

9133-ORA SWEET SF 473 ML**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1 Identification of the substance or preparation**

Name: Ora Sweet SF 473 ml

Bulk code: 9135

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, glycerine, sorbitol, sodium saccharin, xanthan gum and flavouring. Buffered with citric acid and sodium citrate. Preserved with methylparaben (0.03%), potassium sorbate (0.1%) and propylparaben (0.008%).

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Osmolality: 1979 mOsm/kg**5. PROPERTIES/USES**

Ora-Sweet SF is a sugar-free 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 SF 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.



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 SF 473 ML

Ora-Sweet SF is both sugar- and alcohol-free. A small quantity of sodium saccharin has been added to sweeten the preparation. Xanthan gum, glycerine and sorbitol contribute to the texture and good flow properties.

Its flavouring agents help increase palatability. Ora-Sweet SF 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.

9133-ORA SWEET SF 473 ML**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 SF® 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-Blend® SF contains flavouring and therefore contains a small amount of FD&C Red 40 (Allura Red).

CORN:

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