

事務連絡  
令和4年3月15日

各都道府県衛生主管部（局）薬務主管課 御中

厚生労働省医薬・生活衛生局医薬品審査管理課

生理処理用品製造販売承認基準の英訳について

医薬部外品のうち、生理処理用品の製造販売の承認基準については、「生理処理用品製造販売承認基準について」（令和3年6月28日付け薬生発0628第4号厚生労働省医薬・生活衛生局長通知）により示してきたところですが、別添のとおり、当該基準の英訳を作成したのでお知らせいたします。

なお、本事務連絡の発出に伴い、「生理処理用品製造販売承認基準の英訳について」（平成27年11月19日付け厚生労働省医薬・生活衛生局審査管理課事務連絡）は廃止します。

June 28, 2021

Notification PSEHB No.0628-4

## **The Standards for Marketing Approval of Sanitary Napkins**

### 1. Scope of the standards

The standards shall be applied to quasi-drugs designed to absorb and treat menstrual blood (hereinafter referred to as “sanitary napkins”).

### 2. Standards

The following standards are applied to sanitary napkins.

For sanitary napkins that do not meet these standards, the submission of necessary documents regarding the efficacy, safety, and quality of constituent materials, etc. shall be required for review.

- (1) Sanitary napkins shall meet the Quality Specifications for Sanitary Napkins specified in Exhibit 1.
- (2) The materials shall meet the Material Standards for Sanitary Napkins specified in Exhibit 2. Each material shall meet the specifications listed and the scope of use encircled in the matrix of Exhibit 2.

In addition, flavor shall be used in trace amounts (not more than 0.1%) if applicable and formulated in the material so that it would not come in contact with the skin and mucosa.
- (3) Sanitary napkins shall meet the following requirements for components and shape.
  - i. Each sanitary napkin shall consist of “surface material(s)”, “absorbent material(s)”, “leak-protection material(s)”, “binding material(s)”,

“fixing material(s)”, “identification material(s)” and “other material(s)” listed in attached Table.

ii. Each sanitary napkin shall be formed as a single unit, which is not less than 140 mm in length, 45 mm in width, 1 mm in thickness and 2 g in weight.

(4) The dosage and administration shall be “appropriate number of napkins shall be used accordingly as need arises”.

(5) The indication shall be “for menstrual blood treatment.”

Attached Table: List of components

Surface material	Material that covers the absorbent material and is in direct contact with the body
Absorbent material	Material that absorbs menstrual blood
Leak-protection material	Material that protects against leakage of menstrual blood during menstrual blood absorption.
Binding material	Material that binds each component of the product when the materials are assembled.
Fixing material	Material intended to prevent dislocation of the product when the product is worn
Identification material	Material used in an area other than the intended surface of use to identify the intended surface of use
Others	Materials other than the above materials

## Quality Specifications for Sanitary Napkins

1. Sanitary napkins (hereinafter referred to as “the product”) shall be clean and shall be neither irritant nor harmful.
2. The product shall meet the requirements of the following tests. The specifications and test methods shall comply with the General Notices and the General Tests, Processes and Apparatus of the Japanese Pharmacopeia (hereinafter referred to as “JP”) unless otherwise specified.

### 1) Description

The product (except for materials protecting the fixing component) occurs as a white article (except for the marked part indicative of the non-use side). It is almost odorless (except for the product with flavor used in trace amounts) and contains no foreign matters.

### 2) Coloring matter

Weigh accurately the product (except for the material that protects the fixing material) and use it as the sample. Immerse the sample in freshly boiled and cooled water 60 times the mass of the sample for 5 minutes, then stir and filter. Use the filtrate as the sample solution. Transfer 25 mL of the sample solution into a test tube 15 mm in inside diameter and observe downward: almost no color develops.

If the addition of water 60 times the mass of the sample does not produce a necessary amount of the sample solution, take an adequate amount of all components of the product, weigh accurately them, use these as the sample, and prepare the sample solution in the same manner as directed above.

### 3) Acidity or alkalinity

To 25 mL of the sample solution obtained in the coloring matter test, add 2 drops of phenolphthalein TS: no red (deep pink) color develops. Separately, to 25 mL of the same solution, add 1 drop of methyl orange TS: no red color develops.

#### **4) Fluorescence**

##### Method 1

Irradiate the product (except for the material that protects the fixing material) with ultraviolet rays (wavelength: 350 to 370 nm) in a dark place: it shows no fluorescence or no more fluorescence than Fluorescence Reference Standard.

##### Method 2

If the product shows more fluorescence than Fluorescence Reference Standard with Method 1, cut the area that shows fluorescence into a piece of about 5 cm × 5 cm and use this as the sample. If the sample is not more than 25 cm<sup>2</sup>, combine more than one sample to obtain this area.

Add dilute ammonia water (28) (1 in 1000) to 100 mL of water to adjust the pH within the range of 7.5 to 9, elute the sample in this solution for about 10 minutes, and filter through glass wool.

Add dilute hydrochloric acid to the filtrate to adjust the pH within the range of 3 to 5, place gauze (2 cm × 4 cm) in this solution, and heat on a water bath for about 30 minutes. Wash the gauze with water, dry, and irradiate with ultraviolet rays (wavelength: 350 to 370 nm) in a dark place: it shows no fluorescence.

#### **5) Water absorption**

Weigh accurately the product (except for the material that protects the fixation material) and use it as the sample. Place the sample on a tared wire mesh (size: 1700 μm) with its intended surface of use side up, gently pour water over the whole surface until the whole sample is completely soaked. Continue pouring water until the water overflows, allow to stand for 1 minute, and measure the amount of water absorbed: the amount of water absorbed is not less than 10 times the mass of the sample.

