

Voluntary Report – Voluntary - Public Distribution

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Report Name: National Food Safety Standard for Silicone Rubber Materials and Products for Food Contact Use Notified to WTO

Country: China - People's Republic of

Post: Beijing

Report Category: FAIRS Subject Report, Sanitary/Phytosanitary/Food Safety, WTO Notifications

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Report Highlights:

On October 25, 2023, China notified the National Food Safety Standard for Silicone Rubber Materials and Products for Food Contact Use to the World Trade Organization (WTO) under G/SPS/N/CHN/1294. The proposed date of entry into force is to be determined. Comments may be submitted to China's SPS National Notification and Enquiry Center at sps@customs.gov.cn until December 24, 2023. The report provides an unofficial translation of the draft standard.

Report Summary:

On October 25, 2023, China notified the National Food Safety Standard for Silicone Rubber Materials and Products for Food Contact Use to the World Trade Organization (WTO) under [G/SPS/N/CHN/1294](#). The proposed date of entry into force is to be determined. Comments may be submitted to China's SPS National Notification and Enquiry Center at sps@customs.gov.cn until December 24, 2023.

Compared with the current implementing [National Standard for Silicone Rubber Materials and Products for Food Contact Use](#) (link in Chinese), this notified standard revised the scope, terms and definitions, ingredients requirements, sensory requirements, physical and chemical indicators, technical requirements, migration tests and label requirements, codes and requirements in Appendix A, and determination of volatile substances in Appendix B for silicone rubber materials and products intended for use in contact with foods. The report provides an unofficial translation of the draft standard notified to WTO.

BEGIN TRANSLATION

National Food Safety Standard
Silicon Rubber Materials and Products for Use in Contact with Foods

Foreword

This standard replaces relevant requirements for silicon rubber materials and products in GB 4806.11-2016 "National Food Safety Standard for Rubber Materials and Products for Use in Contact with Foods."

As compared with the above-mentioned standard, the following major changes are made to this standard.

- The scope is revised,
- The terms and definitions are revised,
- The requirements for ingredients are modified,
- The sensory requirements are revised,
- The physical and chemical indicators are revised,
- Other technical requirements are added,
- The requirements for migration tests are revised,
- The requirements for labels are revised,
- The serial numbers and stipulated requirements in Appendix A are revised,
- Determination of volatile substances in Appendix B is added.

1. Scope

This standard applies to the silicon rubber materials and products for use in contact with foods.

2. Terms and Definitions

2.1 Food contact silicon rubber materials and products

Materials and products already or expected to be in contact with foods or food additives, or its components might migrate to foods under common usage conditions, formed by substances such as polysiloxane polymer and hydrophobic silica through cross linking curing reactions. The main ingredient is organic silicon elastomer.

3. Basic Requirements

Food contact silicon rubber materials and products should comply with provisions in GB 4806.1.

4. Technical Requirements

4.1 Ingredients requirements

4.1.1 The use of basic ingredients for food contact silicon rubber materials and products should comply with the Appendix A and provisions in relevant public announcements.

4.1.2 The use of additives in food contact silicon rubber materials and products should comply with GB 9685 and provisions in relevant public announcements.

4.2 Sensory requirements

Sensory requirements for food contact silicon rubber materials and products should meet requirements in Table 1.

Table 1: Sensory Requirements

Items	Requirements
Sensory conditions	Regular color, no abnormal smell, and no impurities.
Soaking liquids	The soaking liquids obtained from the migration tests should not have any deterioration in sensory properties such as coloration, turbidity, precipitation, or odor.

4.3 Physical and chemical indicators

4.3.1 Common physical and chemical indicators

The common physical and chemical indicators of food contact silicon rubber materials and products should comply with provisions in Table 2.

Table 2: Common physical and chemical indicators

Items	Indicators	Testing Methods
Total migration volume ^a /(mg/dm ²) ≤	10	GB 31604.8
Potassium permanganate consumption volume/(mg/kg) Water (60°C, 2 h) ≤	10	GB 31604.2
Heavy metal (based on Pb)/(mg/kg) 4% acetic acid (volume fraction) (60°C, 2 h) ≤	1	GB 31604.9
Volatile substances ^b / (%) (mass fraction) ≤	0.5	Appendix B

^a Food contacting silicon rubber materials and products for infants' use should have the results converted to mg/kg according to area and volume ratio in actual use, and its limit is no more

than 60 mg/kg.

^b Volatile substances refer to lost substances from 4 hours exposure at 200°C of food contacting silicon rubber materials and products after dried for 1 hour at 100°C.

4.3.2 Other physical and chemical indicators

4.3.2.1 Food contact silicon rubber materials and products should comply with the provisions in Appendix A and regulations about physical and chemical indicators such as specific migration limit (SML), total specific migration limit [SML(T)], and maximum residual mass (QM) in relevant public announcements.

