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Safety requirements of soothers for babies and young children

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Foreword

The technical content of this standard is mandatory.

This standard is drafted in accordance with the rules given in GB/T 1.1-2009 “Directives for standardization - Part 1: Structure and drafting of standards”.

This standard modifies and adopts the EN 1400-1:2002 “Child use and care articles - Soothers for babies and young children - Part 1: General safety requirements and product information”, EN 1400-2:2002 “Child use and care articles - Soothers for babies and young children - Part 2: Mechanical requirements and tests” and EN1400-3:2002 “Child use and care articles - Soothers for babies and young children - Part 3: Chemical requirements and tests”, AND the main differences between this standard and EN 1400 series standards are as follows:

- ADD the phthalate content requirements and test methods;

- ADD the informative appendix “Method for determining the amount of N-nitrosamines and N-nitrosamines deliverables in soothers”. Please note that some of the contents of this document may be related to patents. The issuer of this document does not assume responsibility for the identification of these patents.

This standard was proposed by the China Light Industry Federation.

This standard shall be under the jurisdiction of the National Toy Standardization Technical Committee (SAC/TC 253).

The drafting organizations of the standard: Guangdong Entry-Exit Inspection and Quarantine Bureau Inspection & Quarantine Technology Center Toy Laboratory, Good boy Products Co., Ltd., Beijing Certification Center of Light Industry Council, Guangzhou Weikai Detection Technology Research Institute, Shenzhen Entry-Exit Inspection and Quarantine Bureau Toy Testing Technology Center, Guangdong Entry-Exit Inspection and Quarantine Bureau East Guangdong Toy Testing Center.

The main drafters of this standard: Liu Yongjian, Li Shili, Lei Zaiming, Zhang Yanfen, Yi Lezhou, Wang Mei, Xu Xiaoguang, Wang Xinyu.

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Safety requirements of soothers for babies and young children

1 Scope

This standard specifies the terms and definitions, safety requirements, test methods, packaging methods and product information of soothers for babies and young children.

This standard applies to the products that resemble OR function as a soother for babies and young children unless they are being marketed as medical devices.

This standard does not apply to products designed for specialist medical applications, e.g., those relating to Pierre-Robin Syndrome or premature babies. These special cases are described in the informative Appendix A.

This standard does not apply to feeding teats.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this Standard.

GB/T 131 Geometrical product specification (GPS) - Indication of surface texture in technical product documentation

GB/T 2828.1 Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

GB/T 2918 Plastics - Standard atmospheres for conditioning and testing

GB/T 3512 Rubber, vulcanized or thermoplastics - Accelerated ageing and heat resistance test

GB/T 6682 Water for analytical laboratory use - Specification and test methods

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GB/T 22048 Toys and children products - Determination of phthalate plasticizers in polyvinyl chloride plastic

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Soother

Article intended for satisfying the non-nutritive sucking need of children.

Note: Soother is also known as pacifiers or babies' dummies.

3.2

Teat

Flexible nipple which is the part of the soother designed to be placed in the mouth.

3.3

Shield

Structure positioned at the rear of the teat to reduce the likelihood of the soother being drawn entirely into the child's mouth.

3.4

Ring or knob

Structure positioned adjacent to OR on the shield to facilitate handling of the soother.

Note: The ring, knob or cover can be integral with the shield or plug or it can be a separate component that is attached to the shield or plug.

3.5

Plug

Device located within the neck of the teat that secures the teat to the shield.

3.6

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If used, imprinted and molded decorations shall be applied only to the parts of the soother behind the sucking face of the shield (SEE Figure 1 to Figure 4). Adhesive labels and decorations shall not be used.

If the soother contains loose particles to produce a rattle effect, the particles shall be inert smooth beads. Such beads shall not be present in the teat.

5.2 Construction

5.2.1 General requirements

The soother shall be free from any sharp projecting points or edges. The surface of the sucking part shall be smooth. The soother shall have no removable parts.

Note: Soothers have been known to become lodged in a child's mouth. Attention shall therefore be made to the design of all soother components to allow the assembled soother to be gripped as easily as possible, thereby facilitating removal of the soother from the child's mouth.

5.2.2 Teat

The effective penetration of the teat shall be a maximum of 35 mm. It shall be checked using for example the test penetration gauge as shown in Figure 5. The soother shall be inserted into the center of the gauge with its major axis vertical and its teat in a downward position. The jaws of the gauge shall be adjusted until they just touch the neck of the teat. The soother shall be rotated to obtain the greatest depth of penetration, solely under the weight of the soother. The tip of the teat shall not touch the top of the gauge block as shown in Figure 6.

Note: Adjust the opening of the jaws slightly if the teat does not have a circular cross section.

The test shall not include any hole in front of the shield.

Any hollow section of the teat shall not contain solid, fluid or gaseous substances (except air) nor shall contain any inserts except for the plug.

