



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 31604.62-2025

**National food safety standard - Food contact materials and
articles - Determination of the migration and release of
N-nitrosamines**

食品安全国家标准 食品接触材料及制品 N-亚硝胺类化合物迁移量和释放量的测定

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1 Scope

GB 31604.62-2025 is the Chinese national food safety method for N-nitrosamines migrating or released from food contact materials. Nitrosamines are among the most potent carcinogens known, and in food contact they come principally from rubber: the accelerators used to vulcanise the elastomer in a teat, a soother, a gasket or a tubing form nitrosamines with the nitrogen oxides in air, and the limits set for baby teats in particular are at the level of a few micrograms per kilogram. The standard distinguishes migration, what passes into a food simulant, from release, what comes off into a saliva simulant, which is the relevant question for a teat or a soother, and describes the determination by gas chromatography-mass spectrometry or by liquid chromatography-tandem mass spectrometry, covering the principle, the reagents, the apparatus, the test conditions for each case, the analytical procedure, the calculation, the precision and the limit of quantification. Effective September 2025.

This Standard specifies the method for determining the migration and release of N-nitrosamine compounds and N-nitrosamine derivatives in food contact materials and articles. The first part of this Standard is applicable to the determination of the migration of 15 N-nitrosamine compounds, including N-nitroso-dimethylamine, N-nitroso-N-methylethylamine, N-nitrosodiethylamine, N-nitrosodiisopropylamine, N-nitrosodi-n-propylamine, N-nitrosodiisobutylamine, N-nitrosodi-n-butylamine, N-nitrosopiperidine, N-nitrosopyrrolidine, N-nitrosomorpholine, N-nitroso-N-ethylaniline,

N-nitroso-N-methylaniline, N-nitrosodiisononylamine, N-nitrosodicyclohexylamine, and N-nitrosodibenzylamine, in rubber materials and products for food contact. It is applicable to the determination of the migration of the above 15 N-nitrosamine products in rubber materials and products for food contact. The second part of this Standard is applicable to the determination of the release of the above 15 N-nitrosamine compounds in pacifiers. It is also applicable to the determination of the release of the above 15 N-nitrosamine products in pacifiers. Part 1 -- Determination of migration of N-nitrosamine compounds and N-nitrosamine products Method One -- Gas chromatography-mass spectrometry

2 Principle

The N-nitrosamine compounds in the soaking solution obtained from the migration test are extracted with dichloromethane under alkaline conditions, concentrated, and determined by gas chromatography-mass spectrometry (GC-MS). The external standard method is used for quantification to obtain the migration amount of N-nitrosamine compounds directly migrated. The N-nitrosamine-derived products in the immersion solution obtained in the migration test react with nitrite in artificial saliva under acidic conditions to generate N-nitrosamine compounds. The N-nitrosamine compounds generated by the reaction and the N-nitrosamine compounds directly migrated are simultaneously determined according to the above steps to obtain the sum of the migration amounts of the N-nitrosamine-derived products and the N-nitrosamine compounds directly migrated. The migration amount of a single N-nitrosamine-derived product is calculated by subtracting the migration amount of the corresponding N-nitrosamine directly migrated from the sum of the measured migration amounts of the two.

3 Reagents and materials

Unless otherwise specified, all reagents used in this method are analytically pure and water is Grade one water as specified in GB/T 6682.

3.1 Reagents

3.1.1 Dichloromethane (CH_2Cl_2). chromatographically pure.

3.1.2 Concentrated hydrochloric acid (HCl).

3.1.3 Sodium hydroxide (NaOH).

3.1.4 Anhydrous ethanol ($\text{C}_2\text{H}_6\text{O}$). chromatographically pure.

3.1.5 Glacial acetic acid ($\text{C}_2\text{H}_4\text{O}_2$). guaranteed reagent.

3.1.6 Sodium bicarbonate (NaHCO_3).

3.1.7 Sodium chloride (NaCl).

3.1.8 Potassium carbonate (K_2CO_3).

3.1.9 Sodium nitrite ($NaNO_2$).

3.2.1 Food simulants. Prepare according to GB 5009.156. 3.2.2

0.1 mol/L hydrochloric acid solution. Prepare according to GB 5009.156. 3.2.3

0.1 mol/L sodium hydroxide solution. Prepare according to GB 5009.156. 3.2.4 1 mol/L hydrochloric acid solution. Measure 83 mL of hydrochloric acid and slowly add it to 500 mL of water. After the solution cools to room temperature, transfer it to a 1 L volumetric flask. Add water to the mark and mix well. 3.2.5 5 mol/L sodium hydroxide solution. Weigh

5.0 g of sodium hydroxide into a polyethylene or polytetrafluoroethylene plastic beaker. Add 250 mL of water to dissolve. After cooling, transfer to a plastic (except PET) bottle and set aside.

3.2.6 Artificial saliva. Prepare according to GB 5009.156, or purchase commercially available artificial saliva.

3.3 Standard products/substances 15 N-nitrosamine compound standard substances. Purity is >98%. For detailed information, see Table A.1 in Annex A, or standard substances certified by the state and awarded with standard substance certificates.

3.4 Preparation of standard solution 3.4.1 15 N-nitrosamines mixed standard stock solution (100 mg/L). Accurately weigh 25 mg (accurate to

0.1 mg) of each of the 15 N-nitrosamines standard substances. Dissolve in anhydrous ethanol and transfer to a 250 mL brown volumetric flask. Add ethanol to the mark. Mix well. Transfer the solution to a brown glass container. Store at $-18^{\circ}C$ away from light. Shelf life is 6 months.

3.4.2 N-nitrosamines mixed standard intermediate solution (

1.00 mg/L). Accurately pipette

1.00 mL of 15 N-nitrosamines mixed standard stock solutions (100 mg/L) into a 100 mL brown volumetric flask. Add anhydrous ethanol to the mark. Mix well. Transfer the solution to a brown glass container. Store at $-18^{\circ}C$ away from light. Shelf life 3 months.

3.4.3 Mixed standard series working solution. Pipette

0.50 mL,

5.00 mL of the mixed standard intermediate solution (

1.00 mg/L) of N-nitrosamine compounds into six 10 mL brown volumetric flasks. Add anhydrous ethanol to the mark. Mix well. The mass concentrations of the 15 N-nitrosamine