#### **6) Exudation**

Place the product (except for the material that protects the fixation material) on a filter paper spread on a glass board with its intended surface of use side up and

touch its center lightly with the tip of a burette containing Congo red TS. Release 10 mL of Congo red TS at a speed of 5 to 10 mL per minute, allow to stand for 1 minute and place a 1-kg weight with 50 mm in diameter onto that area: Congo red TS does not effuse from the leak-protection material within 3 minutes. This does not apply to the products that have no leak-protection material.

## **7) Formaldehyde**

### **(1) Preparation of sample solution**

Weigh accurately the product (except for the material that protects the fixing material) and use this as the sample. Finely cut the sample, place in a hard glass container, exactly add water 60 times the mass of the sample, stopper tightly and extract in a water bath at 40°C for 1 hour with occasional shaking. Filter the solution through a glass filter while warm and use the filtrate as the sample solution.

If the addition of 60 times its weight of water does not produce a necessary amount of the sample solution, take an adequate amount of all components of the product, weigh accurately them, use these as the sample and prepare the sample solution in the same manner as directed above.

### **(2) Test**

#### Method 1

Transfer exactly 15.0 mL of the sample solution into a Nessler tube, add 5.0 mL of acetylacetone TS, shake, heat in a water bath at 40°C for 30 minutes and cool immediately. Separately, transfer 20.0 mL of Potassium Chromate Matching Fluid into a Nessler tube and use this solution as the control solution. Then compare the colors of both solutions by viewing the tubes downward against a white background: the sample solution has no more color than the control solution.

#### Method 2

Transfer exactly 15.0 mL of the sample solution into a Nessler tube, add 5.0 mL of acetylacetone TS, shake, heat in a water bath at 40°C for 30 minutes and cool immediately. Separately, transfer exactly 15.0 mL of Hexamethylenetetramine Matching Fluid into a Nessler tube, add 5.0 mL of acetylacetone TS, shake, heat in

a water bath at 80°C for 30 minutes, cool immediately and use this solution as the control solution. Then compare the colors of both solutions by viewing the tubes downward against a white background: the sample solution has no more color than the control solution.

### Method 3

If the sample solution shows turbidity or if visual comparison is difficult, measure exactly 15.0 mL each of the sample solution and Standard Formaldehyde Solution. Then, add 5.0 mL of acetylacetone TS, shake, heat in a water bath at 40°C for 30 minutes and allow to stand for 30 minutes. Read the absorbance (A) of the solution containing the sample solution and the absorbance (A<sub>S</sub>) of the solution containing Standard Formaldehyde Solution at the maximum wavelength between 412 and 415 nm, with a 1-cm cell, against a blank solution obtained by adding 5.0 mL of acetylacetone TS to 15.0 mL of water and treating it in the same manner as above. Separately, measure 15.0 mL of the sample solution, add 5.0 mL of water instead of acetylacetone TS and proceed as directed above. Read the absorbance (A<sub>0</sub>) of this solution at the same wavelength as that used in the determination of A and A<sub>S</sub>, using water as the blank: A - A<sub>0</sub> is not more than 0.03, or the amount of formaldehyde eluted from 1 g of the sample is not more than 18 µg if it is calculated using the following equation.

$$\begin{aligned} &\text{Amount } (\mu\text{g}) \text{ of eluted formaldehyde in 1 g of the sample} = K \{ (A - A_0) / A_S \} \\ &\times \text{Amount (mL) of water added for preparation of the sample solution} \times \\ &(1/\text{Weight (g) of sample}) \end{aligned}$$

K: Concentration (µg/mL) of Standard Formaldehyde Solution

If the value “A - A<sub>0</sub>” exceeds 0.03, or if the amount of formaldehyde eluted from 1 g of the sample exceeds 18 µg in the above test, perform either test (i) or (ii) below and confirm that the absorption at the same wavelength as that used for determination of absorbance A is attributed to formaldehyde.

#### (i) Dimedon method

Transfer 15.0 mL of the sample solution into a stoppered test tube, add 1.0 mL of dimedon-ethanol TS, shake, heat in a water bath at 40°C for 10 minutes. Then, add 5.0 mL of acetylacetone TS, shake, heat in a water bath at 40°C for 30 minutes and allow to stand for 30 minutes. Determine the absorption spectrum of this

solution between 412 and 415 nm against a blank solution obtained by using 15.0 mL of water instead of the sample solution and treating it in the same manner as above: the absorption spectrum between 412 and 415 nm shall not exhibit similar intensities of absorption at the same wavelengths as those of the spectra obtained in the determination of absorptions A and A<sub>s</sub>.

(ii) Liquid chromatography

Perform the test with 1 µL each of the solution obtained by adding acetylacetone TS to the sample solution, and the solution obtained by adding acetylacetone TS to Standard Formaldehyde Solution, according to the following conditions. If the chromatogram of the solution obtained by adding acetylacetone TS to the sample solution shows a peak at the same retention time as that of the reaction product of formaldehyde and acetylacetone from the solution obtained by adding acetylacetone TS to Standard Formaldehyde Solution, the peak area shall not be more than that of the reaction product of formaldehyde and acetylacetone from the solution obtained by adding acetylacetone TS to Standard Formaldehyde Solution.

Operating conditions

Detector: An ultraviolet-visible detector (wavelength: 412 to 415 nm)

Column: A stainless steel column about 4.6 mm in inside diameter and 150 mm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 µm in particle diameter).

Column temperature: A constant temperature of about 35°C

Mobile phase: A mixture of water and acetonitrile (4:1 - 17:3)

Flow rate: 1.0 mL/minute

**8) Adhesion**

**(1) Pretreatment of sample**

Lay the product (including the material that protects the fixation material) flat, allow to stand at 30 - 31°C for not less than 2 hours and use this as the sample.

