




COVER SHEET

From: NDC Homecare dba Preferred Medical Compliance ***URGENT*** <i>***This is being emailed to the "bill to" account for your company. Please distribute to any/all branches.***</i>	
To: Purchasing or Regulations Department	Date: 7/15/2020
Pages: <u>8</u> (Including cover page)	
Regarding: 4E / Infini - Blumen Hand Sanitizer Items: EBR 4051451; EBR 4051400; EBR 5051405; EBR 4051444 *Various lots listed in attached letter*	
Comments: Dear Distributor, Attached is a letter we received from 4E/Infini regarding the recall on Blumen Hand Sanitizer. Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for EBR 4051451; EBR 4051400; EBR 5051405; EBR 4051444. The various affected lots are listed in the attached letter. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. <u>Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.</u> Additionally, if you have distributed these products to your customers, please advise them of the recall, and have them return any affected product to you. Thanks,  Michael Patton	

402 BNA Dr STE 500, Nashville, TN 37217

Michael Patton- Compliance Specialist / compliance@ndc-inc.com / Phone: 615-366-3230

Tammy Beasley- Compliance Manager / Phone: 615-366-3225



VOLUNTARY DRUG RECALL

07/12/2020

Steve Martin
NDC.,
402 BNA Drive, Suite 500
Nashville, TN 37217

Dear Valued Customer,

This is to inform you of a voluntary product recall involving:


Hand Sanitizers packaged in the following sizes:

1.5 fl oz / 45 ml, 2 fl oz / 60 ml, 3.4 fl oz / 100 ml, 7.5 fl oz / 221 ml, 8 fl oz / 236 ml,
17 fl oz / 503 ml, 18 fl oz / 532 ml, 33.8 fl oz / 1 L, 70 fl oz / 2.07 L, 1.05 GAL / 4 L

See enclosed product labels for ease in identifying the products to the consumer level.




This recall has been initiated due to the potential presence of methanol (wood alcohol). Substantial methanol exposure could result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death. Although all persons using these products on their hands are at risk, young children who accidentally ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute, are most at risk for methanol poisoning.

For ease in identifying the product at retail and commercial level, below are the retail product labels:

Product Name	UPC Codes	NDC Number	Label
Blumen Advanced Hand Sanitizer 7.5 fl oz / 221 ml	814266023624	60599-012-04	

<p>Blumen Advanced Hand Sanitizer</p> <p>33.8 fl oz / 1L</p>	<p>814266023693</p>	<p>60599-012-08</p>	 <p>The image shows the packaging for Blumen Advanced Hand Sanitizer. The main box is blue and white, featuring the Blumen logo and the text 'ADVANCED HAND SANITIZER' and '70% ALCOHOL CONTENT'. It also mentions 'KILLS INSTANTLY UP TO 99.99% OF MOST COMMON GERMS' and '33.8 fl oz / 1 L'. To the right is a detailed label with 'Drug Facts', 'Warnings', 'Directions', and 'Other information'. The label includes a barcode and the number '14266023693'.</p>
<p>Blumen Advanced Instant Hand Sanitizer Clear 33.8 fl oz / 1L</p>	<p>814266023747</p>	<p>60599-015-00</p>	 <p>The image shows the packaging for Blumen Advanced Instant Hand Sanitizer Clear. The main box is white with a blue and yellow design, featuring the Blumen logo and the text 'ADVANCED INSTANT HAND SANITIZER Clear'. It also mentions 'KILLS 70% OF MOST COMMON GERMS' and '33.8 fl oz / 1 L'. To the right is a detailed label with 'Drug Facts', 'Warnings', 'Directions', and 'Other information'. The label includes a barcode and the number '14266023747'.</p>
<p>Blumen Clear Advanced Hand Sanitizer 18 fl oz / 532 ml</p>	<p>814266023914</p>	<p>60599-017-00</p>	 <p>The image shows the packaging for Blumen Clear Advanced Hand Sanitizer. The main box is white with a blue and yellow design, featuring the Blumen logo and the text 'Clear ADVANCED HAND SANITIZER'. It also mentions 'KILLS 70% OF MOST COMMON GERMS' and '18 fl oz / 532 ml'. To the right is a detailed label with 'Drug Facts', 'Warnings', 'Directions', and 'Other information'. The label includes a barcode and the number '14266023914'.</p>