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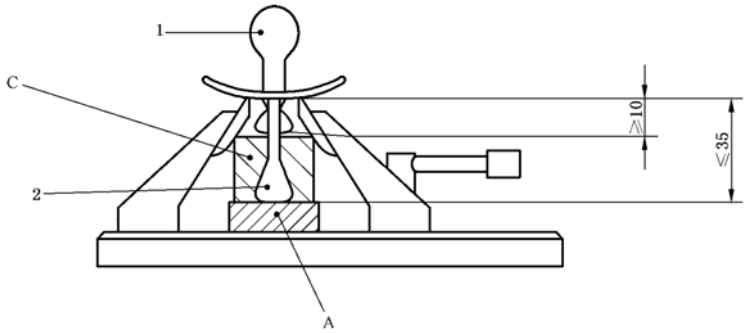

Description:

A - Gauge block “A”;

C - Gauge block “C”;

1 - Teat;

2 - Flexible ring or knob.

Figure 9 -- Test penetration gauge measuring flexible soother ring or flexible knob (SEE 5.2.5.2)

5.2.3 Shield

5.2.3.1 General requirements

The soother shall incorporate a shield. The shield shall be tested as described in 5.2.3.2 AND shall not pull through the template with the shield in any orientation, about the major axis of the soother, relative to the template.

The shield shall have at least two ventilation holes, each of which shall have an area of at least 20 mm^2 and shall allow the unhindered passage of a 4 mm diameter rod even when the ring, if present, is in contact with the shield.

The centers of the two holes shall be at least 15 mm apart and their edges shall be at least 5 mm from the edge of the shield.

The two holes shall be symmetrically located on either side of the axis of the shield and in the case of non-circular shields this requirement shall relate to the minor axis (SEE Figure 10).

Note 1: Certain types of ventilation holes have given rise to finger injuries. Non-circular holes shall avoid V-shaped angles or inward facing angles that are not well rounded, as both these features can lead to fingers becoming caught and injured, SEE 5.2.6.

Note 2: The shape of the edge of the shield and the size, shape and position of ventilation holes affect the ease with which the shield can be gripped in the event of the soother becoming lodged in a child’s mouth.

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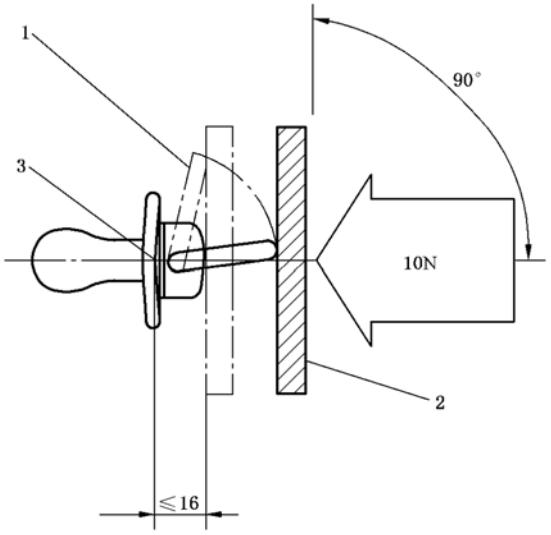
The shape of the ring shall permit the unhindered passage of a test rod with a diameter of at least 14 mm.

The ring shall be either hinged, or free to swivel, or alternatively made of material having sufficient flexibility to meet the requirements. When a force of 10 N ± 0.5 N is applied to the ring, along the major axis of the soother, the ring shall collapse to 16 mm or less above the shield. If necessary, the ring shall be moved slightly to one side of the axis before applying the force and the measurement shall be made from the rear of the shield along the major axis. Test is as shown in Figure 14.

The unit is in millimeters



Description:

1 - Position of ring following applied force of 10 N;

2 - Flat plate;

3 - Rear face of the shield along the major axis.

Figure 14 -- Flexibility requirements of ring (SEE 5.2.4)

Soother fitted with rings that do not meet all the above requirements shall be treated as if they are fitted with a knob (SEE 5.2.5).

The ring shall be accessible, even if it is in contact with the shield, so that in the event of the entire soother entering a child's mouth the ring can be an aid in the removal of the soother. The size, shape and place of attachment of the ring affect is accessibility and the extent to which it might hinder the removal of the soother from the child's mouth.

5.2.5 Knob, plug and/or cover

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6 Mechanical performance requirements

6.1 Impact resistance

The soother shall be tested as described in 7.2.1, AND no part shall break, tear or separate during this test or the tensile strength test as described in 7.2.7.1.

6.2 Puncture resistance

The soother shall be tested in accordance with 7.2.2.

When tested for puncture resistance as described in 7.2.2.1, the load to cut completely through one wall of the teat shall be greater than 30 N.

If the soother is fitted with a flexible knob, when tested for puncture resistance as described in 7.2.2.2, the load to cut completely through one wall of the knob shall be greater than 30 N.

6.3 Tear resistance

The soother shall be tested as described in 7.2.3.

When tested for tear resistance as described in 7.2.3.1, the teat shall not break or separate during the tensile strength test.

If the soother is installed with a flexible knob, when tested for tear resistance as described in 7.2.3.2, the knob shall not break or separate during the tensile strength test.

6.4 Knob, plug and/or cover retention

The soother shall be tested as described in 7.2.4, AND no part shall break or separate to become an accessible part.