**(2) Test**

Method 1

Attach a piece of cotton cloth onto a glass board of Adhesion Test Device (see the illustrations in Separate Figure), previously warmed to 30 - 31°C, lay the



pretreated sample flat, removing the material that protects the fixation material, on the cotton cloth with the adhesive side down, and clip the pulling tab with a pulling clip. Place a 750-g weight for attachment approximately in the center of the sample and allow the sample to attach to the cotton cloth for 1 minute. Remove the weight for attachment, place a 225-g weight for pulling on the sample, attach a 250-g load to the pulling string and pull immediately: the sample is not dislocated within 1 minute.

This does not apply to the products that have no fixation material.

### Method 2

Attach a piece of cotton cloth onto a glass board, previously warmed to 30- 31°C, lay the pretreated sample flat, removing the material that protects the fixation material, on the cotton cloth with the adhesive side down, and clip the pulling tab with a pulling clip. Place a 750-g weight for attachment approximately in the center of the sample and allow the sample to attach to the cotton cloth for 1 minute. Remove the weight for attachment, place a 225-g weight for pulling on the sample, pull immediately at a speed of about 3 to 5 cm per minute and measure the weight of the load using a spring balance when the sample starts moving: it is not less than 250 g.

This does not apply to the products that have no fixation material.

## **9) Reagents, test solutions (TS), reference standards, standard solutions, measuring instruments and appliances**

### **(1) Reagents and test solutions (TS)**

**Acetic acid (100)**  $\text{CH}_3\text{COOH}$  [K8355, Acetic acid, Special class]

**Acetonitrile**  $\text{CH}_3\text{CN}$  [K8032, Special class]

**Acetylacetone**  $\text{CH}_3\text{COCH}_2\text{COCH}_3$  [K8027, Special class]

**Acetylacetone TS** Dissolve 300 g of ammonium acetate in a sufficient quantity of water, add 6 mL of acetic acid (100) and 4 mL of acetylacetone, and add water to make 1000 mL. Prepare before use.

**Amidosulfuric acid (standard reagent)**  $\text{HOSO}_2\text{NH}_2$  [K 8005, Standard substance for volumetric analysis] or [K 8587, Special class]

**Ammonium acetate**  $\text{CH}_3\text{COONH}_4$  [K8359, Special class]

**Ammonia water (solution) (28)**  $\text{NH}_3$  [K8085, Ammonia Water, Special class, Specific

gravity: about 0.90, Density: 0.908 g/mL, Content: 28-30%]

**Anhydrous sodium carbonate**,  $\text{Na}_2\text{CO}_3$  [K 8625, Sodium carbonate, Special class]

**Barium hydroxide octahydrate**  $\text{Ba}(\text{OH})_2 \cdot 8\text{H}_2\text{O}$  [K 8577, Special class] Preserve in tightly stoppered containers.

**Bromothymol blue**  $\text{C}_{27}\text{H}_{28}\text{Br}_2\text{O}_5\text{S}$  [K 8842, Special class] Range of color change: pH (yellow) 6.0-7.6 (blue)

**Bromothymol blue TS** Dissolve 0.1 g of bromothymol blue in 100 mL of dilute ethanol, and filter if necessary.

**Congo red**  $\text{C}_{32}\text{H}_{22}\text{N}_6\text{Na}_2\text{O}_6\text{S}_2$  [K8352, Special class]

**Congo red TS** Add water to 0.2 g of Congo red to make 100 mL.

**Dilute hydrochloric acid** Add water to 23.6 mL of hydrochloric acid to make 100 mL (10%).

**Dilute sulfuric acid** Cautiously add 5.7 mL of sulfuric acid to 10 mL of water, cool and dilute with water to make 100 mL (10%).

**Dimedon**  $\text{C}_8\text{H}_{12}\text{O}_2$  White to pale yellow crystalline powder. Melting point: 145-149°C

**Dimedon-ethanol TS** Dissolve 1 g of dimedon in ethanol to make 100 mL. Prepare before use.

**Ethanol**  $\text{C}_2\text{H}_5\text{OH}$  [K8102, Special class]

**Fluorescent-24**  $\text{C}_{40}\text{H}_{44}\text{N}_{12}\text{Na}_4\text{O}_{16}\text{S}_4$  Delayed-staining stilbene fluorescent brightener. Color index name: C.I. Fluorescent brightener-24 (C.I. No. 40650). Chemical name: Tetrasodium 4,4'-bis[[4-[bis (2-hydroxyethyl)amino]-6-[(3- sulphonatophenyl) amino]-1,3,5-triazin-2-yl] amino] stilbene-2,2'-disulphonate (CAS No. 12224-02-1)

**Fluorescent-351**  $\text{C}_{28}\text{H}_{20}\text{Na}_2\text{O}_6\text{S}_2$  Stilbene fluorescent brightener. Color index name: C.I. Fluorescent brightener-351 (FWA-5) (C.I. No. 482200). Chemical name: Disodium 4,4'-Bis(2-sulfonatostyryl)biphenyl (CAS No. 27344-41-8)

**Formalin**  $\text{HCHO}$  [K8872, Formaldehyde Solution, Special class]

**Hexamethylenetetramine**  $(\text{CH}_2)_6\text{N}_4$  [K8847, Special class]

**Hexamethylenetetramine matching fluid** Weigh 186.7 mg of hexamethylenetetramine and add water to make 1000 mL. Add water to 5 mL of this solution to make 100 mL and use the solution as a stock matching fluid. Measure 5 mL of this stock solution and add water to make 200 mL and use the solution as Hexamethylenetetramine Matching Fluid. The concentration of formaldehyde in this matching fluid is 0.3  $\mu\text{g}/\text{mL}$ .

