

# Thermo Scientific Trutol® Glucose Tolerance Beverages

Used to screen for hyperglycemia (diabetes mellitus and gestational diabetes) and hypoglycemia (low blood sugar). The screening entails administering a precise dose of glucose and then testing the level of glucose in the patient's blood at specific time intervals. For oral consumption only.

- Manufactured to the Food and Beverage industry standards and ISO 13485, cGMP and FDA regulations.
- Available in 50, 75 & 100 gram concentrations, and orange, lemon-lime and fruit punch flavors.
- Dairy-free and free of wheat, barley, rye and oat glutens.
- Caffeine-free and certified Kosher
- Non-carbonated, ready-to-use, with 24 month expiration dating.
- Shatterproof plastic bottles ensure safety and are packaged in economical 24 bottle cases, conveniently shrink wrapped in 6 packs.
- The Pediatric Dosage Chart lists pre-calculated dosages based on body weight.
- Volume graduations are imprinted on the label to aid in dispensing smaller quantities.



Contents include: water, dextrose, citric acid (preservative) and citrus. The flavoring does not contain any herbs; it is comprised of a selected blend of natural oils. The flavoring contains no intact protein or DNA from Genetically Modified Organisms (GMOs). The beverages contains no gelatin and it is gluten free.

These beverages do not contain BVO (Brominated Vegetable Oil).

The glucose additive in the beverage is 100% dextrose. The dextrose is derived from corn; however, is not High Fructose Corn Syrup (HFCS). Fructose does not cause insulin secretions. *Below is a process summary that describes how dextrose is produced from corn, through many conversion and refining steps.*

## DEXTROSE MONOHYDRATE PROCESS

*Dextrose monohydrate is derived from our corn wet-milling process that begins with steeping corn kernels in dilute sulfuric acid under controlled conditions. The softened kernel allows for the physical separation into four components (germ, fiber, protein and starch).*

*The starch slurry is hydrolyzed using enzymes to produce high dextrose (d-glucose) content liquor. The liquor is refined and then crystallized through controlled cooling. The monohydrate crystals are washed, centrifuged, and dried.*

**Lemon-Lime:** The flavoring does not contain major food allergens, such as milk, eggs, wheat, soy, peanuts, tree nuts (walnuts, almonds, pecans, pistachios, hazelnuts-Filberts, cashews, hickory nuts, chestnuts, macadamia nuts, pine nuts, and other varieties of tree nuts), sesame, fish, crustaceans/shellfish (lobster, crayfish, shrimp, crab, prawns, clams, mussels, oysters, abalone-cockles, scallops, snails, squid, octopus, and other varieties or crustacean/shellfish).

The Lemon-Lime flavoring does not contain any herbs, the flavoring is derived from lemon and lime oils. Lemon-lime contains no dyes. Lemon-lime is not always colorless; it may have a tint from the production process. This darkening occurs from the settling of dextrose (sugar) during storage and does not alter product's intended use. Please proceed normal use of the product, it is not defective.

**Fruit Punch:** The flavoring does not contain major food allergens, such as milk, eggs, wheat, soy, peanuts, tree nuts (walnuts, almonds, pecans, pistachios, hazelnuts-Filberts, cashews, hickory nuts, chestnuts, macadamia nuts, pine nuts, and other varieties of tree nuts), sesame, fish, crustaceans/shellfish (lobster, crayfish, shrimp, crab, prawns, clams, mussels, oysters, abalone-cockles, scallops, snails, squid, octopus, and other varieties or crustacean/shellfish).

Fruit punch beverage does not contain apples, cranberries or coconuts in the product or on the line where it is manufactured. Fruit Punch is comprised of ingredients that are naturally occurring in oranges, cherries and strawberries.

**Orange:** The flavoring does not contain major food allergens, such as milk, eggs, wheat, soy, peanuts, tree nuts (walnuts, almonds, pecans, pistachios, hazelnuts-Filberts, cashews, hickory nuts, chestnuts, macadamia nuts, pine nuts, and other varieties of tree nuts), sesame, fish, crustaceans/shellfish (lobster, crayfish, shrimp, crab, prawns, clams, mussels, oysters, abalone-cockles, scallops, snails, squid, octopus, and other varieties or crustacean/shellfish).

Nat. Orange Flavor # 30 (FD&C Yellow #6 and FD&C Red #40) does not contain any of the following: peach, plum, apricot, avocado or tree nut related fruits.