6.5 Biting endurance

The teat and soft flexible knobs of the soother shall be tested as described in 7.2.5. AND no part shall break, tear or separate during this test or tensile strength test as described in 7.2.7.1. If the design of the soother makes it impossible to apply a tensile force to the two sides of the biting surface on the flexible material, then the material shall not exhibit either nay evidence of being cut or any separation between flexible and rigid parts of the soother. Markings, confined to the surface of the flexible material, shall be ignored.

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6.6 Rotation endurance

Soother incorporating any part capable of being rotated (360°) within the teat of the soother when a torque of (1 ± 0.2) N • m is applied, shall be tested as described in 7.2.6 AND the teat shall not tear or separate during this test or tensile strength test as described in 7.2.7.1.

6.7 Integrity

Additional tests shall be carried out to ensure the integrity of all components not already examined as part of 7.2.1 to 7.2.6.

The soother shall be tested as described in 7.2.7.2 AND no part shall break, tear, or separate during the test.

7 Mechanical performance test method

7.1 Preparation of samples and general testing methods for oven treatment

7.1.1 Only samples taken directly from the manufacturer prior to being placed on the market shall be artificially aged for 7 days in an aerated drying cabinet at a temperature of 70 °C ± 2 °C (as described in GB/T 3512) AND conditioned as described in 7.1.3. The sample shall then be boiled as described in 7.1.2, AND again conditioned as described in 7.1.3.

7.1.2 All samples shall be immersed in boiling water, to the requirements of level 3 of GB/T 6682, for 10 min without touching the walls of the container and then conditioned as described in 7.1.3 (this is to remove the surface coating due to manufacturing processes and to ensure that the construction and materials used are stable in boiling water).

7.1.3 All samples shall be subjected conditioned before the tests. The conditioning of the samples shall be performed for at least 40 h in a standard atmosphere in accordance with GB/T 2918, at the temperature of 23 °C ± 2 °C, AND the relative humidity of 50% ± 5%. The samples shall remain in the conditioning atmosphere until the test is carried out. The tests can be carried out in a non-conditioned room.

7.1.4 New samples shall be used for each test (i.e. samples used in one test shall not be used in another test) OR for each testing orientation, unless otherwise stated.

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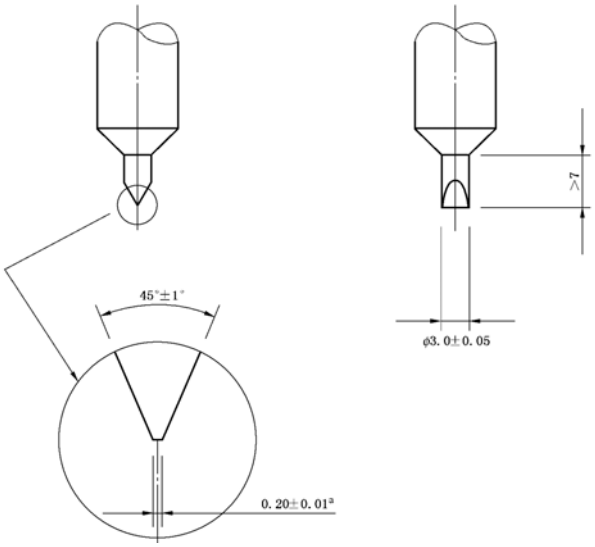
The unit is in millimeters



Note: All dimensions with a tolerance are machined in accordance with GB/T 131 to 0.4/0.8.

[a] This face is flat AND has dimensions of 3.0 × 0.20 mm.

Figure 18 -- Indenter for the puncture and tear test

7.2.3 Tear resistance test

7.2.3.1 Tear resistance test of teat

Using a complete new soother sample place the indenter, the shape and dimension of which are given in Figure 18, with the 3 mm edge of the indenter centered over and at right angles to the major axis of the soother and 7.5 mm ± 0.5 mm from the front face of the shield.

APPLY a load ensuring that the indenter cuts through both walls of the teat and approximately 1 mm into the cutting board.

After this treatment, the soother shall be tensile tested by holding the shield in a suitable fixture and applying the force 90 N ± 5 N to the teat at right angles to the major axis of the soother in accordance with 7.2.7.1. The shield shall be held so that the uppermost hole made by the indenter is facing upwards, i.e. it is subjected to the maximum tearing force.

7.2.3.2 Tear resistance test of flexible knob

If the soother is fitted with a flexible knob, REPEAT the tear resistance test on the knob in a similar manner to that described in 7.2.3.1.

7.2.4 Knob, plug and/or cover retention test

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out in accordance with 7.2.5.2, with the part of the knob pressed by the jaw facing upwards, i.e., it is subjected to the maximum tearing force.

7.2.6 Rotation endurance test

This test is applicable to soothers, where any part can rotate inside the teat in accordance with 6.6.

CLAMP the shield securely and ROTATE the knob, plug, cover or ring at a speed of (50 ± 5) rev/min 250 revolutions in a clockwise direction, then 250 revolutions in a counter clockwise direction.

After this treatment, the soother shall be tested for tensile strength in accordance with 7.2.7.1, by applying the force between the shield and the teat along the major axis of the soother.

7.2.7 Integrity test

7.2.7.1 General instructions for all tensile tests

CLAMP the teat 12 mm ± 2 mm from the shield.

