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(54) **STABLE, HIGHLY PURE L-CYSTEINE COMPOSITIONS FOR INJECTION AND METHODS OF USE**

(58) **Field of Classification Search**
CPC A61K 9/0029; A61K 31/095; A61K 47/02
See application file for complete search history.

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Sigma-Aldrich production information for L-cysteine hydrochloride monohydrate (May 2006). (Year: 2006).*

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(57) **ABSTRACT**

Related U.S. Application Data

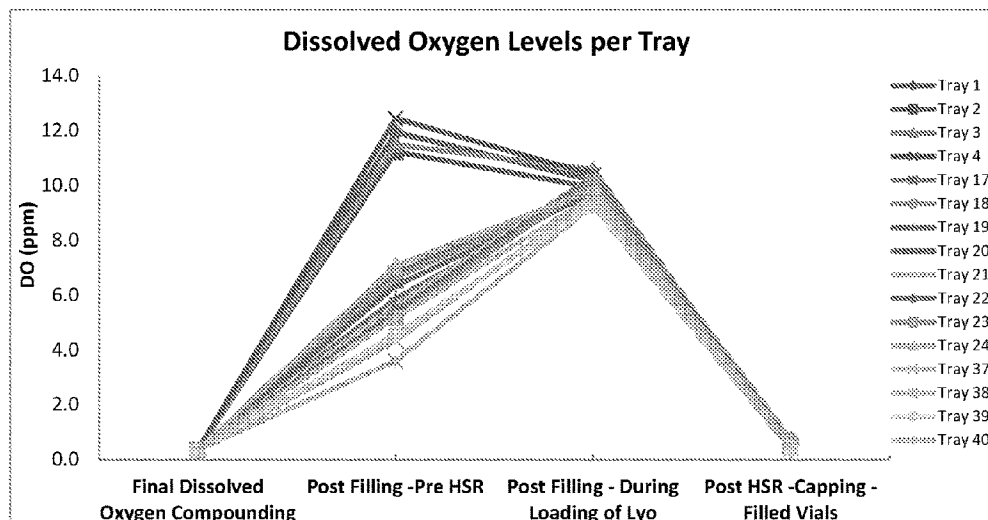
(63) Continuation of application No. 16/248,460, filed on Jan. 15, 2019, now Pat. No. 10,478,453.

The subject matter described herein is directed to stable L-cysteine compositions for injection, comprising: L-cysteine or a pharmaceutically acceptable salt thereof and/or hydrate thereof in an amount from about 10 mg/mL to about 100 mg/mL; Aluminum in an amount from about 1.0 parts per billion (ppb) to about 250 ppb; cystine in an amount from about 0.01 wt % to about 2 wt % relative to L-cysteine; pyruvic acid in an amount from about 0.01 wt % to about 2 wt % relative to L-cysteine; a pharmaceutically acceptable carrier, comprising water; headspace O₂ that is less than 1.0%; dissolved oxygen present in the carrier in an amount from about 0.01 parts per million (ppm) to about 1 ppm, wherein the composition is enclosed in a single-use container having a volume of from 10 mL to 100 mL. Also described are compositions for a total parenteral nutrition regimen and methods for their use.

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