

07-19-70-016

Baxter

Dextrose and Sodium Chloride Injection, USP

in AVIVA Plastic Container

DESCRIPTION

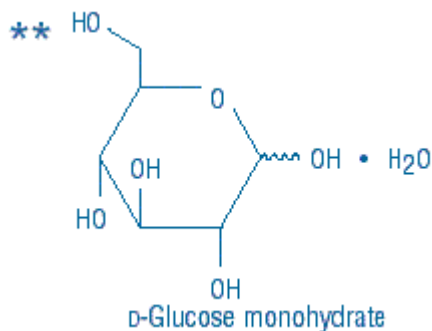
Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

| | Size (mL) | Composition (g/L) | | *Osmolarity (mOsmol/L) (calc.) | pH nominal (range) | Ionic Concentration (mEq/L) | | Caloric Content (kcal/L) |
|--|--------------------|----------------------------|--------------------------------|-----------------------------------|--------------------------|--------------------------------|----------|-----------------------------|
| | | **Dextrose Hydrous, USP | Sodium Chloride, USP (NaCl) | | | Sodium | Chloride | |
| 2.5% Dextrose and 0.45% Sodium Chloride Injection, USP | 500 1000 | 25 | 4.5 | 280 | 4.5 (3.2 to 6.5) | 77 | 77 | 85 |
| 5% Dextrose and 0.2% Sodium Chloride Injection, USP | 250 500 1000 | 50 | 2 | 321 | 4.0 (3.2 to 6.5) | 34 | 34 | 170 |
| 5% Dextrose and 0.33% Sodium Chloride Injection, USP | 250 500 1000 | 50 | 3.3 | 365 | 4.0 (3.2 to 6.5) | 56 | 56 | 170 |
| 5% Dextrose and 0.45% Sodium Chloride Injection, USP | 250 500 1000 | 50 | 4.5 | 406 | 4.0 (3.2 to 6.5) | 77 | 77 | 170 |

| | | | | | | | | |
|--|--------------------|-----|---|-----|---------------------|-----|-----|-----|
| 5% Dextrose and 0.9% Sodium Chloride Injection, USP | 250 500 1000 | 50 | 9 | 560 | 4.0 (3.2 to 6.5) | 154 | 154 | 170 |
| 10% Dextrose and 0.9% Sodium Chloride Injection, USP | 500 1000 | 100 | 9 | 813 | 4.0 (3.2 to 6.5) | 154 | 154 | 340 |

*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.



The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of

supplemental medication (See **DIRECTIONS FOR USE**). The primary function of the overwrap is to protect the container from the physical environment.

CLINICAL PHARMACOLOGY

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

PRECAUTIONS

General

Do not connect flexible plastic containers of intravenous solutions in series connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Administration of hypertonic solutions may cause venous irritation, including phlebitis. Hyperosmolar solutions should be administered with caution, if at all, to patients with hyperosmolar states. See **Table 1** in the **DESCRIPTION** section for the osmolarities of the Dextrose and Sodium Chloride Injection, USP solutions.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also not known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

The use of Dextrose and Sodium Chloride Injection, USP in pediatric patients is based on clinical practice.

Newborns – especially those born premature and with low birth weight – are at increased risk of developing hypo – or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency (applies to solutions containing less than 0.9% Sodium Chloride).

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

- Hypersensitivity reactions, including anaphylaxis and chills
- Hyponatremia (applies to solutions containing less than 0.9% Sodium Chloride)

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

The dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia. The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