Rings shall be held by a clamp, rod or by a hook. Two rods or hooks may be used if the shape of the ring prevents it from being held securely in the required position. Each rod or hook shall have a diameter of 5 mm AND have a circular cross section.

All other components shall be held by clamps or other devices.

Examples of some suitable devices are given in Appendix B. Clamps or other devices shall hold the components securely during the test without giving rise to damage which might affect the test result. Any results where such damage occurs shall be disregarded.

The tensile force shall be applied to one component of the soother whilst another part is firmly held. A preload of 5 N ± 2 N shall be applied to align the specimen AND then the force shall be increased to 90 N ± 5 N at a crosshead speed of (200 ± 5) mm/min, which is maintained for 10 s ± 0.5 s.

Note: The force used is not applicable for the reference test method given in Appendix C.

In some cases, the design of the soother makes it impossible to apply a force exactly at right angles to its major axis, e.g., when the side of the teat contacts the edge of the shield. In such cases, the force shall be applied as near as is practical to a right angle, whilst ensuring that any residual contact between the

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two parts shall not significantly reduce the force actually applied to their junction.

When the force is applied at right angles to the axis, to a component which does not have a circular section about the main axis of the soother, then the test shall be carried out on two samples. The force shall be applied, once to each sample, 90° apart, AND as far as possible in line with the extremes of the section.

7.2.7.2 Additional tests

Additional tests to those in 7.2.1 to 7.2.6 shall be carried out, to ensure the integrity of all components. The force specified in 7.2.7.1 shall be applied along the major axis AND at right angles to the major axis.

All single components shall be tested, AND also every possible combination of pairs of components, where this has not been carried out in other tests.

As the purpose of this series of tests is to reduce the risk of the soother coming apart, the forces shall be applied in the most onerous position.

The following are examples of the likely suitable combinations which additionally may be needed to be tested dependent on the design of the soother.

a) Ring/ring;

b) Ring/shield;

Shield/shield (2-component shield, e.g., rattle shield)

Knob/cover/plug - knob/cover/plug (2-components)

c) Knob/cover/plug - shield

This is not an exhaustive list of such additional tests. Other constructions/designs may have other pairs of components which shall be tested.

Some examples of suitable tests are shown in Figure 22.

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Note: The analytical tolerance considers the inter-laboratory test difference.

If the corrected analytical results are below the limits specified in Table 4, the product complies with the requirements of 8.6 of this standard.

For example:

The analysis result of N-nitrosamines is 0.018 mg/kg.

The analytical tolerance is 0.01mg/kg.

The corrected analytical results are 0.018 mg/kg - 0.01 mg/kg = 0.008 mg/kg.

This shall be considered to meet the requirements of 8.6 in this standard (N-nitrosamines limit is 0.01 mg/kg).

8.7 2-Mercaptobenzothiazole (MBT) release

When the flexible component of the soother is tested in accordance with 9.5, the 2-mercaptobenzothiazole (CAS No. 149-30-4) shall not exceed 8 mg/kg.

8.8 Antioxidants release

When the flexible component of the soother is tested in accordance with 9.5, the release of 2,6-di-tert-butyl-p-cresol (BHT) (CAS No.128-37-0) shall not exceed 30 μg/100 mL or 60 μg/dm^2; AND the release of 2,2'-methylene-bis (4-methyl-6-tert-butylphenol) (antioxidant 2246) (CAS No.119-47-1) shall not exceed 15 μg/100 mL or 30 μg/dm^2.

8.9 Volatile compounds content

When the silicon rubber components of soothers are tested in accordance with 9.6, the volatile compounds content shall not exceed 0.5% (m/m).

9 Chemical performance test methods

9.1 Sample preparation

The sample preparation applies to all tests except for 9.3 and 9.4.

9.1.1 All samples shall be immersed in boiling water (complying with GB/T 6682, grade 3) for 10 min without touching the walls of the container before conditioning.

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Note: This is to remove the surface coating arising from the manufacturing processes AND ensure that the materials used are stable in boiling water.

9.1.2 All samples must be conditioned before testing. The conditioning of the samples shall be performed, for at least 40 h, in a standard atmosphere at a temperature of 23 °C ± 2 °C and relative humidity of (50 ± 5) %. Samples shall remain in the conditioning atmosphere until the tests are carried out. The tests can be carried out in a non-conditioned room.

9.1.3 New samples, preferably from the same batch, shall be used for each test.

9.1.4 Samples and test portions shall only be handled with suitable (non-rubber or plastic) gloves AND shall only be stored in securely fastened, migration free (glass) containers and protected from the light.

9.2 Determination of the migration of certain elements

9.2.1 Principle

Soluble elements (antimony, arsenic, barium, cadmium, chrome, lead, mercury and selenium) are extracted from the individual components of the soother which are accessible to the child. Conditions which simulate contact with stomach acid shall be used. The concentrations of the soluble elements are described quantitatively.

9.2.2 Apparatus

9.2.2.1 Water bath, able to maintain the temperature of the test mixture at (37 ± 2) °C AND having the means to agitate the test mixture.

9.2.2.2 pH meter having an accuracy of ± 0.2 pH unit.

