

Tokyokobunshi

Silicone Coating



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Features of Silicone-Coated Containers

Our silicone coating is created by applying dimethyl silicone (dimethylpolysiloxane) to the inner/outer surface of a glass container and baking the silicone coating on the surface.

A silicone-coated container can repel fluids and powder and the lubricating properties of the container are also improved.

The silicone coating contributes not only to improvements in the stability in quality, the commercial value and product stability, but also the improvement of work efficiency.

General features of a silicone-coated container are as followings:

Liquid Medicine

- 1) Since the silicone-coated container has fluid repellency, an expensive liquid medicine can be used up to the last drop.
- 2) The silicone coating prevents the components of liquid medicine from being adsorbed into a glass container so that the potency of the medicine does not change.
- 3) Since the silicone coating prevents liquid medicine from making direct contact with the inner surface of a glass container, alteration of the medicine can be prevented.

Freeze- drying Medicine

- 1) Since the silicone-coated container has a high lubricating property, the internal pressure is released in the vertical direction when the contents are frozen and therefore breakage of the container can be prevented.
- 2) Since a freeze-drying medicine does not make contact with the inside of a container directly, the freeze-drying treatment can be sped up.
- 3) Since a silicone-coated container has a tendency to keep sprays of a medicine that spattered onto the inner wall of a container from adhering when it is injected, the appearance of the freeze-drying medicine can be improved.

Powder Medicine

- 1) Since the silicone coating prevents a powder medicine from adhering to the inner surface of a container, final inspection of the contents can be facilitated.
- 2) Since the silicone coating prevents the contents from adhering to the inner surface of a container, the appearance of the product is improved.

Lubricating Property of Inner Surface

- 1) By applying the silicone coating to the inner surface of a syringe, the sliding property of a plunger is improved.

Lubricating Property of Outer Surface

- 1) Since the silicone coating improves the lubricating property of an automatic manufacturing line, troubles with the medicine manufacturing line such as occurrence of a bridge can be reduced.
- 2) The silicone coating reduces the damage of and flaws in containers that is caused by the friction between the containers.

Water-Repelling Mechanism of Silicone-Coated Container

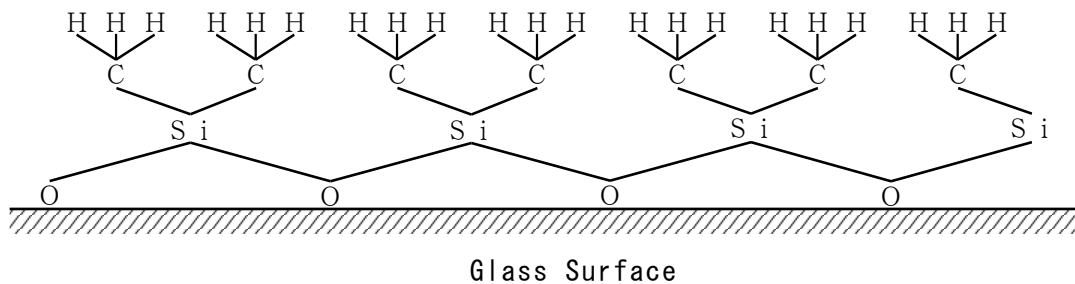
A silicone-coated surface has high water repellency. The repellency is equivalent to that of paraffin. When glass is coated with dimethyl silicone, the contact angle between the glass and water is 90-100 degrees.

