

**ANTI-BACTERIAL DOUGH- anti-bacterial dough gel**  
**Dongguan City Dexu Toys Co., Ltd.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**78048-016**  
**ANTI-BACTERIAL DOUGH**

**Active Ingredient(s)**

Benzalkonium Chloride 0.09%

**Purpose**

Anti-septic

**Use**

Anti-bacterial dough helps reduce bacteria that potentially can cause disease.

Read the attached instructions before use.

**Warnings**

For external use only.

Keep appropriately in container after use.

**Do not use**

in children less than 3.

on open skin wounds.

**When using this product**

Keep out of eyes, ears, and mouth.

in case of contact with eyes, rinse eyes thoroughly with water.

**Stop use**

Stop use and ask a doctor if irritation or rash occurs.

If swallowed, get medical help.

Keep out of eyes , ears , and mouth.

In case of contact with eyes , rinse eyes thoroughly with water.

## Directions

Before use, read the label and the product information.

Place enough in hands and rub hands not less than 1-2 minutes.

Anti-bacterial dough can be used over and over and best within 1 month if kept appropriately closed container when not in use.

## Other information

Store in room temperature ( 25°C / 77 °F )

Avoid freezing and excessive heat above 70 °C ( 158 °F )

## Inactive ingredients

Whole Wheat Flour , Aqua , Glycerol , Polyvinyl alcohol , Phenoxyethanol , Caprylyl Glycol , Pentylene glycol, Pentasodium Pentetate, Silver Nitrate, Denatonium benzoate, Red 40, Yellow 5, Blue 1, Red 28

## Package Label - Principal Display Panel

FRONT



BACK





**ANTI-BACTERIAL Dough**

**CLEAN & FUN!**

**ANTI-BACTERIAL MODELING DOUGH**

- SAFE NON-TOXIC
- ALCOHOL-FREE
- USE OVER & OVER\* PLAY AND CLEAN!

PATENT - GRANTED  
N° EP20181544.6

**SANITIZE YOUR HANDS WHILE YOU PLAY!**

2+

1 DOUGH COLORS 4.01 OZ. (114g)

**ANTI-BACTERIAL Dough**

**MIX AND CREATE NEW COLORS!**

**Drug Facts**

Active ingredient	Purpose
Benzalkonium Chloride 0.09%	Anti-septic

**Uses**

- Anti-bacterial dough helps reduce bacteria that potentially can cause disease.
- Read the attached instructions before use.

**Warnings**

For external use only.

**Keep appropriately in container after use.**

**Do not use** ■ On children less than 2 years. ■ On open skin wounds.

**When using this product**

- Keep out of eyes, ears, and mouth. ■ In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or rash occurs. If swallowed, get medical help.

**Directions**

- Before use, read the label and the product information.
- Place enough in hands and rub hands not less than 1-2 minutes.
- Anti-bacterial dough can be used over and over and best within 1 month if kept appropriately in a closed container when not in use.

**Other information**

- Store in room temperature (25 °C / 77 °F)
- Avoid freezing and excessive heat above 70 °C (158 °F)

**Inactive ingredients**

Whole Wheat Flour, Aqua, Glycerol, Polyvinyl alcohol, Phenoxyethanol, Caprylyl Glycol, Pentylene glycol, Pentasodium Pentetate, Silver Nitrate, Denatonium benzoate, Red 40, Yellow 5, Blue 1, Red 28.

NOTICE: THIS PRODUCT CONTAINS WHEAT.  
\*REUSE IT OVER AND OVER AGAIN ... EFFECTIVE FOR UP TO 1 MONTH!

Expiration Date: DD/MM/YYYY 6900

KEEP THE MODELING DOUGH IN ITS CLOSED CONTAINER BETWEEN EACH USE. Lot No: #327027 USA 1

- Conforms to ASTM D-4236, ASTM E2315
- Contents contain colorants that may stain certain surfaces.
- Remove all packaging before giving to a child.
- Styles and colors of contents may vary from pictures.
- Please retain this information for future reference.
- Do not eat or ingest contents. Do not put near eyes, mouth, or nose.
- Avoid contact with abraded skin.
- Avoid contact with eyes. In case of accidental contact with eyes, rinse with water thoroughly.
- To avoid slime residue or staining other surfaces wash hands again after use.
- In case of adverse reaction stop using.
- Store dough in sealed container when not in use.