9.2.2.3 Membrane filter with a pore size of 0.45 μm.

9.2.2.4 Centrifuge capable of centrifuging at (5000 ± 500) r/min.

9.2.3 Reagents (analytical reagent grade unless otherwise specified)

9.2.3.1 Hydrochloric acid solution, (0.07 ± 0.005) mol/L.

9.2.3.2 hydrochloric acid solution, (2.0 ± 0.2) mol/L.

9.2.3.3 Distilled water.

9.2.4 Selection of test portions

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9.3 Determination of phthalate content

The phthalates content in the soother are determined in accordance with GB/T 22048.

9.4 Determination of N-nitrosamines and N-nitrosatable substances release

The release of N-nitrosamines and N-nitrosatable substances in the soother shall be determined in accordance with Appendix D.

9.5 Determination of 2-Mercaptobenzothiazole (MBT) and antioxidants release

9.5.1 Principle

The MBT and its metal-salts are quantitatively determined following extraction into an aqueous migration liquid. MBT is identified and determined by high performance liquid chromatography (HPLC) and UV-detection at a specific wavelength, either by direct injection of the aqueous migration liquid, OR in a concentrated solution. The identification is confirmed by comparing the UV-spectrum of the sample peak produced by a diode array detector with the spectrum of the peak of an authentic MBT-sample.

The method is also used for the qualitative and quantitative determination of the antioxidants 2,6- di-tert-butyl-p-cresol (BHT) and 2,2'-methylene-bis (4-methyl-6-tert-butylphenol) (antioxidant 2246). The identification is confirmed by comparing the UV-spectra of the sample peaks produced by a diode array detector with the spectra of the peak of authentic substances.

9.5.2 Apparatus

9.5.2.1 HPLC with a 20 μL injection loop and diode array detector.

9.5.2.2 High performance liquid chromatography column

9.5.3 Chemical reagents (analytical reagents grade unless otherwise specified)

9.5.3.1 Water (chromatographic pure)

9.5.3.2 Acetonitrile (chromatographic pure)

9.5.3.3 Distilled water

9.5.3.4 Dichloromethane (residual analysis grade)

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times. COMBINE the organic phases; USE the anhydrous sodium sulfate (9.5.3.5) to dry it and evaporate it dry carefully. USE 5 mL of acetonitrile to re-dissolve the residues.

Note: Concentrated columns can be used instead of shaken extraction with dichloromethane.

Or ADD 2.0 mL of acetic acid (9.5.3.6) to the aqueous migration liquid and MAINTAIN at 4 °C until analysis of the liquid by direct injection into the HPLC.

9.5.7 Result calculation

9.5.7.1 MBT

INJECT the six standard solutions (9.5.5.1) into a high performance liquid chromatograph for test, AND each standard solution is repeated three times to obtain a calibration curve of MBT.

MAKE the sample solution (9.5.6) be subjected to sample injection analysis; USE the calibration curve to determine the MBT content in the sample solution. AND the MBT detection limit is ≤ 0.1 μg/mL.

Note: Appendix E describes the appropriate liquid chromatograph columns and test methods, as well as the precision of the method.

9.5.7.2 Antioxidants

INJECT the standard solution (9.5.5.2) into a high performance liquid chromatograph for test. USE the same method to inject the sample solution (9.5.6). DETERMINE the amounts of migrated antioxidants, in micrograms antioxidant/square decimeter material, by comparison of the peak areas in the chromatograms of the standard solution and the sample solution.

If the peak area of the antioxidant in the sample solution is larger than the peak area of the standard solution, PREPARE different concentrations of standard solution for sample injection to establish the calibration curve. The migration of the antioxidant can be determined from the calibration curve.

Note: Appendix E describes the appropriate liquid chromatograph columns and test methods.

9.6 Determination of volatile compounds content

CUT appropriately 10 g of sample into pieces of approximately 2 cm^2. STORE the sample for 48 h in a desiccator at room temperature.

WEIGH the pre-conditioned sample into an open shallow container (accurate to ± 0.1 mg) and PLACE the bottle in a drying oven at 200 °C ± 5 °C with fresh

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air inlet. After 4 h, COOL the weighing bottle in a desiccator and RE-WEIGH it. CALCULATE the percentage of volatiles based on the difference in weight.

10 Consumer packaging

The soother shall be sold in a clean condition in closed parks.

The pack as received by the consumer shall include clear, legible instructions for use and hygienic care of the soother.

These instructions shall be given as described in Chapter 11 and may be included on a separate leaflet placed inside the packaging.

If the packaging includes removable protection for the teat, a special warning (SEE 11.3) shall be provided.

Note: It is essential that the packaging shall not contaminate the product in any way.

11 Product information

11.1 General requirements

The text shall be printed in the official language or at least one of the official languages of the country of retail sale. If other languages are included, they shall be easy to distinguish, e.g. by separate presentation.

The text shall be clearly legible. Sentences shall be short and of simple construction. The words used shall uncomplicated and in everyday use.

Note: It is recommended that products or packaging be batch coded.