4.3.2.2 Food contact silicon rubber materials and products should comply with provisions in GB 9685 and relevant regulations on physical and chemical indicators of additives used such as SML, SML(T), and QM in relevant public announcements.

4.4 Other technical requirements

Food contact silicon rubber materials and products that use materials such as paint, ink, and (or) adhesive agents should also comply with specifications in relevant national food safety standards for paint, ink, and (or) adhesive agents.

5. Others

5.1 Migration tests

5.1.1 General requirements

Unless otherwise specified in this standard, migration tests should be conducted according to GB 31604.1 and GB 5009.156.

5.1.2 Special requirements

Conditions for the tests of total migration on the silicon rubber materials and products with an expected contact temperature (T) no more than 40°C and contact time (t) no more than 24 hours should comply with Table 3.

Table 3: Conditions for a total migration test

Expected conditions for use	Conditions for migration tests
$T \leq 40^\circ\text{C}$, $t \leq 10$ min	40°C, 10 min
$T \leq 40^\circ\text{C}$, 10 min < $t \leq 30$ min	40°C, 30 min
$T \leq 40^\circ\text{C}$, 30 min < $t \leq 2$ h	40°C, 2 h
$T \leq 40^\circ\text{C}$, 2 h < $t \leq 24$ h	40°C, 24 h

5.2 Labels

Labels should comply with provisions in GB 4806.1.

Appendix A

Allowable basic materials to be used for food contact silicon rubber materials and products and usage requirements

A.1 Table A.1 stipulates the allowable basic materials to be used for food contact silicon rubber materials and products and the usage requirements. The basic materials listed in A.1 are subject to CAS numbers and Chinese name prevails if the material doesn't have a CAS number.

A.2 Substances with relative molecular mass greater than 1,000 Da formed by polymerization or other means from ingredients such as monomers, other starting materials, and basic polymers listed in Table A.1 are also allowed to be used as basic ingredients for food contact materials silicone rubber materials and products. They shall comply with the corresponding restrictive requirements for basic ingredients such as monomers, other starting materials, and basic polymers.

A.3 The total specific migration limits [SML (T)] and group numbers of SML (T) in GB 9685 apply to this standard.

A.4 If the monomers or other starting materials in Table A.1 used to synthesize polymers are the substances in the categories of acid, alcohol, or phenol, then their sodium salts, kali salts, and calcium salts (including acidic and double salts) can also be used in synthesizing polymers, and should comply with the restrictive requirements for relevant monomers and other starting materials in the categories of acid, alcohol, and phenol. The sodium salts, kali salts, and calcium salts (including acidic and double salts) of monomers and other starting materials listed in Table A.1 should be used according to this standard.

Table A.1: Allowable basic materials to be used for silicon rubber and usage requirements

SN	Chinese name	CAS No.	SML/QM (mg/kg)	SML(T) (mg/kg)	SML(T) Group No.	Other requirements
1	[(Vinyl dimethylsilyl) oxy and modified (trimethylsilyl)] oxy silanes	68988-89-6				
2	Condensates of phenyltriethoxysilane and (siloxanes and polysiloxanes)	72480-33-2				
3	Monovinyl-terminated dimethylmethylvinyl (siloxanes and polysiloxanes)	68951-99-5				
4	Reaction product of dimethyl (silicone and polysiloxane) and silica	67762-90-7				
5	Polymers of dimethylsiloxane with polysiloxane and ethoxy terminated methylsilsesquioxane	68554-66-5				
6	Dimethyl Methyl Hydrogenation (Siloxanes and Polysiloxanes)	68037-59-2				
7	Methyl Silsesquioxane	68554-70-1	1 (Methyltri methoxysilane, QM)			
8	Methyl hydrogen siloxane and polysiloxane	63148-57-2				
9	Methyl vinyl dimethyl (silicone and polysiloxane)	67762-94-1				

10	Polymers of methylvinyl dimethyl (siloxane and polysiloxane) and methylphenylsilsesquioxane	68037-69-4				
11	Polydimethylsiloxane	63148-62-9; 9016-00-6				Relative molecular mass >6,800 Da
12	Copolymer of polydimethylsiloxane and phenylsilsesquioxane	73138-88-2				
13	Hydroxy terminated dimethylmethylvinyl (siloxanes and polysiloxanes)	67923-19-7				
14	Hydroxy-terminated polydimethylsiloxane;hydroxyl-terminated dimethyl (siloxanes and polysiloxanes)	70131-67-8				
15	Hydrogen-terminated dimethyl (siloxanes and polysiloxanes)	70900-21-9				
16	Vinyl-terminated dimethyl (silicone and polysiloxane)	68083-19-2				
17	Vinyl-terminated dimethylmethylvinyl (silicone and polysiloxane)	68083-18-1				
18	Hydrolyzate of tetraethyl orthosilicate, 1,3-divinyl-1,1,3,3-tetramethyldisiloxane, and hexamethyldisiloxane	104199-38-4				
19	Polymer of tetraethyl orthosilicate and hexamethyldisiloxane	104133-09-7				
20	Hydrolyzate of 1,1,1-trimethyl-N-(trimethylsilyl)silylamine and silica	68909-20-6				Maximum usage: organic silicon filling: 50%
21	Silica	112945-52-5				Used in reasonable amount according to production requirements
22	Acetylene cyclohexanol	78-27-3				Used in reasonable amount according to production requirements