©2021 Anti-Bacterial Dough™ a Canal Toys® brand  
Jordan Lye / musician / Tsyo Ojoh / LoopAJ / forton / zenstock / Shutterstock.com

MADE IN CHINA

MANUFACTURED FOR AND DISTRIBUTED BY:  
CANAL TOYS USA, LTD.  
1700 WEST PARK DRIVE  
WESTBOROUGH, MA 01581 USA  
Questions or Comments Email: CustomerService@canaltoys.com

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N° EP20181544.6

**SANITIZE YOUR HANDS WHILE YOU PLAY!**

2+

1 DOUGH COLORS 5.01 OZ. (142g)

**ANTI-BACTERIAL Dough**

**MIX AND CREATE NEW COLORS!**

**Drug Facts**

Active ingredient	Purpose
Benzalkonium Chloride 0.09%	Anti-septic

**Uses**

- Anti-bacterial dough helps reduce bacteria that potentially can cause disease.
- Read the attached instructions before use.

**Warnings**

For external use only.

**Keep appropriately in container after use.**

**Do not use** ■ On children less than 2 years. ■ On open skin wounds.

**When using this product**

- Keep out of eyes, ears, and mouth. ■ In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or rash occurs. If swallowed, get medical help.

**Directions**

- Before use, read the label and the product information.
- Place enough in hands and rub hands not less than 1-2 minutes.
- Anti-bacterial dough can be used over and over and best within 1 month if kept appropriately in a closed container when not in use.

**Other information**

- Store in room temperature (25 °C / 77 °F)
- Avoid freezing and excessive heat above 70 °C (158 °F)

**Inactive ingredients**

Whole Wheat Flour, Aqua, Glycerol, Polyvinyl alcohol, Phenoxyethanol, Caprylyl Glycol, Pentylene glycol, Pentasodium Pentetate, Silver Nitrate, Denatonium benzoate, Red 40, Yellow 5, Blue 1, Red 28.

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PATENT - GRANTED  
N° EP20181544.8

**SANITIZE YOUR HANDS WHILE YOU PLAY!**

2+

1 DOUGH COLORS 6.01 OZ. (170g)

**ANTI-BACTERIAL Dough**

**MIX AND CREATE NEW COLORS!**

**Drug Facts**

**Active ingredient** Benzalkonium Chloride 0.09% **Purpose** Anti-septic

**Uses**  
Anti-bacterial dough helps reduce bacteria that potentially can cause disease.  
Read the attached instructions before use.

**Warnings**  
For external use only.  
Keep appropriately in container after use.

**Do not use** On children less than 2 years. On open skin wounds.

**When using this product**  
Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** Irritation or rash occurs. If swallowed, get medical help.

**Directions**  
Before use, read the label and the product information.  
Place enough in hands and rub hands not less than 1-2 minutes.  
Anti-bacterial dough can be used over and over and best within 1 month if kept appropriately in a closed container when not in use.

**Other information**  
Store in room temperature (25 °C / 77 °F)  
Avoid freezing and excessive heat above 70 °C (158 °F)

**Inactive ingredients**  
Whole Wheat Flour, Aqua, Glycerol, Polyvinyl alcohol, Phenoxyethanol, Caprylyl Glycol, Pentylene glycol, Pentasodium Pentetate, Silver Nitrate, Denatonium benzoate, Red 40, Yellow 5, Blue 1, Red 28.

NOTICE: THIS PRODUCT CONTAINS WHEAT. Expiration Date: DD/MM/YYYY  
\*REUSE IT OVER AND OVER AGAIN... EFFECTIVE FOR UP TO 1 MONTH!

KEEP THE MODELING DOUGH IN ITS CLOSED CONTAINER BETWEEN EACH USE. Lot No: 6900 #327027 USA 1

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- Store dough in sealed container when not in use.

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PATENT - GRANTED  
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2+

1 DOUGH COLORS 7.01 OZ. (199g)

**ANTI-BACTERIAL Dough**

**MIX AND CREATE NEW COLORS!**

**Drug Facts**

**Active ingredient** Benzalkonium Chloride 0.09% **Purpose** Anti-septic

**Uses**  
Anti-bacterial dough helps reduce bacteria that potentially can cause disease.  
Read the attached instructions before use.

**Warnings**  
For external use only.  
Keep appropriately in container after use.

**Do not use** On children less than 2 years. On open skin wounds.

**When using this product**  
Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** Irritation or rash occurs. If swallowed, get medical help.

**Directions**  
Before use, read the label and the product information.  
Place enough in hands and rub hands not less than 1-2 minutes.  
Anti-bacterial dough can be used over and over and best within 1 month if kept appropriately in a closed container when not in use.