11.2 Sale packaging information

The following information shall be visible at the point of retail sale on the outside of the packaging:

- The name, trademark or other means of identification and the address of the manufacturer, distributor or retailer. The particulars may be abbreviated provided that the abbreviation enables the manufacturer, the distributor or the retailer to be identified and easily contacted;

- The name of this standard, the year may not be indicated;

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Appendix A

(Informative)

Information for medical devices

In this standard, a soother is defined as “article intended for satisfying the non-nutritive sucking need of children”. However, it is clear that there are many products which either resemble a soother or function as a soother as well as having another function, or functions. In addition some soothers are specially designed for dedicated applications, such as for premature babies. There are some products which although clearly resembling a soother, are kept out of the scope of this standard.

These products can be summarized under the following headings:

1 Resemble a soother but no other function;

2 Resemble a soother but having another minor function;

3 Resemble a soother but having another major function;

4 Specialized applications;

5 Medical devices.

A.1 Resemble a soother but no other function

These are products that resemble a soother BUT are designed for other purposes, such as decoration or ornaments.

It is recommended that all such products be labeled with a statement saying that the product is not a soother and that it shall be kept away from young children.

A.2 Resemble a soother but having another minor function

An example of this type of product is a soother with soft edges on the shield for chewing or as a teething aid.

It is recommended that such products shall fulfill all requirements of this standard.

A.3 Resemble a soother but having another major function

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This category includes products for example that are marketed as teething rings BUT resemble a soother in shape and appearance. Similarly some temperature sensors can have a teat to allow measurement within the mouth.

It is recommended that unless specifically covered by other standards (such as medical devices or toy standards), these products shall fulfill all the requirements of this standard.

A.4 Specialized applications

These are products that are designed to deal with specific medical problems AND will be used under qualified medical supervision. Examples are soothers for Pierre Robin Syndrome (also known as cleft lip and palate) and premature babies.

It is recognized that many of these extremely important products will not fulfill all the requirements of this standard (such as the size of shield) and they are excluded from the scope of this standard.

However, it is recommended that these products shall fulfill as many of the requirements as is practicable. It is also recommended that such products be labelled with a statement that the product is not for general use.

A.5 Medical devices

Some products resembling a soother are marketed as medical devices. These include soothers for temperature measurement and medicine dispensing devices. It is likely that other products will appear on the market in the future.

In the event that these products do not meet the requirements of this standard, the manufacturer can argue that they meet the requirements of medical device standards.

It is recommended that when conducting a risk assessment all the requirements of this standard are taken into account. In addition a prominent warning regarding the inadvisability of using the product as a soother, when it is being used for its medical purposes shall be provided.

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Appendix C

(Informative)

Standard compliance assessment of soother - Sampling plan and compliance level of newly manufactured samples

C.1 General

This Appendix is not suitable for samples purchased in stores.

The sampling test method described in C.2 to C.5 applies if an organization wishes to be able to identify and test the final product by a group of soothers that are produced in accordance with this standard.

For example:

a) Product type test;

b) The purchaser in the form of a contractual purpose;

c) Through the national inspection authority.

This Appendix takes into account the inevitable changes that have taken place in the production process. However, if any test results are lower than the minimum requirement of 90 N given in the clause 7 of this standard, the soother is considered to fail to pass the test. The test is designed to perform until the sample is destroyed and the force has been used higher than the threshold as specified in Appendix C of this standard.

C.2 Sampling

Single sampling test method or double sampling test method can be used.

Each sampling shall be in accordance with the requirements of special inspection level S-4 in GB/T 2828.1.

Note 1: In order to obtain the number of test samples in accordance with GB/T 2828.1, it is necessary to be clear of the number of samples. The batch size of the sample is different due to different manufacturers AND is considered part of the manufacturer's process control and quality control.

Note 2: If the batch number of the test sample cannot be determined, then the batch number can be assumed to be between 35001 and 150000.

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Appendix D

(Informative)

Methods for the determination of N-nitrosamines and N-nitrosatable substances release in soother

D.1 Scope

Appendix D specifies the extraction, identification and detection method of N-nitrosamines and N-nitrosatable substances release from artificial rubber or rubber soothers to artificial saliva.

D.2 Principle

N-nitrosamines and N-nitrosatable substances migrate into the nitrite-containing artificial saliva salt solutions, after conversion (if containing N-nitrosatable substances) and concentration, the N-nitrosamines in the test solution is detected by the gas chromatograph (GC) with a chemiluminescence detector or other suitable analytical method.

Warning: N-nitrosamines are toxic AND can endanger human health.

Note 1: N-nitrosamine, a substance containing -N-N=O functional group, which is usually formed by reaction of amine (mainly a secondary amine) with a nitrosatable reagent (e.g., nitrite) under acidic conditions.

Note 2: N-nitrosatable substance, when transferred into the test solution, it may form N-nitrosamines through the nitrosatable reaction under certain conditions.

D.3 Reagents

D.3.1 Unless otherwise specified, all chemical reagents are of analytical pure; AND the water is distilled water or at least reaches to level 3 requirements of GB/T 6682.

D.3.2 Sodium bicarbonate

D.3.3 Sodium chloride

D.3.4 Potassium carbonate

D.3.5 Sodium nitrite

Note: The reagent is only valid for about two years.