As indicated in the figure below, the structure of the water-repelling mechanism

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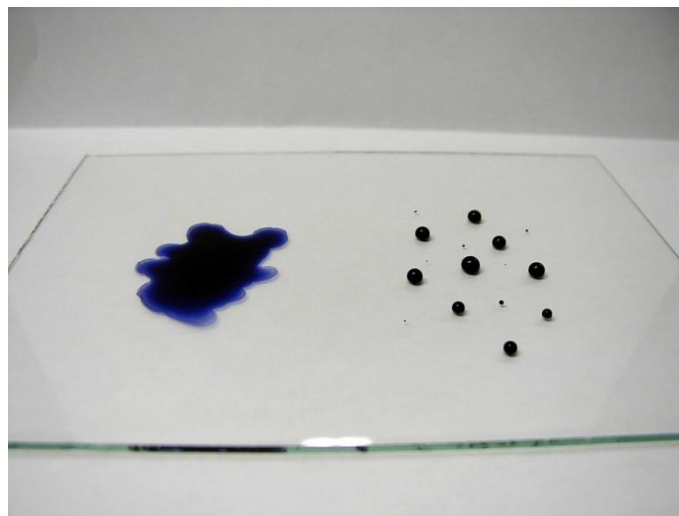
is as follows.

Since the methyl group ($-CH_3$), which is the hydrophobic group of dimethyl silicone, shifts its position outwardly by applying a dimethyl silicone coating, the glass surface exhibits high water repellency.



The photo below shows that the silicone-coated glass repels water.

On the glass surface coated with silicone, a colored fluid is repelled and therefore droplets are formed. On the surface without the silicone coating, the colored fluid is not repelled and spreads.



Non-treated Surface Silicone-Coated Surface

Safety of Silicone-Coated Container

Today, the safety of dimethyl silicone is widely known.

In this page, the results of a cytotoxicity test of silicone-coated products performed by us and part of a safety data sheet (SDS) of dimethyl silicone issued by Silicone Industry Association of Japan will be introduced.

Cytotoxicity

The cytotoxicity tests (colony forming tests) were performed in accordance with Test Methods for Plastic Medical and Pharmaceutical Containers (the 13th amendment of the Japanese Pharmacopoeia) and Guidelines for Biological Tests Required for Application for Manufacturing (and Import) of Medical Devices (Laws on Securement of Quality, Effectiveness and Safety of Medical and Pharmaceutical Products No. 99 issued on Jun. 27, 1995).

The cytotoxicity tests were performed by requesting Hatano Research Institute of Food and Drug Safety Center perform them.

The tests prove that silicone-coated products do not have cytotoxicity. (Refer to Table 1.)

Table 1 Results of Colony Forming Tests

Specimen	Concentration (%)	Colony/Well			Average \pm Standard	Colony Forming	IC ₅₀ (%)
		1	2	3			
Control	0	91	81	82	84.7 \pm 5.5	100.0	
Plastic sheet (negative reference material)	25	92	84	92	89.3 \pm 4.6	105.4	
	50	78	88	82	82.7 \pm 5.0	97.6	
	75	97	77	95	89.7 \pm 1.0	105.9	
	100	89	73	77	79.7 \pm 8.3	94.1	
Polyurethane film containing 0.1% of ZDEC (positive reference material)	0.312	94	77	90	87.0 \pm 8.9	102.7	0.95
	0.625	84	87	91	87.3 \pm 3.5	103.1	
	1.25	4	2	3	3.0 \pm 1.0	3.5	
	2.5	0	0	0	0.0 \pm 0.0	0.0	
	5	0	0	0	0.0 \pm 0.0	0.0	
Polyurethane film containing of 0.25% of ZDBC (positive reference material)	40	67	84	90	80.3 \pm 1.9	94.8	54.7
	50	64	74	83	73.7 \pm 9.5	87.0	
	60	8	6	7	7.0 \pm 1.0	8.3	
	70	0	0	0	0.0 \pm 0.0	0.0	
	80	0	0	0	0.0 \pm 0.0	0.0	
	100	0	0	0	0.0 \pm 0.0	0.0	
Silicone-coated product	25	82	96	87	88.3 \pm 7.1	104.3	
	50	82	81	88	83.7 \pm 3.8	98.8	
	75	81	92	92	88.3 \pm 6.4	104.3	
	100	95	95	61	83.7 \pm 9.6	98.8	

IC₅₀: A concentration that inhibits 50% of colony forming.