Appendix B

Determination of volatile substances

B.1 Scope

This standard stipulates the methods for determining the volatile substances in food contact silicon rubber materials and products.

This standard applies to the determination of volatile substances in food contact silicon rubber materials and products.

B.2 Principles

After dehydration of the food contact silicon rubber materials or products, use volatilization method at 101.3 kPa to determine its mass before and after drying at high temperatures, and calculate content of volatile substances according to the differences between the two results.

B.3 Reagent and materials

B.3.1 Reagent

Water: level III water in compliance with GB/T 6682.

B.3.2 Materials

B.3.2.1 Flat aluminum weighing vessel.

B.3.2.2 Dryer: contains effective desiccant.

B.4 Instrument and equipment

B.4.1 Electronic scales: with a sensitivity of 0.1 mg.

B.4.2 Electric blast drying oven: at 100 °C accurate to $\pm 2^{\circ}\text{C}$, at 200°C accurate to $\pm 3^{\circ}\text{C}$.

B.5 Analytic steps

B.5.1 Sample pre-treatment

Soak the sample of a nipple in the boiling water for 10 minutes, stir with a glass rod from time to time during the soaking process to ensure the sample is not in contact with the container walls. Take out the sample after soaking process and spin dry the sample. If the next step cannot be carried out immediately, place the sample in the dryer for storage. Other samples don't need the preparation processes.

B.5.2 Sample preparation

Cut the sample into small pieces with length, width, and thickness not exceeding 2 cm respectively, put them into a container (such as watch glass, evaporating dish, weighing vessel, crucible), and make sure the pieces of sample cannot overlap.

B.5.3 Testing sample pre-processing

Place the container specified in B.5.2 in the electric thermostatic drying oven at $(100 \pm 2)^{\circ}\text{C}$, stop ventilation or air circulation, take out the container after (60 ± 5) minutes of drying, and place it in the desiccator for cooling for (60 ± 5) minutes.

B.5.4 Determination of volatile substances

Take out a clean flat aluminum weighing vessel, place it in an electric thermostatic drying oven at $(200 \pm 3)^{\circ}\text{C}$ to dry for (60 ± 5) minutes, take it out and put it in a desiccator for cooling for (60 ± 5) minutes, accurately weigh it, and repeat the drying processes until the differences in mass

between two consecutive measurements do not exceed 2 mg, in which case the weight is constant weight. Take 10 g of the sample specified in B.5.3, place it in the weighing vessel where the sample pieces cannot overlap, place it in the electric thermostatic drying oven at $(200 \pm 3) ^\circ\text{C}$, stop ventilation or air circulation, take it out after (240 ± 5) minutes of drying, place it in the desiccator for cooling for (120 ± 5) minutes, then accurately weigh it.

B.6 Description of the analytic results

The content of volatile substances in the sample is calculated according to the formula (1):

$$X = \frac{m_1 - m_2}{m_1 - m_0} \times 100 \quad \dots\dots\dots (1)$$

Where:

- X - volatile substances content in the sample, expressed in fraction (%),
- m_1 - total mass of sample and weighing vessel before being dried at $(200 \pm 3) ^\circ\text{C}$ for (240 ± 5) minutes, expressed in gram (g),
- m_2 - total mass (g) of sample and weighing vessel after being dried at $(200 \pm 3) ^\circ\text{C}$ for (240 ± 5) minutes, expressed in gram (g),
- m_0 - weight of the weighing vessel, expressed in gram (g),

The calculation result is expressed as the arithmetic mean of the two independently determined results obtained under repetitive conditions, accurate to two decimals.

B.7 Accuracy

When the volatile substances content in the sample is no more than 0.2%, the value of differences between the two independently determined results obtained under repetitive conditions should not exceed 30% of the arithmetic mean. When the volatile substances content in the sample is more than 0.2%, the value of differences between the two independently determined results obtained under repetitive conditions should not exceed 15% of its arithmetic mean.

END TRANSLATION

Attachments:

No Attachments.