated use and sterilization without cracking or deteriorating. Its shape and nipple should mimic natural breastfeeding, providing a comfortable feeding experience for the baby. It should allow **controlled liquid flow, preventing choking** and ensuring proper nutrition intake.

· Material Safety:

- Teats should be made from natural or silicone rubber without harmful additives.
- They must be free from any compounds that could leach out and contaminate milk or food, impart undesirable tastes, or cause skin irritation.

· Physical Requirements:

- The teats should be clear or translucent, free from visual defects like blisters or embedded particles.
- They should be able to withstand autoclaving (high-heat cleaning) without deforming or cracking.

· Chemical Safety:

- The teats must meet limits on the release of harmful chemicals, such as N-Nitrosamines, heavy metals (like lead and mercury), and other toxic substances.
- Testing protocols are specified to ensure that exposure to these chemicals remains within safe limits.

· Mechanical Strength:

- Teats should resist tearing and must pass tensile strength tests, ensuring they don't puncture easily during use.

· Packaging and Labeling:

- Each teat should be individually packed and labeled with key information, such as the manufacturer, production date, and usage instructions.
- Safety warnings, including instructions on boiling for sterilization, should be included

IS 3565: 2018 addressed the above mentioned expectation by the following tests as specified in the standard.

· **Material Safety:**

- Use **Approved Materials:** Only natural or silicone rubber should be used, and the mix must exclude harmful substances. Avoid any recycled rubber, grits, or toxic additives.
- **Avoid Harmful Ingredients:** Ensure that any vulcanizing agents, antioxidants, or accelerators used do not leach harmful compounds into milk or food. This requires sourcing high-quality, food-grade ingredients and verifying their safety.

· **Physical Quality Control:**

- **Visual Inspection:** Conduct thorough visual inspections to ensure teats are clear or translucent and free from blisters, porosity, or other defects.
- **Autoclave Resistance Testing:** Test teats for deformation by subjecting them to autoclaving (as per Annex A of the document) and ensuring they do not show any signs of deterioration, such as cracks or color changes.

· **Chemical Testing:**

• **Limit Release of Hazardous Chemicals:**

- **Heavy Metal Migration Test:** Follow the procedure specified in the standard (see Table 3) to check for metals like lead, cadmium, mercury, and arsenic, ensuring they are within permissible levels.
- **N-Nitrosamines and N-Nitrosatable Substances:** Perform extractions as outlined in Annex G, using gas chromatography to verify that N-Nitrosamines and N-Nitrosatables remain below 0.01 mg/kg and 0.1 mg/kg, respectively.
- **2-Mercaptobenzothiazole (MBT) and Antioxidants:** Check migration levels of MBT and antioxidants through high-performance liquid chromatography (HPLC) as detailed in Annex H, ensuring MBT levels are below 8 mg/kg and antioxidant residues are within prescribed limits.

· **Mechanical Strength Testing:**

- **Tear and Tensile Tests:** Test the teats for tear resistance (Annex K) and tensile strength (Annex L) to ensure durability and prevent punctures during use. If a teat punctures in the tear resistance test, conduct a tensile test to confirm its strength.

· **Packaging and Labeling Requirements:**

- **Individual Packaging and Information:** Each teat should be packaged in a protective, hygienic wrapper with clear instructions on care, such as boiling before the first use and avoiding direct sunlight exposure. Instructions should include warnings (like avoiding prolonged sucking to prevent tooth decay).
- **Marking and Labeling:** Clearly label the packaging with the manufacturer's name, production date, batch number, and type of material used. If the teat contains natural rubber latex, include an allergy warning as specified.