ZDEC: zinc diethyldithiocarbamate

ZDBC: zinc dibuthyldithiocarbamate

Acute Toxicity

Specimen	LD ₅₀ : mg/kg (Oral Administration to Rat)
Dimethyl silicone	35,000 or more
Sugar	35,400
Ethanol	10,900
Salt	8,070
Acetic acid	3,310

Toxicity	Degree of Toxicity	LD ₅₀ : mg/kg (Oral Administration to Rat)
1	Very high	1 or less
2	High	1-50
3	Medium	50-500
4	Low	500-5,000
5	Substantially nontoxic	5,000-15,000
6	Nontoxic	15,000 or more

LD₅₀: A lethal dose that may kill 50% of a group of animals used in an experiment.

Other Tests Methods

Test Method	Laboratory Animal	Dose	Result
Contact with rubbed skin	Rabbit	—	Not absorbed
Contact with eye	Rabbit	—	Temporary and weak discomfort
Repeated patch tests	Human	—	Non-irritative, no sensitization
Repeated skin irritation	Rabbit	0.2 g/ kg/day continued for 28 days	No effect
Feed	Rat	1% of feed, continued for 2 years	No effect
Oral administration	Pregnant rat	3.8 g/ kg/day, 6-15 days of pregnancy	No embryotoxicity, no mutagenicity

Fluid Repellency of Silicone-Coated Glass Bottle

Fluid Levels in Silicone-Coated Bottles



When a solution is put into a glass bottle without a silicone coating, the fluid level becomes concave. Whereas the level of a fluid put in a glass bottle becomes convex.

This is because the contact angle between the glass and the solution is small and the contact angle between the silicone coating and the solution is large.

Repellency to Suspension

A silicone-coated bottle exhibits high fluid repellency and a suspension does not adhere to the inner wall of the bottle. The inside of the bottle and a residual quantity can be observed at a glance. For the bottle without a silicone coating, the contents adhere to the inner wall of the bottle and the adhesion mars the appearance of the product. In addition to the compromising of the appearance, the non-treated bottle has some drawbacks such as that the contents adhering to the inner wall are wasted and the remaining quantity cannot be confirmed easily.



Repellency to Powder



Since a silicone-coated bottle has a disposition to keep powder from adhering to the inner wall, the inside of the bottle can be observed easily and the appearance is enhanced. For a bottle without the silicone coating, the powder adheres to the inner wall. Not only does the adhesion mar the appearance of the product but it also interferes with an inspection of the inside of the bottle.

Freeze-Drying Product

By using a silicone-coated bottle, freeze-drying medicine can be manufactured beautifully.

The silicone-coated bottle facilitates final inspection of the medicine.



Instructions for Handling of Silicone-Coated Containers

- ④ Silicone coating processing conditions differ depending on what is put in a silicone-coated container. When we receive an order for silicone coating, we will propose the optimal coating to suit your needs.
- ④ Similar to a glass container, a silicone-coated container has susceptibility to alkali.
- ④ The repellency of a silicone-coated container changes slightly by heating at high temperatures. If the silicone-coated container is heated at a temperature higher than 200°C for a long time for the purpose of dry sterilization, confirm the effect of the heating before use.
- ④ The durability of a silicone coating varies depending on what is put in a container. When the silicone-coated container is used for a liquid medicine, confirm the effect of the medicine on the coating sufficiently before use.
- ④ Since a silicone-coated container has water repellency, attention must be paid when washing the container. To wash the silicone-container, ultrasonic washing is optimal. If the container is washed with another method such as jet washing, check the water amount and pressure before washing so that the whole container can be washed sufficiently.
- ④ If you have any questions about the contents of this material or the use of a silicone-coated container, contact Research and Development Division or Quality Control Division. For a request for a sample or estimation of silicon coating, contact Sales Division.