# Meglumine

## 1 Nonproprietary Names

BP: Meglumine
JP: Meglumine
USP: Meglumine

## 2 Synonyms

1-Methylamino-1-deoxy-D-glucitol; N-methylglucamine; *N*-methyl-D-glucamine.

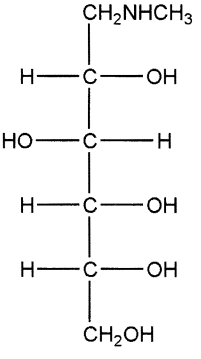
## 3 Chemical Name and CAS Registry Number

1-Deoxy-1-(methylamino)-D-glucitol [6284-40-8]

## 4 Empirical Formula and Molecular Weight

$C_7H_{17}NO_5$ 195.21

## 5 Structural Formula




## 6 Functional Category

Organic base.

## 7 Applications in Pharmaceutical Formulation or Technology

Meglumine is an organic base used as a pH-adjusting agent and solubilizing agent primarily in the preparation of soluble salts of iodinated organic acids used as X-ray contrast media.

## 8 Description

Meglumine occurs as a white to slightly yellow-colored crystalline powder; it is odorless or with a slight odor.

## 9 Pharmacopeial Specifications

*See* Table I.

**Table I:** Pharmacopeial specifications for meglumine.

| Test | BP 2001 | JP 2001 | USP 25 |
|---|---|---|---|
| Identification | + | + | + |
| Characters | + | — | — |
| Completeness and color of solution | — | — | + |
| Melting point | 128–131 °C | 128–131 °C | 128–132 °C |
| Specific optical rotation (10% w/v aqueous solution) | −16.0 to −17.0 ° | −16.0 to −17.0 ° | −15.7 to −17.3 ° |
| Reducing sugars | + | — | — |
| Loss on drying | ⩽1.0% | ⩽0.5% | ⩽1.0% |
| Residue on ignition | — | ⩽0.10% | ⩽0.1% |
| Sulfated ash | ⩽0.1% | — | — |
| Absence of reducing substances | — | + | + |
| Heavy metals | — | ⩽10 ppm | ⩽0.002% |
| Arsenic | — | ⩽1 ppm | — |
| Chloride | — | ⩽0.009% | — |
| Sulfate | — | ⩽0.019% | — |
| Pyrogens[a] | + | — | — |
| Assay (dried basis) | 99.0–100.5% | ⩾99.0% | 99.0–100.5% |

[a] Note only applicable for meglumine intended for parenteral use.

## 10 Typical Properties

**Acidity/alkalinity:** pH = 10.5 (1% w/v aqueous solution).
**Dissociation constant:** $pK_a$ = 9.5 at 20 °C
**Melting point:** 128–132 °C
**Osmolarity:** a 5.02% w/v aqueous solution is iso-osmotic with serum.
**Solubility:** *see* Table II.

**Table II:** Solubility of meglumine.

| Solvent | Solubility at 20 °C unless otherwise stated |
|---|---|
| Chloroform | Practically insoluble |
| Ethanol (95%) | 1 in 80<br>1 in 4.8 at 70 °C |
| Ether | Practically insoluble |
| Water | 1 in 1 |

**Specific rotation** $[\alpha]_D^{20}$: −16.5 ° (10% w/v aqueous solution)

## 11 Stability and Storage Conditions

Meglumine does not polymerize or dehydrate unless heated above 150 °C for prolonged periods.

The bulk material should be stored in a well-closed container in a cool, dry place. Meglumine should not be stored in aluminum containers since it reacts to evolve hydrogen gas; it discolors if stored in containers made from copper or copper alloys. Stainless steel containers are recommended.

## 12 Incompatibilities

Incompatible with aluminum, copper, mineral acids, and oxidizing materials.

## 13 Method of Manufacture

Meglumine is prepared by the imination of glucose and monomethylamine, in an alcoholic solution, followed by catalytic hydrogenation.

## 14 Safety

Meglumine is widely used in parenteral pharmaceutical formulations and is generally regarded as a nontoxic material at the levels usually employed as an excipient.

$LD_{50}$ (mouse, IP): 1.68 g/kg

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Meglumine should be handled in a well-ventilated environment and eye protection, gloves, and a respirator are recommended. Exposure to meglumine dust should be kept below 10 mg/m$^3$ for total inhalable dust (8-hour TWA) or 5 mg/m$^3$ for respirable dust (8-hour TWA). There is a risk of explosion when meglumine dust is mixed with air.

## 16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (injections). Included in parenteral medicines licensed in the UK.

## 17 Related Substances

Eglumine.

### Eglumine

**Empirical formula::** $C_8H_{19}NO_5$
**Molecular weight:** 209.24
**CAS number:** [14216-22-9]
**Synonyms:** 1-deoxy-1-(ethylamino)-D-glucitol; *N*-ethylglucamine.
**Melting point:** ≈138 °C
**Comments:** eglumine is prepared similarly to meglumine except that monoethylamine is used as the precursor, instead of monomethylamine.

## 18 Comments

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## 19 Specific References

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## 20 General References

Bremecker KD, Seidel K, Böhner A. Polyacrylate gels: use of new bases in drug formulation [in German]. *Dtsch Apoth Ztg* 1990; **130**(8): 401–403.

Chromy V, Kulhanek V, Fischer J. D-(–)-*N*-Methylglucamine buffer for pH 8.5 to 10.5. *Clin Chem* 1978; **24**(2): 379–381.

Chromy V, Zahradnicek L, Voznicek J. Use of *N*-methyl-D-glucamine as buffer in the determination of serum alkaline phosphatase activity. *Clin Chem* 1981; **27**(10): 1729–1732.

Japan Pharmaceutical Excipients Council. *Japanese Pharmaceutical Excipients Directory 1996*. Tokyo: Yakuji Nippon, 1996: 305.

## 21 Author

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## 22 Date of Revision

30 April 2002.