**Hydrochloric acid**  $\text{HCl}$  [K 8180, Special class]

**Iodine**  $\text{I}$  [K 8920, Special class]

**Methyl orange**  $\text{C}_{14}\text{H}_{14}\text{N}_3\text{NaO}_3\text{S}$  [K 8893, Special class] Range of color change: pH

(red) 3.1-4.4 (orange-yellow).

**Methyl orange TS** Dissolve 0.1 g of methyl orange in 100 mL of water, and filter if necessary.

**Ordinary water** [Water (JP monograph)]

**Octadecylsilanized silica gel for liquid chromatography** Prepared for liquid chromatography.

**Phenolphthalein**  $C_{20}H_{14}O_4$  [K 8799, Special class] Range of color change: pH (colorless) 8.3-10.0 (red)

**Phenolphthalein TS** Dissolve 1 g of phenolphthalein in 100 mL of ethanol (95).

**Potassium chromate**  $K_2CrO_4$  [K8312, Special class]

**Potassium chromate matching fluid** Weigh 261.7 mg of potassium chromate and add water to make exactly 1000 mL. Measure 10 mL of this solution, add water to make exactly 100 mL and use the solution as Potassium Chromate Matching Fluid.

**Potassium hydroxide** KOH [K 8574, Special class]

**Potassium iodate (standard reagent)**  $KIO_3$  [K 8005, Standard reagent for volumetric analysis]

**Potassium iodide** KI [K 8913, Special class]

**Sodium chloride** NaCl [K8150, Special class]

**Sodium thiosulfate pentahydrate**  $Na_2S_2O_3 \cdot 5H_2O$  [K 8637, Special class]

**Starch** [K8658, Special class]

**Starch TS** Triturate 1 g of starch with 10 mL of cold water, and pour the mixture slowly, with constant stirring, into 200 mL of boiling water. Boil the mixture until a thin, translucent fluid is obtained. Allow to settle, and use the supernatant liquid. Prepare before use.

**Sulfuric acid**  $H_2SO_4$  [K 8951, Special class]

**Water** [Purified Water (JP monograph)]

## **(2) Reference standards**

**Fluorescence reference standard (1)** Weigh exactly 7 mg of Fluorescent-24 in a brown volumetric flask, add water to make exactly 500 mL and store protected from light. To 5 mL of this solution, add 0.1 g of sodium chloride and water to make 50 mL, immerse a filter paper (8 cm × 15 cm) into the resultant solution for 1 hour with occasional inverting and air-dry it on a filter paper.

**Fluorescence reference standard (2)** Weigh exactly 7 mg of Fluorescent-351 in a brown volumetric flask, add water to make exactly 500 mL and store protected from light. To 0.35 mL of this solution, add 0.1 g of sodium chloride and water to make 50 mL,

immerse a filter paper (8 cm × 15 cm) into the resultant solution for 1 hour with occasional inverting and air-dry it on a filter paper.

**Gauze** Use medical gauze conforming to the requirements of Notification No. 0630001 of the Medical Devices Evaluation, the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, the MHLW (June 30, 2005).

**Piece of cotton fabric** Use white cloth conforming to the requirements of JIS L0803 “Standard Adjacent Fabrics for Staining of Color Fastness Test” (Type: Cotton, Nominal No.: 3-1).

### **(3) Standard solutions and volumetric standard solutions (VS)**

#### **Iodine VS, 0.05 mol/L**

1000 mL of this solution contains 12.690 g of iodine (I: 126.90).

Preparation: Dissolve 13 g of iodine in 100 mL of a solution of potassium iodide (2 in 5), add 1 mL of dilute hydrochloric acid and water to make 1000 mL, and standardize the solution as follows:

Standardization: Measure exactly 15 mL of the iodine solution, and titrate with 0.1 mol/L sodium thiosulfate VS (indicator: starch TS). When the solution assumes a pale yellow color as the end point is approached, add 3 mL of starch TS, and continue the titration until the blue color disappears. Calculate the molarity factor.

Note: Store protected from light. This solution, if stored for a long period, should be restandardized before use.

#### **Potassium hydroxide VS, 1 mol/L**

1000 mL of this solution contains 56.11g of potassium hydroxide (KOH: 56.11).

Preparation: Dissolve 65 g of potassium hydroxide in 950 mL of water. Add a freshly prepared, saturated solution of barium hydroxide octahydrate until no more precipitate is produced. Shake the mixture thoroughly, and allow it to stand for 24 hours in a tightly stoppered bottle. Decant the supernatant liquid or filter the solution through a glass filter (G3 or G4), and standardize the solution as follows:

Standardization: Weigh accurately about 2.5 g of amidosulfuric acid (standard reagent), previously dried in a desiccator (in vacuum, silica gel) for 48 hours. Dissolve it in 25 mL of freshly boiled and cooled water, and add 2 drops of bromothymol blue TS. Titrate the solution with the prepared potassium hydroxide solution until it acquires a green color. Calculate the molarity factor.

Each mL of 1 mol/L potassium hydroxide VS = 97.09 mg of  $\text{HOSO}_2\text{NH}_2$

Note: Store in tightly stoppered bottles or in containers provided with a carbon dioxide-absorbing tube (soda-lime). This solution, if stored for a long period, should be

restandardized.

### **Standard formaldehyde solution**

Standardization: Weigh accurately about 1 g of formalin in a weighing bottle containing water and add water to make exactly 100 mL. Take exactly 10 mL of the solution, add 50 mL of 0.05 mol/L iodine VS and 20 mL of 1 mol/L potassium hydroxide VS and allow to stand at ordinary temperature for 15 minutes. Add 15 mL of dilute sulfuric acid to the solution and titrate an excessive amount of iodine with 0.1 mol/L sodium thiosulfate VS (indicator: starch TS). Separately, perform a blank determination using 10 mL of water in the same manner.

