### WATER-BASED PERSONAL LUBRICANT, ACVIOO 001- personal lubricant oil Shenzhen Dikailong Technology Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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#### Water-based Personal Lubricant, ACVIOO 001 (400mL)

#### **Active ingredient**

butylene glycol (20%): 80g/package or 80mL/package

#### **Inactive ingredient**

Inactive ingredient:

water (77.52%): 310.08mL/package

hydroxyethylcellulose (1.6%): 6.4mL/package

polyethylene glycol 300000 (0.5%): 2mL/package

phenoxyethanol (0.3%): 1.2mL/package

chlorphenesin (0.08%): 0.32mL/package

#### **Purpose**

It can achieve higher lubricantion, longer lubrication time and less dosage.

This product is not a contraceptive and does not contain a spermicide.

#### When using

Virginal dryness and/or intimate sexual activity.

This product is not a contraceptive and does not contain a spermicide.

#### Do not use

Do not use when wound or skin infection.

It should be cautiously used if you are kind of allergic constitution or you have inflammation.

Do not use if quality seal on the opening of the tube is broken or missing.

Do not use if tamper-evident seal is removed or broken.

#### Stop use

If irritation or discomfort occurs, discontinue the use and consult a physician.

Very slippery on surfaces, clean spills immediately.

#### Ask doctor

If irritation or discomfort occurs, discontinue the use and consult a physician.

#### Ask doctor/pharmacist

Ask doctor/pharmacist when you current use other drugs.

#### Keep out of reach of children

Keep out of reach of children and away from eyes and ears.

#### Questions

Please contact us when you have any questions.

#### Pregnancy or breast feeding

Pregnant or breast feeding women shall follow doctor advice.

#### **Indications & usage**

ACVIOO 001 is a water-based personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity, help relieve virginal dryness, and supplement to the body's natural lubricant.

Apply a small amount to genital areas. Reapply as needed or desired.

#### **Dosage & administration**

One bottle of 400mL in one package.

#### **Dosage forms & strengths**

The lubricant is like oil form.

A small amount one time, or reapply as needed or desired.

The active ingredient strength is 20%.

#### Warnings

If irritation or discomfort occurs, discontinue the use and consult a physician. Very slippery on surfaces, clean spills immediately.

This product is not a contraceptive and does not contain a spermicide.

#### Package label. Principal display panel

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Container Label

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Package Label

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# WATER-BASED PERSONAL LUBRICANT, ACVIOO 001 personal lubricant oil Product Information Product Type HUMAN OTC DRUG CUTANEOUS, EXTRACORPOREAL, VAGINAL, TOPICAL CUTANEOUS, EXTRACORPOREAL, VAGINAL, TOPICAL

## Active Ingredient/Active Moiety Ingredient Name BUTYLENE GLYCOL (UNII: 3XUS85K0RA) (BUTYLENE GLYCOL - UNII:3XUS85K0RA) BUTYLENE GLYCOL (BUTYLENE GLYCOL - UNII:3XUS85K0RA) BUTYLENE GLYCOL (BUTYLENE GLYCOL - UNII:3XUS85K0RA)

Inactive Ingredients			
Ingredient Name	Strength		
HYDROXYETHYL CELLULOSE (280 MPA.S AT 2%) (UNII: 12VCE9HR9E)	6.4 mL in 400 mL		
WATER (UNII: 059QF0KO0R)	310.08 mL in 400 mL		
PHENOXYETHANOL (UNII: HIE492ZZ3T)	1.2 mL in 400 mL		
POLYETHYLENE GLYCOL 300000 (UNII: 4QIB4U4CQR)	2 mL in 400 mL		
CHLORPHENESIN (UNII: 1670 DAL4SZ)	0.32 mL in 400 mL		

Product Characteristics			
Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging				
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 1	NDC:71847-2215-7	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/07/2018	

#### Labeler - Shenzhen Dikailong Technology Ltd (544556869)

#### **Registrant -** Shenzhen Dikailong Technology Ltd (544556869)

Establishment			
Name	Address	ID/FEI	Business Operations
Shenzhen Dikailong Technology Ltd		544556869	label(71847-2215), manufacture(71847-2215)

Revised: 5/2018 Shenzhen Dikailong Technology Ltd