



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

**TECHNICAL DATA SHEET**

Review date:

**15.11.2022**

Version:

**3.0**

## 9133-ORA SWEET 473 ML

### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

#### 1.1 Identification of the substance or preparation

Name: Ora Sweet 473 ml

Bulk code: 9136

Internal code: 49491

#### 1.2 Synonyms

No information available.

### 2. DESCRIPTION

Appearance: Liquid.

Colour: Transparent with slight colouration.

Odour/Taste: Sweet (berries, citrus).

### 3. COMPOSITION/INFORMATION ON COMPONENTS

Purified water, sucrose, glycerine, sorbitol and flavouring.

Buffered with citric acid and sodium phosphate. Preservatives: methylparaben and potassium sorbate.

### 4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

**Osmolality:** 4109 mOsm/kg

### 5. PROPERTIES/USES

Ora-Sweet is a syrup vehicle used to simplify the flavouring and sweetening process for extemporaneous oral formulas.

It allows pharmacists to quickly formulate sophisticated oral solutions.

It can be used alone or in combination with other agents. Ora-Sweet will retain its flavouring properties when diluted by up to 50% with water or suspending agents. Its versatility makes it ideal for formulating:

- paediatric preparations
- geriatric preparations

It is an ideal flavouring and sweetener for a wide range of suspensions but has been specially formulated to supplement ORA PLUS. Both can be combined in a 50:50 ratio to make suspensions with optimal properties.



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Ora-Sweet contains sucrose, which acts as a sweetening agent.

Small amounts of glycerine and sorbitol have been added to avoid the “cap-locking” problems that are common in most syrups. Its flavouring agents help increase palatability. Ora-Sweet is buffered at a slightly acidic pH to help decrease the degradation of medicinal agents through oxidation.

### General modus operandi:

- Calculate the total amount of active ingredient and the volume of solution needed to create a suspension at the appropriate concentration (it may be desirable to add around a 10% surplus to compensate for losses arising from the formulation process).
- Grind the active ingredient to a fine powder using a mortar.
- Add a small amount of ORA-Plus and mix until a thick, smooth paste is obtained. Add the rest of the ORA-Plus by geometric dilution. This should be 50% of the final volume of the formula.
- Complete to the required volume with the ORA Sweet.
- Mix briefly in the mortar until an even mixture is obtained.
- Dispense into an airtight, light-resistant amber bottle with proper labelling.

### 6. DOSAGE

No information available.

### 7. REMARKS

#### STORAGE:

Store at room temperature, in a cool, dry place, away from sunlight, in a tightly closed container.

The documentation available related to the product’s regulatory compliance is included below.



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### **BSE/TSE:**

The above-mentioned products are not made and do not come into contact with human or animal products. The ingredients, excipients, adjuvants, components and reagents used to manufacture the above elements do not come into contact with bovine, ovine or caprine materials during the manufacturing process. Therefore, the above-mentioned products are free of any form of bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE). They comply with the applicable regulations and guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3).

### **GMOs:**

ORA SWEET® contains sorbitol. Sorbitol is produced from corn syrup. The corn syrup supplier does not guarantee GMO-free products and does not perform an analysis to confirm the absence of GMO DNA protein. As such, it cannot be stated or guaranteed that ORA SWEET® is GMO-free as sorbitol is used as a vehicle in ORA SWEET®. The labelling of GMOs is not mandatory in accordance with EC 1830/2003 on the traceability and labelling of genetically modified organisms and the traceability of food and feed produced from genetically modified organisms.

### **ALLERGENS:**

According to the manufacturer, all raw materials used to produce the above products have been certified as free of the following allergens:

- Crustaceans
- Eggs
- Fish
- Gluten
- Milk and dairy products
- Peanuts
- Soy products
- Tree nuts

### **COLOURANTS:**

ORA-Sweet® SF contains a flavouring.

### **CORN:**

ORA-Sweet contains sorbitol and therefore may contain corn by-products.