Determine the content C (%) of formaldehyde in formalin using the following equation.

$$C (\%) = 1.5013 ((V_0 - V) F / 1000) \times (100 / 10) \times (1 / W) \times 100$$

$V_0$ : Volume (mL) of 0.1 mol/L sodium thiosulfate VS consumed in the blank determination

$V$ : Volume (mL) of 0.1 mol/L sodium thiosulfate VS consumed for titration of the sample

$F$ : Factor of 0.1 mol/L sodium thiosulfate VS

$W$ : Weight (g) of formalin

Preparation: Weigh exactly 300/C g of formalin and add water to make 100 mL. Take exactly 10 mL of this solution and dilute with water to exactly 10 times the initial volume. Repeat the procedure 5 times and use the resulting solution as Standard Formaldehyde Solution.

Each mL of Standard Formaldehyde Solution = 0.3  $\mu$ g HCHO

### **Sodium thiosulfate VS, 0.1 mol/L**

1000 mL of this solution contains 24.818 g of sodium thiosulfate pentahydrate ( $\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$ : 248.18).

Preparation: Dissolve 25 g of sodium thiosulfate and 0.2 g of anhydrous sodium carbonate in sufficient, freshly boiled and cooled water to make 1000 mL, and standardize as follows:

Standardization: Weigh accurately about 50 mg of potassium iodate (standard reagent), previously dried between 120°C and 140°C for 1.5-2 hours and allowed to cool in a desiccator (silica gel), and transfer to an iodine flask. Dissolve it in 25 mL of water, add 2 g of potassium iodide and 10 mL of dilute sulfuric acid, and stopper the flask. After allowing the mixture to stand for 10 minutes, add 100 mL of water, and titrate the liberated iodine with the prepared sodium thiosulfate solution. When the solution assumes a light yellow color as the end point is approached, add 3 mL of starch TS. Continue the titration until the blue color disappears. Perform a blank determination. Calculate the

molarity factor.

Each mL of 0.1 mol/L sodium thiosulfate = 3.567 mg of  $\text{KIO}_3$

Note: This solution, if stored for a long period, should be re-standardized.

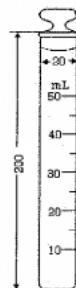
#### **(4) Measuring instruments and appliances**

**Filter papers** Use the filter papers confirming to the specifications for filter papers for qualitative analysis (for chemical analysis) provided in P3801 of the Japanese Industrial Standards (hereinafter referred to as JIS).

**Glass filters** Use the glass filters provided in R3503 of the JIS. Use the filter plates 40 to 50  $\mu\text{m}$  in pore size.

**Glass wool** Use glass wool of special grade provided in K8251 of the JIS.

**Nessler tubes** Use colorless, glass-stoppered cylinders 1.0 to 1.5 mm in thickness, made of hard glass as shown in the figure below. The difference of the height of the graduation line of 50 mL from the bottom among cylinders does not exceed 2 mm.



The figures are in mm.

**Sieves** Use sieve No. 10 provided in Z8801 of the JIS. Use the sieve number of nominal size ( $\mu\text{m}$ ) as the designation.

Sieve No	Nominal size ( $\mu\text{m}$ )	Specification of sieves				
		Size (mm)	Sieve opening		Wire (mm)	
			Permissible variation (%)		Diameter	Permissible variation
			Average	Maximum		
10	1700	1.70	$\pm 0.051$	0.17	0.80	$\pm 0.025$

**Volumetric measures** Use volumetric flasks and burettes conforming to the specifications under the JIS.

<Separate Figure> Adhesion Test Device

Fig. 1

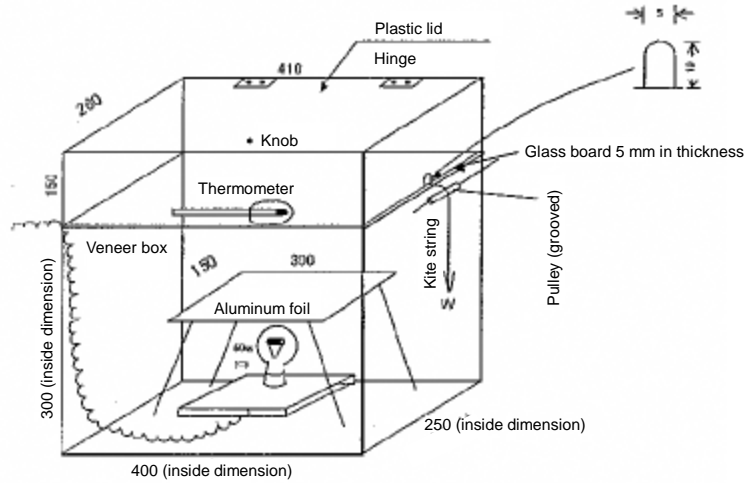


Fig. 2

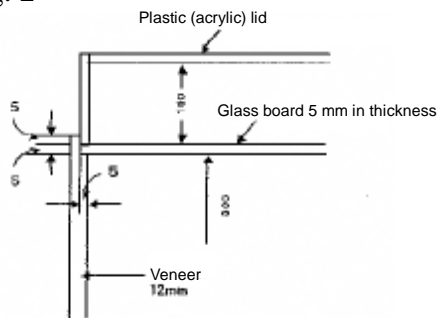
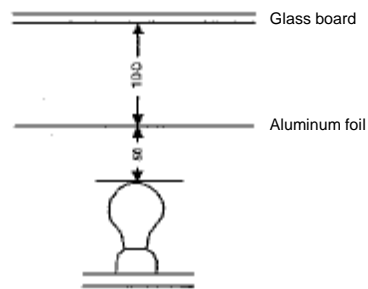


