

**SAFE OPA- o-phthalaldehyde liquid
Valley Inc.**

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.

ACTIVE INGREDIENT

O-PHTHALALDEHYDE 0.55%

INACTIVE INGREDIENTS

Water, Monopotassium phosphate, Dipotassium hydrogen phosphate

PURPOSE

Antifungal

WARNINGS

For external use only
Do not use on the human body
Avoid contact with eyes.
Discontinue use if signs of irritation or rashes appear.
Keep out of reach of children

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children

Uses

Helps prevent sterilant





Directions

- Rinse thoroughly for more than 5 minutes. Rinse for more than 15 seconds with sterile purified water flowing out after soaking.
- After the disinfection of the medical instrument is completed, confirm the persistence.
- Excess water may be used depending on the purpose of use.

QUESTIONS

+82 02 1566 2723

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<p>Must keep stand during storage & transportation</p>																	
<p>Safe OPA</p> <table border="1"> <tr> <td>Drug Facts</td> <td>Purpose</td> </tr> <tr> <td>Active ingredients O-PHTHALALDEHYDE 0.55%</td> <td>Antifungal</td> </tr> <tr> <td>Uses Helps prevent sterilant</td> <td></td> </tr> <tr> <td>Warnings For external use only Do not use on the human body Avoid contact with eyes Discontinue use if signs of irritation or rashes appear Keep out of reach of children</td> <td></td> </tr> <tr> <td>Directions Rinse thoroughly for more than 5 minutes. Rinse for more than 15 seconds with sterile purified water flowing out after soaking. After the disinfection of the medical instrument is completed, confirm the persistence. Excess water may be used depending on the purpose of use.</td> <td></td> </tr> <tr> <td>Questions +82 02 1568 2723</td> <td></td> </tr> <tr> <td>Inactive ingredients Water, Monopotassium phosphate, Dipotassium hydrogen phosphate</td> <td></td> </tr> </table> <p>Manufacturer: Valley Inc. 19 Paedong-ro 32-gil, Suseong-gu, Daegu, 42230, Korea 4,000ml / 135.26 Fl. Oz</p>	Drug Facts	Purpose	Active ingredients O-PHTHALALDEHYDE 0.55%	Antifungal	Uses Helps prevent sterilant		Warnings For external use only Do not use on the human body Avoid contact with eyes Discontinue use if signs of irritation or rashes appear Keep out of reach of children		Directions Rinse thoroughly for more than 5 minutes. Rinse for more than 15 seconds with sterile purified water flowing out after soaking. After the disinfection of the medical instrument is completed, confirm the persistence. Excess water may be used depending on the purpose of use.		Questions +82 02 1568 2723		Inactive ingredients Water, Monopotassium phosphate, Dipotassium hydrogen phosphate		 <p>HANDLE WITH CARE</p>  <p>8 800557 000247</p>	<p>Safe OPA</p> <p>4,000ml / 135.26 Fl. Oz</p> 	<p>Cleaner and disinfectant for endoscopes & other medical instruments</p>
Drug Facts	Purpose																
Active ingredients O-PHTHALALDEHYDE 0.55%	Antifungal																
Uses Helps prevent sterilant																	
Warnings For external use only Do not use on the human body Avoid contact with eyes Discontinue use if signs of irritation or rashes appear Keep out of reach of children																	
Directions Rinse thoroughly for more than 5 minutes. Rinse for more than 15 seconds with sterile purified water flowing out after soaking. After the disinfection of the medical instrument is completed, confirm the persistence. Excess water may be used depending on the purpose of use.																	
Questions +82 02 1568 2723																	
Inactive ingredients Water, Monopotassium phosphate, Dipotassium hydrogen phosphate																	
<p>Manufacturer VALLEY INC</p>																	
 <p>8 800557 000124</p>																	

SAFE OPA

o-phthalaldehyde liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81803-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
O-PHTHALALDEHYDE (UNII: 4P8QP9768A) (O-PHTHALALDEHYDE - UNII:4P8QP9768A)	O-PHTHALALDEHYDE	22.0 g in 4000 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
MONOBASIC POTASSIUM PHOSPHATE (UNII: 4J9FJ0HL51)	

DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81803-030-02	1 in 1 CARTON	05/01/2022	
1	NDC:81803-030-01	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2022	

Labeler - Valley Inc. (695095445)

Registrant - Valley Inc. (695095445)

Establishment

Name	Address	ID/FEI	Business Operations
Valley Inc.		695095445	manufacture(81803-030)

Revised: 6/2022

Valley Inc.