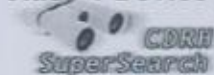


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## Class 1 Device Recall Naturalyte Liquid Bicarbonate Concentrate

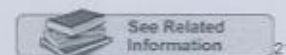


510(k)<sup>7</sup> | Registration & Listing<sup>8</sup> | Adverse Events<sup>9</sup> | Recalls<sup>10</sup> | PMA<sup>11</sup> | Classification<sup>12</sup> | Standards<sup>13</sup> | Inspections<sup>14</sup>  
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### Class 1 Recall Naturalyte Liquid Bicarbonate Concentrate



<b>Date Posted</b>	May 22, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1639-2014
<b>Recall Event ID</b>	<u>67922</u> <sup>22</sup>
<b>Premarket Notification 510(K) Number</b>	<u>K071387</u> <sup>23</sup>
<b>Product Classification</b>	Dialysate Concentrate For Hemodialysis (Liquid Or Powder) <sup>24</sup> - <b>Product Code KPO</b> <sup>25</sup>
<b>Product</b>	Naturalyte Liquid Bicarbonate Concentrate, 6.4 Liter Bottle Part Number: 08-4000-LB The concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates
<b>Code Information</b>	Lot Numbers (49 lots) recalled on 4/10/14: 13KMLB001 13LMLB001 14AMLB002 13KMLB002 13LMLB002 14AMLB003 13KMLB003 13LMLB003 14AMLB004 13KMLB004 13LMLB004 14AMLB005 13KMLB005 13LMLB005 14AMLB006 13KMLB006 13LMLB006 14AMLB007 13KMLB007 13LMLB007 14AMLB008 13KMLB008 13LMLB008 14AMLB009 13KMLB009 13LMLB009 14AMLB010 13KMLB010 13LMLB010 14AMLB012 13KMLB011 13LMLB011 13JMLB005 13KMLB012 13LMLB012 13JMLB008 13KMLB013 13LMLB013 13JMLB006 13KMLB014 13LMLB014 13JMLB007 13KMLB015 13LMLB015 13JMLB004 13KMLB016 13LMLB016 13KMLB017 14AMLB001 Expanded Recall (9 lots): 13LMLB005 13LMLB006 14AMLB011 14AMLB013 14AMLB014 14AMLB015 14AMLB016 14AMLB017 14BLMB001
<b>Recalling Firm/ Manufacturer</b>	Fresenius Medical Care Holdings, Inc. 920 Winter St Waltham, Massachusetts 02451-1521
<b>Manufacturer Reason for Recall</b>	Naturalyte Liquid Bicarbonate maybe contaminated
<b>FDA Determined Cause<sup>2</sup></b>	OTHER/UNDETERMINED: Under Investigation by the firm
<b>Action</b>	Fresenius Medical Care North America issued an Urgent Medical Device Recall Letter dated April 10, 2014, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to examine their stock immediately and determine whether they have any of the affected parts on hand. If customers have the affected product, they were instructed to discontinue use and place all Naturalyte Liquid Bicarbonate Concentrate in a secure area for return to Fresenius Medical Care Renal Therapies Group, LLC (FMC-RTG). Customers will be instructed to contact their Fresenius Medical Care Technical Services Team for instructions on how to return the recalled product. Firm will also conduct 100% telephone calls. If you have any additional questions, please contact your FMCNA Customer Service Team at 1-800-323-5188. Fresenius Medical Care sent an Urgent Expanded Medical Device Recall letter on May 1, 2014 for 9 additional lots. Customers were instructed to complete and return the attached FAX BACK FORM to confirm that they have received the notice and to indicate whether or not they have the affected product in their possession. For questions regarding this recall call 800-662-1237. Firm issued Press on 5/21/14.
<b>Quantity in Commerce</b>	672,784 units

**Distribution** Worldwide Distribution - USA (nationwide) and Canada.

**Total Product Life Cycle** [TPLC Device Report](#)<sup>26</sup>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)<sup>27</sup>

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

**510(K) Database** [510\(K\)s with Product Code = KPO and Original Applicant = FRESINIUS MEDICAL CARE NORTH AMERICA](#)<sup>28</sup>

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22. [/scripts/cdrh/cfdocs/cfRES/res.cfm?start\\_search=1&event\\_id=67922](/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=67922)
23. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K071387>
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