Fig. 3



		Thickness	Depth	Width	Height
(1) Box (Fig. 1)	Veneer,	12 mm	250 mm × 400 mm × 300 mm (inside dimension)		
(2) Lid (Fig. 2)	Acrylic board,	3 to 5 mm	250 mm × 400 mm × 150 mm (inside dimension)		
(3) Glass board		5 mm	260 mm × 410 mm		
(4) Aluminum foil (Fig. 3)			150 mm × 300 mm		

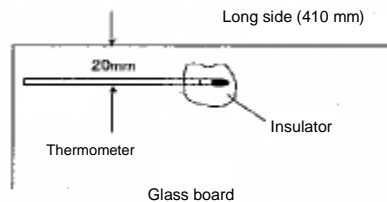
Lay flat a piece of aluminum foil at a distance of 100 mm from the underside of the glass board.

(5) Light bulb:

Place one 60W light bulb in the center of the box so that the distance between the top of the light bulb and the aluminum foil is 50 mm.

(6) Thermometer:

Place a thermometer on the glass board parallel to and at a distance of 20 mm from the long side of the glass board so that the bulb of the thermometer is positioned approximately in the center of the side, and cover with an insulator (glass wool).



(7) Pulley Grooved

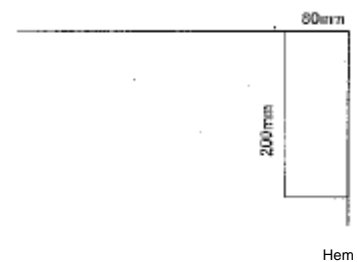
(8) Pulling string Kite string

(9) Pulling clip Chevron clip (Clipping width: 109 mm)

(10) Piece of cotton fabric

Use white fabric conforming to the requirements of JIS L0803 “Standard Adjacent Fabrics for Straining of Color Fastness Test” (Cotton No. 3-1).

Cut the white fabric into a piece 80 mm × 200 mm as designating the hem side of the original fabric as the long side of the fabric for the test.



(11) Weight for attachment 50 mm × 150 mm in size, 750 g in weight

(12) Weight for pulling 50 mm × 150 mm in size, 225 g in weight



Material Standards for Sanitary Napkins

No.	Specification	Ingredient Name	Precedent Usages for Materials in Sanitary Napkins						
			Surface Materials	Absorbent Materials	Leak - protection Materials	Binding Materials	Fixing Materials	Identification Materials	Others
1	55	Ionomer Resin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
2	51	Alkyl Acrylate Copolymer				<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> <sup>1)</sup>
3	51	Alkyl Acrylate Copolymer Emulsion (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4	51	Alkyl Acrylate Copolymer Emulsion (2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5	51	Alkyl Acrylate · Vinyl Acetate Copolymer Solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	51	Alkyl Acrylate · Vinyl Acetate Copolymer Emulsion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
7	55	Alkyl Acrylate · Vinyl Acetate Copolymer Emulsion (2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
8	55	Partial Potassium Salt of Polyacrylic Acid		<input type="checkbox"/>					
9	55	Partial Sodium Salt of Polyacrylic Acid		<input type="checkbox"/>					
10	25	Starch Acrylate 300		<input type="checkbox"/>					
11	25	Starch Acrylate 1000		<input type="checkbox"/>					
12	51	Sodium Ascorbate		<input type="checkbox"/>					
13	55	Acetate Fiber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
14	55	Alkyl Ketene Dimer Emulsion			<input type="checkbox"/>			<input type="checkbox"/>	
15	51	Sodium Alginate				<input type="checkbox"/>	<input type="checkbox"/>		
16	51	Propyleneglycol Alginate				<input type="checkbox"/>	<input type="checkbox"/>		
17	55	Alkenyl Succinic Anhydride Solution			<input type="checkbox"/>			<input type="checkbox"/>	
18	25	Pregelatinized Starch	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
19	51	Benzoic Acid				<input type="checkbox"/>	<input type="checkbox"/>		
20	55	Sulfur			<input type="checkbox"/>				
21	55	Polyurethane Fiber			<input type="checkbox"/>				
22	55	Polyurethane Film			<input type="checkbox"/>				
23	55	Polyurethane Foam		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		
24	31, 55	Ester Gum				<input type="checkbox"/>	<input type="checkbox"/>		
25	55	Ethylene · Ethylene Acrylate Copolymer (EEA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
26	55	Ethylene · Acrylic Acid Copolymer (EAA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	

