



Standard Specification for Volatile *N*-Nitrosamine Levels in Rubber Nipples on Pacifiers¹

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1. Scope

1.1 This specification applies to the nitrosamine content of rubber used in the manufacture of nipples for infant pacifiers.

1.2 This specification does not apply to plastic nipples (on pacifiers).

1.3 The purpose of this specification is to establish a maximum level of allowed nitrosamines in rubber nipples and to outline a uniform testing method to determine such level.

1.4 The values stated in SI units are to be regarded as standard. The values given in parentheses are for information only.

1.5 The following precautionary statement pertains only to the test method portions, Sections 5, and Appendix X4 of this specification. *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* Specific hazards are given in Appendix X2.

2. Terminology

2.1 Definitions:

2.1.1 *lot*—normal production run or, in the case of imports, a shipment of items produced in the same time frame.

2.1.2 *nitrosamines*—chemically active compounds principally formed by the reaction of amines with oxides of nitrogen present in the environment.

3. Significance and Use

3.1 This specification is intended for use in reducing the normal exposure to nitrosamines.

¹ This specification is under the jurisdiction of ASTM Committee F15 on Consumer Products and is the direct responsibility of Subcommittee F15.22 on Toy Safety.

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3.2 This specification refers only by way of example to the eight volatile *N*-nitrosamines identified below:

- 3.2.1 *N*-nitrosodimethylamine,
- 3.2.2 *N*-nitrosodiethylamine,
- 3.2.3 *N*-nitrosodibutylamine,
- 3.2.4 *N*-nitrosomorpholine,
- 3.2.5 *N*-nitrosopiperidine,
- 3.2.6 *N*-nitrosopyrrolidine,
- 3.2.7 *N*-ethylphenylnitrosamine.

4. Test Method

4.1 Determine nitrosamine levels by using either the methylene chloride extraction method described in the collaborative study conducted by the National Center for Toxicological Research² or the Food and Drug Administration method.²

5. Acceptable Level

5.1 A test sample of nipples, drawn from a standard production lot, shall not contain more than 10 ppb (in each of 3 aliquots) of any one nitrosamine. In addition, the total nitrosamines of the sample shall not exceed 20 ppb.

5.2 Each manufacturer or distributor of the product shall test the product in such a manner and at such intervals to ensure compliance in accordance with the methodology prescribed by the test procedure utilized. Records of all testing shall be retained for a period of up to three years.

6. Report

6.1 Report the following information:

- 6.1.1 Lot number,
- 6.1.2 Date samples,
- 6.1.3 Date tested,
- 6.1.4 Individual nitrosamine content, and
- 6.1.5 Total nitrosamine content.

² Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.