Nat. Orange Flavor contains a select blend of natural orange extractives

Refrigeration can cause crystallization, If crystallization occurs, allow product to come to room temperature; then, thoroughly mix the product (shake vigorously) for 2-3 minutes to ensure homogenization. View product for crystals, product should be discarded if crystallization is still present.

Freezing of product is not recommended; however, if product is frozen dextrose crystallization can occur. If frozen, follow same directions above for crystallization from extended refrigeration.

If this product is consumed by a patient after expiry, there are no additional adverse health effects, apart from those of an in-date drink (examples include: nausea, bloating, headache, vomiting, low blood sugar (rarely), etc.). The patient test should be abandoned or repeated at another date with an in-date (not expired) product, as to ensure accuracy of intended product dosage and acceptability of test result(s).

## Specifications:

### 50 gram:

pH:	<4.00	Dextrose Concentration:	46.3 - 53.8 g/bottle
Storage:	15 - 30°C	Bioburden:	≤ 1 CFU/mL, Complies
Shelf Life:	24 months	Coliform:	0 Coliform/100mL, Complies

### 75 gram:

pH:	<4.00	Dextrose Concentration:	69.4 - 80.6 g/bottle
Storage:	15 - 30°C	Bioburden:	≤ 1 CFU/mL, Complies
Shelf Life:	24 months	Coliform:	0 Coliform/100mL, Complies

### 100 gram:

pH:	<4.00	Dextrose Concentration:	92.5 - 107.5 g/bottle
Storage:	15 - 30°C	Bioburden:	≤ 1 CFU/mL, Complies
Shelf Life:	24 months	Coliform:	0 Coliform/100mL, Complies

# Thermo Scientific Trutol<sup>®</sup> Glucose Tolerance Beverages

## Dosage Guidelines

**50 GRAM GTT:** for use in the detection of (or screening for) glucose intolerance in the evaluation of gestational diabetes mellitus in **pregnant women**.

**75 GRAM GTT:** for use in the diagnosis of glucose intolerance in the evaluation of diabetes mellitus and related disease conditions in **non-pregnant adults** and **children**. (1.75 g/kg ideal body weight for children. Not to exceed 75 g. See chart below).

**100 GRAM GTT:** For use in the diagnosis of glucose intolerance in the evaluation of gestational diabetes mellitus in **pregnant women**.

## Pediatric Dosage Chart

Ideal Body Weight		75 g Concentration		100 g Concentration	
lb.	kg	oz.	ml	oz.	ml
94	42.7+	10.0	295	7.5	221
90	40.9	9.5	283	7.2	212
85	38.6	9.0	267	6.8	200
80	36.4	8.5	251	6.4	188
75	34.1	8.0	235	6.0	177
70	31.8	7.4	220	5.6	165
65	29.5	6.9	204	5.2	153
60	27.3	6.4	188	4.8	141
55	25.0	5.8	173	4.4	130
50	22.7	5.3	157	4.0	118
45	20.5	4.8	141	3.6	106
40	18.2	4.2	125	3.2	94
35	15.9	3.7	110	2.8	82
30	13.6	3.2	94	2.4	71
25	11.4	2.7	78	2.0	59
20	9.1	2.1	63	1.6	47

Reference: Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications, p 5, Section 2.3, World Health Organization, 1999.

Certificates of Analysis (COAs) are available online for these products.

## CAT No(s)

401272P	Orange	50 gram	24x10 fl. oz. (296 ml)
401223P	Orange	75 gram	24x10 fl. oz. (296 ml)
401207P	Orange	100 gram	24x10 fl. oz. (296 ml)
401074P	Lemon-Lime	50 gram	24x10 fl. oz. (296 ml)
401025P	Lemon-Lime	75 gram	24x10 fl. oz. (296 ml)
401009P	Lemon-Lime	100 gram	24x10 fl. oz. (296 ml)
401576P	Fruit Punch	50 gram	24x10 fl. oz. (296 ml)
401526P	Fruit Punch	75 gram	24x10 fl. oz. (296 ml)
401503P	Fruit Punch	100 gram	24x10 fl. oz. (296 ml)

Any further questions may be directed to Technical Support at 1 (800) 528-0494, Option 2, or e-mail to [techsupport.diagnostics.mtn@thermofisher.com](mailto:techsupport.diagnostics.mtn@thermofisher.com)