

**SODIUM SALICYLATE- sodium salicylate solution**  
**Aurora Pharmaceutical, 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.*

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**ORAL-PRO®**  
**Sodium Salicylate**  
**Concentrate 48.6% w/v**

<b>ACTIVE INGREDIENT</b>	
Sodium Salicylate	48.6% w/v

**CALF LABEL CLAIM**

**Indications For Use, Calves**

Supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g., anti-infective) therapy if necessary.

**Contraindications, Calves**

Do not use Sodium Salicylate in neonates or calves less than 2 weeks of age.

**Dosage, Calves**

40 mg Sodium Salicylate per kg body weight (4 mL per 100 lbs.) once daily, for 1-3 days. Administer orally in drinking water or milk (replacer).

**SWINE AND POULTRY LABEL CLAIM**

**Indications**

For use in the drinking water of poultry and swine as an aid in reducing pain, fever and inflammation.

**DIRECTIONS FOR USE**

**For Analgesic and Antipyretic Use**

**Water Proportioner Use:**

Add 8 ounces (236 mL) of Sodium Salicylate 48.6% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 11.3 mg/lb (25 mg/kg) body weight daily.

**Livestock Tank Use:**

Add 8 ounces (236 mL) of Sodium Salicylate 48.6% Concentrate to 128 gallons of

drinking water. This will achieve a target dose of 11.3 mg/lb (25 mg/kg) body weight daily.

### **For Anti-Inflammatory/Anti-Prostaglandin Use - Day 1**

#### **Water Proportioner Use:**

Add 16 ounces (473 mL) of Sodium Salicylate 48.6% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 22.7 mg/lb (50 mg/kg) body weight daily.

#### **Livestock Tank Use:**

Add 16 ounces (473 mL) of Sodium Salicylate 48.6% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 22.7 mg/lb (50 mg/kg) body weight daily.

### **Day 2 through 7**

#### **Water Proportioner Use:**

Add 10 ounces (296 mL) of Sodium Salicylate 48.6% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 13.6 mg/lb (30 mg/kg) body weight daily.

#### **Livestock Tank Use:**

Add 10 ounces (296 mL) of Sodium Salicylate 48.6% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 13.6 mg/lb (30 mg/kg) body weight daily.

Prepare fresh solutions daily. Repeat as necessary.

### **Warning**

Do not administer concentrated solution by direct oral administration — gastro-intestinal irritation or overdose may occur. Do not use in piglets less than 3 weeks of age.

### **Storage**

Store upright up to 25° C (77° F) with brief excursions to 40° C (104° F).

Do not use if allergic or sensitive to the active ingredients.

### **Caution**

Keep container closed when not in use. Product may solidify at cold storage temperatures. Place container in room temperature storage, which will thaw the solution, or place in warm water. Gently invert container to ensure uniformity of product.

Gradual darkening will not affect product stability.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.



**MANUFACTURED IN THE USA**

**REORDER NO: 21004**

MANUFACTURED BY:

**Aurora Pharmaceutical, Inc.**

NORTHFIELD, MINNESOTA 55057

**1-888-215-1256**

**www.aurorapharmaceutical.com**

IN 50-1108 12/2024

**PRINCIPAL DISPLAY PANEL - 3.79 Liters Bottle Label**

NDC 51072-038-01

**ORAL-PRO®**

**Sodium Salicylate  
Concentrate 48.6% w/v**

For Use in Livestock Only

Keep Out of Reach of Children

Net Contents:

**1 Gallon (3.79 Liters)**

**AURORA PHARMACEUTICAL®**

The image shows a detailed view of the product label for ORAL-PRO Sodium Salicylate Concentrate 48.6% w/v. The label is yellow with a red and blue curved border. It includes the following information:

- ACTIVE INGREDIENT:** Sodium Salicylate 48.6% w/v
- CALF LABEL CLAIM:** Indications For Use, Conves: Supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g., antimicrobial) therapy if necessary. Contraindications, Calves: Do not use Sodium Salicylate in neonates or calves less than 2 weeks of age. Dosage, Calves: 40 mg Sodium Salicylate per kg body weight (4 mL per 100 lbs.) once daily, for 1-3 days. Administer orally in drinking water or milk (replacer).
- SWINE AND POULTRY LABEL CLAIM:** Indications: For use in the drinking water of poultry and swine as an aid in reducing pain, fever and inflammation. (continued on next panel)
- REORDER NO:** 21004
- MANUFACTURED BY:** Aurora Pharmaceutical, Inc., NORTHFIELD, MINNESOTA 55057, 1-888-215-1256, www.aurorapharmaceutical.com, IN 50-1108 12/2024
- Barcode:** 3 51072 03801 0
- TAKE TIME OBSERVE LABEL DIRECTIONS logo**
- TAKE TIME OBSERVE LABEL DIRECTIONS logo**
- MANUFACTURED IN THE USA logo**
- aurora PHARMACEUTICAL logo**
- NDC 51072-038-01**
- ORAL-PRO®**
- Sodium Salicylate Concentrate 48.6% w/v**
- For Use in Livestock Only**
- Keep Out of Reach of Children**
- Net Contents: 1 Gallon (3.79 Liters)**
- DIRECTIONS FOR USE:**
  - For Analgesic and Antipyretic Use:** Water Proportioner Use: Add 8 ounces (236 mL) of Sodium Salicylate 48.6% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 11.3 mg/lb (25 mg/kg) body weight daily. Livestock Tank Use: Add 8 ounces (236 mL) of Sodium Salicylate 48.6% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 11.3 mg/lb (25 mg/kg) body weight daily.
  - For Anti-inflammatory/Anti-Prostaglandin Use — Day 1:** Water Proportioner Use: Add 16 ounces (473 mL) of Sodium Salicylate 48.6% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 22.7 mg/lb (50 mg/kg) body weight daily. Livestock Tank Use: Add 16 ounces (473 mL) of Sodium Salicylate 48.6% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 22.7 mg/lb (50 mg/kg) body weight daily.
  - Day 2 through 7:** Water Proportioner Use: Add 10 ounces (296 mL) of Sodium Salicylate 48.6% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 13.6 mg/lb (30 mg/kg) body weight daily. Livestock Tank Use: Add 10 ounces (296 mL) of Sodium Salicylate 48.6% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 13.6 mg/lb (30 mg/kg) body weight daily. Prepare fresh solutions daily. Repeat as necessary.
- WARNING:** Not for use in lactating dairy cattle. Do not administer concentrated solution by direct oral administration — gastrointestinal irritation or overdose may occur. Do not use in piglets less than 3 weeks of age.
- STORAGE:** Store upright up to 25°C (77°F) with brief excursions to 40°C (104°F). Do not use if allergic or sensitive to the active ingredients.
- CAUTION:** Keep container closed when not in use. Product may solidify at cold storage temperatures. Place container in room temperature storage, which will thaw the solution, or place in warm water. Gently invert container to ensure uniformity of product. Gradual darkening will not affect product stability.

**Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.**

**SODIUM SALICYLATE**

sodium salicylate solution

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:51072-038
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM SALICYLATE</b> (UNII: MQ1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SODIUM SALICYLATE	48.6 g in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51072-038-01	3790 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/16/2011	

**Labeler** - Aurora Pharmaceutical, Inc. (832848639)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurora Pharmaceutical, Inc.		832848639	MANUFACTURE

Revised: 5/2025

Aurora Pharmaceutical, Inc.