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D.3.6 Hydrochloric acid solution, c (HCl) = 0.1 mol/L

D.3.7 Sodium hydroxide solution, c (NaOH) = 0.1 mol/L

D.3.8 Artificial saliva salt solution

DISSOLVE 4.2 g of sodium bicarbonate (D.3.2), 0.5 g of sodium chloride (D.3.3), 0.2 g of potassium carbonate (D.3.4) and 30 mg of sodium nitrite (D.3.5) in water, and DILUTE it to 900 mL. ADJUST the pH to 9.0, if necessary, ADD hydrochloric acid solution (D.3.6) or sodium hydroxide solution (D.3.7) for regulation. TRANSFER it into a 1 L volumetric flask; ADD water to make its volume reach to the mark.

Note: Even if the storage is well sealed AND the space above the liquid level to a minimum, the solution is valid only for not more than two weeks.

D.3.9 Dichloromethane

PERFORM re-evaporation and inspection (D.5.5) to ensure that no N-nitrosamines and N-nitrosamine derivative are produced.

D.3.10 Diatomite

The specific surface area of 1 m^2/g, the pore size is 3000 nm to 8500 nm, AND the grain size is 150 μm to 650 μm; HEAT it to 200 °C; BAKE it for 1 h; COOL it down; USE dichloromethane (D.3.9) to wash it.

Note: it may also use other proven separation materials that are comparable to diatomite.

D.3.11 n-hexane

D.3.12 Hydrochloric acid solution, c (HCl) = 1 mol/L

D.3.13 Sodium hydroxide solution, c (NaOH) = 1 mol/L

D.3.14 Pure nitrogen

D.3.15 Zeolite

D.3.16 Sintered porous glass plate

D.3.17 Acetone, or other suitable solvent

D.3.18 N-nitrosamine standard solution

PREPARE the n-hexane (D.3.11) solution having a N-nitrosamine concentration from 100 ng/mL to 300 ng/mL.

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D.4 Instrument

D.4.1 Conventional laboratory equipment

The glass device used in this test, if cleaned with an acid cleaner, shall be treated with ammonia solution (D.3.21) before use, AND then washed with water and dried.

D.4.2 Incubator, which can maintain the temperature at (40 ± 2) °C.

D.4.3 Glass column with polytetrafluoroethylene (PTFE) plug; column length of about 300 mm AND inner diameter of about 26 mm.

D.4.4 Glass column with polytetrafluoroethylene (PTFE) plug; column length of about 300 mm AND inner diameter of about 15 mm.

D.4.5 K-D distillation flasks and concentrators.

Note: Other concentrators with comparable performance to K-D devices can also be used.

D.4.6 Water bath, which can maintain the temperature at 40 °C ~ 60 °C.

D.4.7 Jaw inlet injection bottle.

D.4.8 Gripper.

D.4.9 Glass wool, washed with dichloromethane (D.3.9).

D.4.10 Separatory funnel (200 mL).

D.4.11 Separatory funnel (100 mL).

D.4.12 Chemiluminescence detector (thermal energy analyzer).

Note: Other detectors that are comparable to chemiluminescent detectors can also be used.

D.4.13 Gas chromatograph

The following chromatographic reference conditions have been shown to be suitable for the detection of N-nitrosamines.

Example 1:

Inlet temperature: 200 °C

Program temperature rise: $60\,℃\ (0\ \text{min}) \xrightarrow{10\ ℃/\text{min}} 230\ ℃\ (0\ \text{min})$

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D.5.1.4 PIPETTE 10.0 mL of solution from the graduated cylinder into a 25 mL conical flask; PLUG the flask, AND this is the solution B.

D.5.1.5 The remaining 40.0 mL solution in the graduated cylinder is the solution A.

D.5.2 Extraction of N-nitrosamines in solution A.

D.5.2.1 PIPETTE 1.0 mL of the internal standard solution (D.3.19) and 1.0 mL of sodium hydroxide solution (D.4.13) into the solution A (D.5.1.5) in the graduated cylinder.

Note: The purification procedure may follow the method of D.5.2.1.1 or D.5.2.1.2.

D.5.2.1.1 Method A

D.5.2.1.1.1 ADD 25 g of diatomaceous earth (D.3.10) into a 26 mm inner diameter glass column (D.4.3); USE the glass wool (D.4.9) to seal the bottom. The top of the column is covered with a sintered porous glass plate (D.3.16) or about 1 cm thick sand (D.3.22).

When filling the column, USE hand to gently tap the outer wall of the glass column to make the filling more uniform.

D.5.2.1.1.2 COVER and SHAKE the solution (D.5.2.1) uniformly; slowly POUR solution (D.5.2.1) into the prepared diatomaceous earth column (D.5.2.1.1. 1). The sample is absorbed on a porous substrate for 10 min ~ 15 min. AND the bottom of the column will leave 50 mm ~ 70 mm width dry belt.

D.5.2.1.1.3 Slowly ADD 60 mL to 80 mL of dichloromethane (D.3.9) into the column over 15 min to 25 min. COLLECT the eluate (about 40 mL) into a K-D flask (D.4.5); USE the polytetrafluoroethylene plug to adjust the liquid drop speed.