**Other information**  
Store in room temperature (25 °C / 77 °F)  
Avoid freezing and excessive heat above 70 °C (158 °F)

**Inactive ingredients**  
Whole Wheat Flour, Aqua, Glycerol, Polyvinyl alcohol, Phenoxyethanol, Caprylyl Glycol, Pentylene glycol, Pentasodium Pentetate, Silver Nitrate, Denatonium benzoate, Red 40, Yellow 5, Blue 1, Red 28.

NOTICE: THIS PRODUCT CONTAINS WHEAT. Expiration Date: DD/MM/YYYY  
\*REUSE IT OVER AND OVER AGAIN... EFFECTIVE FOR UP TO 1 MONTH!

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PATENT GRANTED N° EP20181544.6

**SANITIZE YOUR HANDS WHILE YOU PLAY!**

2+

1 DOUGH COLORS 8.01 OZ. (227g)

**ANTI-BACTERIAL Dough**

**MIX AND CREATE NEW COLORS!**

**Drug Facts**

Active ingredient	Purpose
Benzalkonium Chloride 0.09%	Anti-septic

**Uses**

- Anti-bacterial dough helps reduce bacteria that potentially can cause disease.
- Read the attached instructions before use.

**Warnings**

For external use only.

Keep appropriately in container after use.

**Do not use** ■ On children less than 2 years. ■ On open skin wounds.

**When using this product**

- Keep out of eyes, ears, and mouth. ■ In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or rash occurs. If swallowed, get medical help.

**Directions**

- Before use, read the label and the product information.
- Place enough in hands and rub hands not less than 1-2 minutes.
- Anti-bacterial dough can be used over and over and best within 1 month if kept appropriately in a closed container when not in use.

**Other information**

- Store in room temperature (25 °C / 77 °F)
- Avoid freezing and excessive heat above 70 °C (158 °F)

**Inactive ingredients**

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NOTICE: THIS PRODUCT CONTAINS WHEAT. Expiration Date: DD/MM/YYYY

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**ANTI-BACTERIAL Dough**

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**ANTI-BACTERIAL MODELING DOUGH**

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PATENT GRANTED N° EP20181544.6

**SANITIZE YOUR HANDS WHILE YOU PLAY!**

2+

1 DOUGH COLORS 9.01 OZ. (255g)

**ANTI-BACTERIAL Dough**

**MIX AND CREATE NEW COLORS!**

**Drug Facts**

Active ingredient	Purpose
Benzalkonium Chloride 0.09%	Anti-septic

**Uses**

- Anti-bacterial dough helps reduce bacteria that potentially can cause disease.
- Read the attached instructions before use.

**Warnings**

For external use only.

Keep appropriately in container after use.

**Do not use** ■ On children less than 2 years. ■ On open skin wounds.

**When using this product**

- Keep out of eyes, ears, and mouth. ■ In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or rash occurs. If swallowed, get medical help.

**Directions**

- Before use, read the label and the product information.
- Place enough in hands and rub hands not less than 1-2 minutes.
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**Inactive ingredients**

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## ANTI-BACTERIAL DOUGH

anti-bacterial dough gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78048-016
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.09 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WHEAT</b> (UNII: 4J2I0SN84Y)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>SILVER NITRATE</b> (UNII: 95IT3W8JZE)	
<b>PHENOXYETHANOL</b> (UNII: HIE492Z3ZT)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

<b>PENTASODIUM PENTETATE</b> (UNII: 961TOZ5L7T)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>DENATONIUM BENZOATE</b> (UNII: 4YK5Z54AT2)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78048-016-01	29 g in 1 BOX; Type 0: Not a Combination Product	12/25/2021	
2	NDC:78048-016-02	57 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	
3	NDC:78048-016-03	85 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	
4	NDC:78048-016-04	114 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	
5	NDC:78048-016-05	142 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	
6	NDC:78048-016-06	170 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	
7	NDC:78048-016-07	199 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	
8	NDC:78048-016-08	227 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	
9	NDC:78048-016-09	255 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	
10	NDC:78048-016-10	284 g in 1 BOX; Type 0: Not a Combination Product	03/30/2021	



FRONT



BACK



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/23/2021	

**Labeler** - Dongguan City Dexu Toys Co., Ltd. (403382659)

## Establishment

Name	Address	ID/FEI	Business Operations
Dongguan City Dexu Toys Co., Ltd.		403382659	manufacture(78048-016)

Revised: 12/2021

Dongguan City Dexu Toys Co., Ltd.