Dextrose and Sodium Chloride Injection, USP in AVIVA plastic container is supplied as follows:

| Code | Size (mL) | NDC | Product Name |
|--------|-----------|--------------|--|
| 6E1023 | 500 | 0338-6315-03 | 2.5% Dextrose and 0.45% Sodium Chloride Injection, USP |
| 6E1024 | 1000 | 0338-6315-04 | |
| 6E1092 | 250 | 0338-6310-02 | 5% Dextrose and 0.2% Sodium Chloride Injection, USP |
| 6E1093 | 500 | 0338-6310-03 | |
| 6E1094 | 1000 | 0338-6310-04 | |
| 6E1082 | 250 | 0338-6309-02 | 5% Dextrose and 0.33% Sodium Chloride Injection, USP |
| 6E1083 | 500 | 0338-6309-03 | |
| 6E1084 | 1000 | 0338-6309-04 | |
| 6E1072 | 250 | 0338-6308-02 | 5% Dextrose and 0.45% Sodium Chloride |

| | | | |
|--------|------|--------------|--|
| 6E1073 | 500 | 0338-6308-03 | Injection, USP |
| 6E1074 | 1000 | 0338-6308-04 | |
| 6E1062 | 250 | 0338-6305-02 | 5% Dextrose and 0.9% Sodium Chloride Injection, USP |
| 6E1063 | 500 | 0338-6305-03 | |
| 6E1064 | 1000 | 0338-6305-04 | |
| 6E1163 | 500 | 0338-6314-03 | 10% Dextrose and 0.9% Sodium Chloride Injection, USP |
| 6E1164 | 1000 | 0338-6314-04 | |

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF AVIVA PLASTIC CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. Moisture and some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Printed in USA

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| *For Bar Code Position Only |
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07-19-70-016

Rev. September 2013

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Dextrose and Sodium Chloride Injection, USP

in VIAFLEX Plastic Container

DESCRIPTION

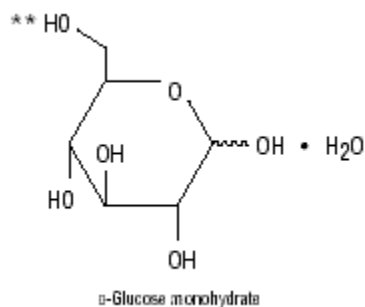
Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1.

| | Size (mL) | Composition (g/L) | | *Osmolarity (mOsmol/L) (calc.) | pH | Ionic Concentration (mEq/L) | | Caloric Content (kcal/L) |
|--|--------------------|-------------------------|-----------------------------|--------------------------------|---------------------|-----------------------------|----------|--------------------------|
| | | **Dextrose Hydrous, USP | Sodium Chloride, USP (NaCl) | | | Sodium | Chloride | |
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* Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.



The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

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Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.

The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

PRECAUTIONS

General

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

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Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also not known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

The use of Dextrose and Sodium Chloride Injection, USP in pediatric patients is based on clinical practice.

Newborns – especially those born premature and with low birth weight – are at increased risk of developing hypo– or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

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Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond

differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS

- Hypersensitivity reactions, including anaphylaxis and chills

- Hyponatremia (applies to solutions containing less than 0.9% Sodium Chloride)

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

The dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia. The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

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HOW SUPPLIED

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| 2B1093 | 500 | 0338-0077-03 | |
| 2B1094 | 1000 | 0338-0077-04 | |
| 2B1082 | 250 | 0338-0081-02 | 5% Dextrose and 0.33% Sodium Chloride Injection, USP |
| 2B1083 | 500 | 0338-0081-03 | |
| 2B1084 | 1000 | 0338-0081-04 | |
| 2B1072 | 250 | 0338-0085-02 | 5% Dextrose and 0.45% Sodium Chloride Injection, USP |
| 2B1073 | 500 | 0338-0085-03 | |
| 2B1074 | 1000 | 0338-0085-04 | |
| 2B1062 | 250 | 0338-0089-02 | 5% Dextrose and 0.9% Sodium Chloride Injection, USP |
| 2B1063 | 500 | 0338-0089-03 | |
| 2B1064 | 1000 | 0338-0089-04 | |
| 2B1163 | 500 | 0338-0095-03 | 10% Dextrose and 0.9% Sodium Chloride Injection, USP |
| 2B1164 | 1000 | 0338-0095-04 | |

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

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To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
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To Add Medication

WARNING

Additives may be incompatible.

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1. Prepare medication site.
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4. Remove container from IV pole and/or turn to an upright position.
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7. Return container to in use position and continue administration.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Printed in USA

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07-19-70-15

Rev. September 2013

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