No.	Specification	Ingredient Name	Precedent Usages for Materials in Sanitary Napkins						
			Surface Materials	Absorbent Materials	Leak - protection Materials	Binding Materials	Fixing Materials	Identification Materials	Others
27	55	Ethylene · Octene-1 Copolymer	○	○	○	○	○	○	
28	55	Ethylene · Vinyl Acetate Copolymer (EVA) (1)			○ <sup>1)</sup>	○	○		
29	55	Ethylene · Vinyl Acetate Copolymer (EVA) (2)	○	○	○		○	○	
30	55	Ethylene · Vinyl Acetate Copolymer (EVA) Emulsion	○	○	○			○	
31	55	Ethylene · Vinyl Acetate (EVA) / Polypropylene (PP) Bicomponent Fiber	○	○	○			○	
32	55	Ethylene · Butene Copolymer (EBR)	○	○	○			○	
33	55	Ethylene · Propylene Copolymer (EPR)	○	○	○			○	
34	55	Ethylene · Pentene-1 Copolymer	○	○	○			○	
35	55	Ethylene · Methacrylic Acid Copolymer	○	○	○			○	
36	55	Ethylene · Methyl Methacrylate Copolymer	○	○	○			○	
37	55	Ethylene · 4-Methylpentene-1 Copolymer	○	○	○			○	
38	55	Chemical Pulp	○	○	○			○	
39	31, 55	Active Carbon		○					
40	51	Carnauba Wax			○			○	
41	01, 51	Sodium Carboxymethylcellulose	○	○	○			○	
42	55	Flocculent Sodium Carboxymethylcellulose		○	○			○	
43	55	Absorbent Paper	○	○	○			○	
44	51	Glycerine	○	○	○			○	
45	31	Glycerol Esters of Fatty Acids	○	○					
46	51	Magnesium Silicate	○	○	○				
47	51	Hydrogenated Castor Oil			○	○	○		
48	55	High-density Polyethylene (HDPE)	○	○	○	○	○	○	○
49	01	Wheat Starch			○			○	
50	55	Cycloaliphatic Saturated Hydrocarbon Resin				○	○		○ <sup>1)</sup>
51	55	Cycloparaffin			○	○	○		
52	55	Dibenzothiazyl Disulfide			○				
53	55	Aliphatic Hydrocarbon Resin				○	○		○ <sup>1)</sup>
54	55	Aliphatic and Aromatic Copolymer Resin (Aromatic and Denatured Aliphatic Hydrocarbon Resin)				○	○		○ <sup>1)</sup>

No.	Specification	Ingredient Name	Precedent Usages for Materials in Sanitary Napkins						
			Surface Materials	Absorbent Materials	Leak - protection Materials	Binding Materials	Fixing Materials	Identification Materials	Others
55	55	Aliphatic Saturated Hydrocarbon Resin				○	○		○ <sup>1)</sup>
56	51	Silicone Resin			○	○	○		
57	51	Glyceryl Monooleate, Lipophilic	○	○					
58	51	Glyceryl Monostearate, Lipophilic	○	○		○	○	○	
59	55	Hydrogenated Aliphatic and Aromatic Copolymer Resin				○	○		○ <sup>1)</sup>
60	55	Hydrogenated Dicyclopentadiene-group Hydrocarbon Resin				○	○		○ <sup>1)</sup>
61	25, 55	Styrene · Isoprene · Styrene Block Copolymer				○	○		○ <sup>1)</sup>
62	55	Styrene · Ethylene-Butylene · Styrene Block Copolymer			○	○	○		○ <sup>1)</sup>
63	55	Styrene · Ethylene-Propylene · Styrene Block Copolymer				○	○		○ <sup>1)</sup>
64	55	Styrene · Butadiene · Styrene Block Copolymer			○ <sup>1)</sup>	○	○		○ <sup>1)</sup>
65	55	Styrene · Methacrylate Copolymer Solution			○			○	
66	51	Stearic Acid	○	○	○	○	○	○	
67	51	Zinc Stearate	○	○	○				
68	51	Stearic Acid Amide			○	○	○		
69	01·51	Calcium Stearate	○	○	○				
70	51	Stearic Acid Diethanolamide	○	○					
71	51	Magnesium Stearate	○	○					
72	51	Sodium Di(2-Ethylhexyl) Sulfosuccinate	○	○					
73	55	Hydrophobic Zeolite		○					
74	31	D-Sorbitol			○			○	
75	51	Sorbic Acid				○	○		
76	55, 74	Absorbent Cotton	○	○	○			○	
77	55	Calcium Carbonate			○ <sup>1)</sup>				
78	55	Linear Low-density Polyethylene (LLDPE)	○	○	○	○	○	○	○
79	55	Low-density Polyethylene (LDPE)	○	○	○	○	○	○	○
80	25	Terpene Resin				○	○		
81	55	Natural Rubber Thread			○ <sup>1)</sup>				
82	25, 51	Natural Rubber Latex			○ <sup>1)</sup>	○	○		
83	55	Partial Sodium Salt of Starch · Acrylic Acid Graft Polymer		○					

No.	Specification	Ingredient Name	Precedent Usages for Materials in Sanitary Napkins						
			Surface Materials	Absorbent Materials	Leak - protection Materials	Binding Materials	Fixing Materials	Identification Materials	Others
84	55	Cuprammonium Rayon	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
85	24, 31	Sodium Copper Chlorophyllin		<input type="radio"/>					
86	25	Raw Rubber			<input type="radio"/> <sup>1)</sup>	<input type="radio"/>	<input type="radio"/>		
87	51	Nitrocellulose			<input type="radio"/> <sup>2)</sup>				
88	51, 55	Paraffin			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> <sup>1)</sup>
89	55	Paraffin Oil			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> <sup>1)</sup>
90	55	Amorphous Propylene · Ethylene Copolymer				<input type="radio"/>	<input type="radio"/>		<input type="radio"/> <sup>1)</sup>
91	55	Amorphous Propylene · Ethylene · Butene-1 Ternary Copolymer				<input type="radio"/>	<input type="radio"/>		<input type="radio"/> <sup>1)</sup>
92	55	Amorphous Propylene · Butene-1 Copolymer				<input type="radio"/>	<input type="radio"/>		<input type="radio"/> <sup>1)</sup>
93	55	Amorphous Polypropylene Resin				<input type="radio"/>	<input type="radio"/>		<input type="radio"/> <sup>1)</sup>
94	51	Rayon	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
95	51	Castor Oil			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
96	55	Emulsion of Rosin Denatured with Fumaric Acid			<input type="radio"/>			<input type="radio"/>	
97	51	Behenyl Alcohol	<input type="radio"/>	<input type="radio"/>					
98	55	Aromatic Denatured Terpene Resin				<input type="radio"/>	<input type="radio"/>		
99	55	Polyacrylamide Solution	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
100	55	Polyacrylamide · Polyvinyl Alcohol Copolymer Emulsion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
101	51	Polyamide Epichlorohydrin Resin Solution (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
102	51	Polyamide Epichlorohydrin Resin Solution (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
103	55	Polyester / Copolymer Polyester Bicomponent Fiber (PET / PET · Polyethylene Isophthalate Copolymer Bicomponent Fiber)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
104	55	Polyethylene Terephthalate (PET) Resin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
105	55	Polyethylene Terephthalate (PET) Fiber	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
106	55	Polyethylene Terephthalate (PET) / Polyethylene (PE) Bicomponent Fiber	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
107	51	Polyethyleneimine Solution	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
108	55	Polyethylene Oxide	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
109	51	Polyethylene Glycol (PEG) 200	<input type="radio"/>	<input type="radio"/>					
110	51	Polyethylene Glycol (PEG) 300	<input type="radio"/>	<input type="radio"/>					
111	51	Polyethylene Glycol (PEG) 400	<input type="radio"/>	<input type="radio"/>					