<p>Blumen Clear Advance Hand Sanitizer</p> <p>Sanitizer 2 fl oz / 60 ml</p>	<p>814266023716</p>	<p>60599-018-01</p>	 <p>The image shows a 2 fl oz / 60 ml bottle of Blumen Clear Advance Hand Sanitizer next to its packaging box. The bottle is white with a blue cap and a label that reads 'blumen Clear ADVANCED HAND SANITIZER'. The box is white with a blue and green design and also reads 'blumen Clear ADVANCED HAND SANITIZER'. Both the bottle and the box are labeled with 'KILLS UP TO 99.9% OF GERMS' and 'WITH 70% ALCOHOL'. The dimensions of the bottle are 62 mm in height and 32 mm in width. The dimensions of the box are 62 mm in height and 32 mm in width.</p>
<p>Blumen Clear Advance Hand Sanitizer</p> <p>Sanitizer 17 fl oz / 503 ml</p>	<p>814266024096</p>	<p>60599-018-04</p>	 <p>The image shows a 17 fl oz / 503 ml bottle of Blumen Clear Advance Hand Sanitizer next to its packaging box. The bottle is white with a blue cap and a label that reads 'blumen Clear ADVANCED HAND SANITIZER'. The box is white with a blue and green design and also reads 'blumen Clear ADVANCED HAND SANITIZER'. Both the bottle and the box are labeled with 'KILLS UP TO 99.9% OF GERMS' and 'WITH 70% ALCOHOL'. The dimensions of the bottle are 140 mm in height and 50 mm in width. The dimensions of the box are 140 mm in height and 50 mm in width.</p>
<p>Blumen Clear Advance Hand Sanitizer</p> <p>Sanitizer 1.05 GAL / 4L</p>	<p>814266023686</p>	<p>60599-018-06</p>	 <p>The image shows a 1.05 GAL / 4L bottle of Blumen Clear Advance Hand Sanitizer next to its packaging box. The bottle is white with a blue cap and a label that reads 'blumen Clear ADVANCED HAND SANITIZER'. The box is white with a blue and green design and also reads 'blumen Clear ADVANCED HAND SANITIZER'. Both the bottle and the box are labeled with 'KILLS UP TO 99.9% OF GERMS' and 'WITH 70% ALCOHOL'. The dimensions of the bottle are 140 mm in height and 50 mm in width. The dimensions of the box are 140 mm in height and 50 mm in width.</p>

<p>Blumen Clear Advance Hand Sanitizer</p> <p>Sanitizer 7.5 fl oz / 221 ml</p>	<p>814266023624</p>	<p>60599-018-02</p>	
<p>Blumen Clear Advanced Hand Sanitizer, with 70% alcohol 3.4 fl oz 100 ml</p>	<p>814266023594</p>	<p>60599-018-07</p>	
<p>Blumen Aloe Advanced Hand Sanitizer, with 70% Alcohol 3.4 fl oz / 100 ml</p>	<p>814266023587</p>	<p>60599-028-00</p>	



We began shipping this product in April 2020.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers, and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall should be carried out to the consumer level. Your assistance is appreciated and necessary to prevent consumer illness or patient harm.

Please complete and return the enclosed response form as soon as possible.

If you have any questions please contact:

Toll Free: 888-843-0254 8-5 EST
FAX: 888-214-7430
Email: 4EBrands8797@stericycle.com
Event: 8797

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Enclosure(s)

A handwritten signature in black ink, appearing to be 'JGO', enclosed within a large, loopy oval shape.

Jorge González Olvera
Chief Executive Officer
4e Brands North America, LLC



LOT NUMBERS

2128	2226	2267	2400	2510	2678	2787	2885
2129	2227	2268	2401	2512	2679	2788	2886
2130	2228	2269	2438	2513	2680	2797	2887
2131	2229	2293	2439	2514	2681	2799	2888
2132	2230	2294	2440	2515	2682	2801	2889
2133	2234	2295	2441	2518	2683	2804	2890
2134	2243	2296	2457	2531	2684	2805	2891
2135	2244	2297	2458	2542	2740	2830	2892
2136	2245	2351	2459	2543	2741	2832	2894
2140	2246	2352	2460	2544	2743	2833	2895
2141	2247	2360	2461	2546	2744	2834	2896
2187	2249	2361	2462	2567	2746	2835	2897
2188	2250	2362	2463	2571	2747	2836	2898
2202	2251	2363	2464	2573	2748	2837	2899
2212	2252	2364	2465	2574	2749	2838	2905
2213	2253	2365	2466	2575	2750	2839	2906
2215	2254	2366	2467	2576	2752	2843	2907
2216	2255	2367	2497	2600	2753	2844	2908
2217	2256	2368	2499	2601	2773	2845	2909
2218	2257	2369	2500	2602	2774	2846	2910
2219	2259	2370	2501	2669	2775	2847	2911
2220	2261	2371	2504	2670	2776	2876	2969
2221	2262	2372	2505	2671	2777	2877	2998
2222	2263	2374	2506	2672	2780	2878	3007
2223	2264	2382	2507	2673	2781	2879	
2224	2265	2383	2508	2675	2784	2880	
2225	2266	2399	2509	2676	2785	2884	



7/15/2020

4E / Infini - Blumen Hand Sanitizer

Please fill out and email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and email to: compliance@ndc-inc.com

REQUEST FOR RETURN FORM**Customer Information**

Account No.	_____
Account Name	_____
Address	_____
City/State/Zip	_____
Contact Name	_____
Phone No.	_____
Fax No.	_____
Email	_____

Inventory Information

Item number	Lot number	Expiration date	Quantity to return
EBR 4051451			
EBR 4051400			
EBR 5051405			
EBR 4051444			

- ☐ I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.
- ☐ We have inspected our inventory and have no product related to this recall

Completed by: (Print Name /Signature/Date)

Return Completed form to:

Email:

Michael Patton

compliance@ndc-inc.com

Delivering Efficiency to Healthcare®

402 RNA Drive, Suite 500 / Nashville, TN 37217
www.ndc-inc.com / 615.366.3230