Note: When rinsing with dichloromethane, the width of the dry belt is narrowed to 15 mm to 30 mm. The process is easy to observe because the color of the diatomaceous earth impregnated with dichloromethane. NOTE that this dry belt shall not disappear, otherwise the eluent may contain water.

D.5.2.1.2 Method B

D.5.2.1.2.1 COVER and SHAKE the solution (D.5.2.1) uniformly; slowly POUR it into the separatory funnel.

D.5.2.1.2.2 ADD at least 20 mL of dichloromethane (D.3.9) and SHAKE vigorously for 1 min. LET it stand for stratification. If necessary, USE centrifugal

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for demulsification. COLLECT the lower layer liquid; MAKE it pass through the pre-washed 30 g of anhydrous sodium sulfate (D.3.20); USE the K-D flask (D.4.5) to collect it.

D.5.2.1.2.3 REPEAT the procedures of D.5.2.1.2.2 twice.

D.5.2.1.2.4 USE 25 mL of dichloromethane (D.3.9) to rinse the sodium sulfate (D.3.20); INCLUDE it into the K-D flask (D.4.5).

D.5.2.2 Concentration of N-nitrosamines in solution A.

D.5.2.2.1 ADD 2 mL of n-hexane (D.3.11) and 2-3 pieces of zeolite (D.3.15) into the K-D flask which contains the extract (prepared as described in D.5.2.1.1 or D.5.2.1.2). CONNECT the air condenser tube to the K-D flask. MAKE the solution concentrate to 4 mL to 6 mL in a water bath (D.4.6). AND the initial temperature of the water bath is (40 ± 2) °C, which is slowly raised to (60 ± 2) °C (temperature rising rate of about 2 °C/min). After cooling, USE about 2 mL of dichloromethane to rinse the inner wall of the concentrator.

D.5.2.2.2 REMOVE the air condenser tube; BLOW nitrogen (D.3.14) to about 1 mL for concentration. After the temperature equilibrates to room temperature, TRANSFER it into the injection bottle (D.4.7) for sealing.

Note: ADJUST the flow rate of nitrogen to ensure that the surface depression of the concentrated solution does not exceed 4 mm ~ 5 mm, otherwise the liquid will splash or subcooled. If the concentrated sample needs more than 1 h for analysis, it shall be preserved in dark at less than 5 °C.

D.5.3 Extraction of N-nitrosamine derivatives in solution B (first converted to N-nitrosamines)

D.5.3.1 PIPETTE 1.0 mL of hydrochloric acid solution (D.3.12) into the solution B (D.5.1.4); MIX it uniformly (pH about 1.4). PLACE it in the dark for 30 min.

D.5.3.2 ADD 2.0 mL of sodium hydroxide solution (D.3.13) to make the solution alkaline, then PIPETTE 1.0 mL of the internal standard solution (D.3.19); MIX it uniformly.

Note: The purification procedure can be done using the method of D.5.3.2.1 or D.5.3.2.2.

D.5.3.2.1 Method C

D.5.3.2.1.1 USE the method as described in D.5.2.1.1.1 to prepare a 15 mm inner diameter glass column containing 8 g of diatomaceous earth (D.3.10).

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D.6.2 N-nitrosatable substances release of solution B (in terms of N-nitrosamines)

D.6.2.1 USE the formula (D.2) and formula (D.3) to calculate the migration of each N-nitrosamine in solution B, which is subtracted by the corresponding N-nitrosamine migration as measured for the solution A, to obtain the migration of each N-nitrosamine derivatives.

$$M(\mu g/kg) = \frac{5FA_{NA}}{A_{NDiPA^R}} \quad \cdots\cdots (D.3)$$

Where:

M - The amount of N-nitrosamines transferred from the sample to the artificial saliva, in micrograms per kilogram (μg/kg);

F - The factor calculated by the formula (D.2);

A_{NA} - The peak area of some N-nitrosamines migrated from the sample into artificial saliva (solution B);

A_{NDiPA^R} - The N_{DiPA} internal standard peak area in solution B.

D.6.2.2 The total migration of N-nitrosamines is the sum of the amount of migration of the various N-nitrosamines (the migration of each N-nitrosamine derivative is deducted of the N-nitrosamine migration in solution A). If a N-nitrosamine does not have a detection signal (i.e., less than 3 times the background noise), it shall be recorded as “not detected” or “ND” AND its value is zero.

D.7 Confirmation of N-nitrosamines

D.7.1 N-nitrosamines shall be confirmed by one of the following methods if the total migration of N-nitrosamine as measured in artificial saliva exceeds the limit:

a) TAKE a portion of the remaining test solution and PLACE it into a transparent vial which can completely make ultraviolet pass through; LET it be exposed in the ultraviolet of wavelength 366 nm for 3 h. Since the N-nitrosamine can decompose under the exposure of ultraviolet radiation, if may found from gas chromatography analysis that the chromatographic peaks corresponding to all N-nitrosamines will disappear OR the peak area will reduce significantly. However, if the peak area of the sample is not significantly reduced after irradiation, then the initial peak is false-positive, AND no further confirmation is required.

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