No.	Specification	Ingredient Name	Precedent Usages for Materials in Sanitary Napkins						
			Surface Materials	Absorbent Materials	Leak - protection Materials	Binding Materials	Fixing Materials	Identification Materials	Others
112	51	Polyethylene Glycol (PEG) 600	<input type="checkbox"/>	<input type="checkbox"/>					
113	51	Polyethylene Glycol (PEG) 1000	<input type="checkbox"/>	<input type="checkbox"/>					
114	51	Polyethylene Glycol (PEG) 1500	<input type="checkbox"/>	<input type="checkbox"/>					
115	51	Polyethylene Glycol (PEG) 4000	<input type="checkbox"/>	<input type="checkbox"/>					
116	51	Polyethylene Glycol (PEG) 6000	<input type="checkbox"/>	<input type="checkbox"/>					
117	51	Polyethylene Glycol (PEG) 20000	<input type="checkbox"/>	<input type="checkbox"/>					
118	55	Polyethylene (PE) Resin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
119	55	Polyethylene (PE) Fiber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
120	55	Polyethylene (PE) / Polypropylene (PP) Bicomponent Fiber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
121	51	Polyethylene (PE) Wax				<input type="checkbox"/>	<input type="checkbox"/>		
122	55	Polyvinyl Chloride (PVC) Fiber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
123	51	Poly (Oxyethylene/Oxypropylene) Methylpolysiloxane Copolymer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
124	51	Polyoxyethylene Nonylphenylether	<input type="checkbox"/>	<input type="checkbox"/>					
125	51	Polyoxyethylene Behenylether	<input type="checkbox"/>	<input type="checkbox"/>					
126	51	Polyoxyethylene Laurylether	<input type="checkbox"/>	<input type="checkbox"/>					
127	51	Polyvinyl Acetate Emulsion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
128	51, 55	Polyvinyl Alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
129	31	Polybutene				<input type="checkbox"/>	<input type="checkbox"/>		
130	55	Polypropylene Copolymer Fiber (Propylene · Ethylene Copolymer Fiber)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
131	55	Polypropylene / Copolymer Polypropylene Bicomponent Fiber (PP / Propylene · Ethylene Copolymer Bicomponent Fiber)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
132	55	Polypropylene (PP) Resin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
133	55	Polypropylene (PP) Fiber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	
134	51	Polypropylene (PP) Powder				<input type="checkbox"/>	<input type="checkbox"/>		
135	51	Microcrystalline Wax			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
136	55	Solution of Petroleum Resin Denatured with Maleic Acid			<input type="checkbox"/>			<input type="checkbox"/>	
137	55	Solution of Rosin Denatured with Maleic Acid			<input type="checkbox"/>			<input type="checkbox"/>	
138	51	Silicic Anhydride	<input type="checkbox"/>	<input type="checkbox"/>					
139	55	α-Mthylstyrene-group Resin				<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> <sup>1)</sup>

No.	Specification	Ingredient Name	Precedent Usages for Materials in Sanitary Napkins						
			Surface Materials	Absorbent Materials	Leak - protection Materials	Binding Materials	Fixing Materials	Identification Materials	Others
140	55	Flocculent Pulp	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
141	51	Sorbitan Monooleate	<input type="radio"/>	<input type="radio"/>					
142	51	Sorbitan Monostearate	<input type="radio"/>	<input type="radio"/>					
143	51	Polyethyleneglycol Monostearate				<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
144	25, 51, 55	Sorbitan Monolaurate	<input type="radio"/>	<input type="radio"/>					
145	51	Polyethyleneglycol Monolaurate	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
146	55	Cotton	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
147	51, 55	Aluminum Sulfate Aqua Solution	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
148	51	Liquid Petrolatum			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> <sup>1)</sup>
149	55	Flocculent Rayon	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
150	55	Rayon Fiber	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>			<input type="radio"/>	
151	51	Petrolatum	<input type="radio"/>	<input type="radio"/>					

#### Remarks

Definitions of Specification Codes

01: The Japanese Pharmacopoeia (JP)

24: Japanese Pharmaceutical Codex (JPC)

25: Japan Pharmaceutical Excipients (JPE)

31: The Japanese Standards for Food Additives

51: The Japanese Standards of Quasi-drug Ingredients (JSQI)

55: The Japanese Specifications of Sanitary Napkin Materials (JSNM)

74: Standards for Medical Guaze and Medical Absorbent Cotton

#### Notes

1) This material can be used only when the material does not directly contact to skin and mucosa.

2) This material can be used only when the material does not directly contact to mucosa.