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FDA Updates on Hand Sanitizers with Methanol

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Methanol Contaminated Products List					

Spanish version

7/2/2020: UPDATE - FDA warns consumers of risk of methanol contamination in certain hand sanitizers

[7-2-2020] FDA is warning consumers and health care providers that the agency has seen a sharp increase in hand sanitizer products that are labeled to contain ethanol (also known as ethyl alcohol) but that have tested positive for methanol contamination. Methanol, or wood alcohol, is a substance that can be toxic when absorbed through the skin or ingested and can be life-threatening when ingested.

The agency is aware of adults and children ingesting hand sanitizer products contaminated with methanol that has led to recent adverse events including blindness, hospitalizations and death.

Methanol is not an acceptable active ingredient for hand sanitizers and must not be used due to its toxic effects. FDA's investigation of methanol in certain hand sanitizers is ongoing. The agency will provide additional information as it becomes available.

Consumers who have been exposed to hand sanitizer containing methanol and are experiencing symptoms should seek immediate treatment for potential reversal of toxic effects of methanol poisoning. Substantial methanol exposure can 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 for methanol poisoning, young children who accidently ingest these products and adolescents and adults who drink these

products as an alcohol (ethanol) substitute, are most at risk.

FDA reminds consumers to wash their hands often with soap and water for at least 20 seconds, especially after going to the bathroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommend consumers use an alcohol-based hand sanitizer that contains at least 60 percent ethanol (also referred to as ethyl alcohol).

FDA remains vigilant and will continue to take action when quality issues arise with hand sanitizers. The agency is especially concerned with:

- The dangers of drinking any hand sanitizer under any conditions. While hand sanitizers with possible methanol contamination are more life-threatening than those that are not contaminated, FDA urges consumers not to drink any of these products.
- Certain hand sanitizers that may not contain a sufficient amount of ethyl alcohol or isopropyl alcohol.
- Hand sanitizers that are sold or offered for sale with false and misleading, unproven claims that they can prevent the spread of viruses such as COVID-19, including claims that they can provide prolonged protection (e.g., for up to 24-hours).
- Products that are fraudulently marketed as "FDA-approved" since there are no hand sanitizers approved by FDA.
- Products packaged to appear as drinks, candy or liquor bottles, as well as products marketed
 as drinks or cocktails because their appearance could result in accidental ingestion or
 encourage ingestion. Children are particularly at risk with these products since ingesting only
 a small amount of hand sanitizer may be lethal in a young child.

FDA is aware of reports of adverse events associated with hand sanitizer products. FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's MedWatch Adverse Event Reporting program (please provide the agency with as much information as possible to identify the product):

- Complete and submit the report online; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

FDA's testing and manufacturer/distributor recalls

The following chart outlines the information on hand sanitizer labels for consumers to use to identify a product:

• That has been tested by FDA and found to contain methanol.

- That is being recalled by the manufacturer or distributor.
- That is purportedly made at the same facility as products that have been tested by FDA and found to contain methanol.

FDA advises consumers not to use hand sanitizers from these companies, or products with these names or NDC numbers.

Company	Date added to table	Product(s)	NDC(s)	Product status
4E Global, SAPI de CV (Mexico)	07/08/2020	Blumen Clear Advanced Hand Sanitizer with 70% Alcohol	Not listed	FDA tested product; contains methanol; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Blumen Advanced Instant Hand Sanitizer Clear Ethyl Alcohol 70%	Not listed	FDA tested product; contains methanol; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Advanced Instant Hand Sanitizer Clear	60599-015-00 60599-015-01 60599-015-02	FDA tested product; contains methanol; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	KLAR AND DANVER Instant Hand Sanitizer (labeled with Greenbrier International Inc.)	33992-8010-1	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	MODESA Instant Hand Sanitizer Moisturizers and Vitamin E	60599-007-33	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Advanced Hand Sanitizer	60599-012-00 60599-012-01 60599-012-02 60599-012-03 60599-012-04 60599-012-05 60599-012-07 60599-012-08 60599-012-10	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI	07/08/2020	BLUMEN Advanced	60599-013-00	Product purported to be made at the

de CV (Mexico)		Hand Sanitizer Aloe	60599-013-01 60599-014-00	same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Advanced Instant Hand Sanitizer Lavender	60599-016-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Clear LEAR Advanced Hand Sanitizer	60599-017-00 60599-017-01 60599-018-00 60599-018-01	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUEMEN Clear Advanced Hand Sanitizer	60599-018-02 60599-018-03 60599-018-04 60599-018-05 60599-018-06 60599-018-08 60599-019-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	The Honeykeeper Hand Sanitizer	60599-020-00 60599-020-01	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Advanced Hand Sanitizer Clear	60599-024-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Clear Advanced Instant Hand Sanitizer	60599-025-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Clear Advanced Instant Hand Sanitizer Aloe	60599-026-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Clear Advanced Instant Hand Sanitizer Lavender	60599-027-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Aloe Advanced Hand Sanitizer, with 70 Alcohol	60599-028-00 60599-029-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Blumen Advanced Hand Sanitizer Lavender, with 70% alcohol	60599-046-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020

4E Global, SAPI de CV (Mexico)	07/08/2020	Blumen Advanced Hand Sanitizer Aloe, with 70% alcohol	60599-047-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Blumen Antibacterial Fresh Citrus Hand Sanitizer	60599-501-01	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Blumen Hand Sanitizer Fresh Citrus	60599-502-01	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	KLAR and DANVER INSTANT HAND SANTIZER	60599-801-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Hello Kitty by Sanrio Hand Sanitizer	60599-802-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Assured Instant Hand Sanitizer (Vitamin E and Aloe)	60599-850-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Assured Instant Hand Sanitizer (Aloe and Moisturizers)	60599-851-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Assured Instant Hand Sanitizer Vitamin E and Aloe	60599-852-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Assured Instant Hand Sanitizer Aloe and Moisturizers	60599-853-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Instant Hand Sanitizer Fragrance Free	60599-854-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	BLUMEN Instant Hand Sanitizer Aloe Vera	60599-855-00	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020
4E Global, SAPI de CV (Mexico)	07/08/2020	Assured Aloe	60599-999-10	Product purported to be made at the same facility; FDA recommended a recall on 07/06/2020

AAA Cosmetica (Mexico)	07/06/2020	bio aaa Advance Hand Sanitizer	76987-402-01	FDA tested product; contains methanol; FDA recommended a recall on 07/02/2020; added to import alert to stop products from entering the U.S. on 7/7/2020
AAA Cosmetica (Mexico)	07/06/2020	LumiSkin Advance Hand Sanitizer 4 oz	76987-120-01	Product purported to be made at the same facility; FDA recommended a recall on 07/02/2020; added to import alert to stop products from entering the U.S. on 7/7/2020
AAA Cosmetica (Mexico)	07/06/2020	LumiSkin Advance Hand Sanitizer 16 oz	76987-402-02	Product purported to be made at the same facility; FDA recommended a recall on 07/02/2020; added to import alert to stop products from entering the U.S. on 7/7/2020
AAA Cosmetica (Mexico)	07/06/2020	QualitaMed Hand Sanitizer	76987-250-01	Product purported to be made at the same facility; FDA recommended a recall on 07/02/2020; added to import alert to stop products from entering the U.S. on 7/7/2020
DDI Multinacional SA de CV (Mexico)	07/08/2020	Earths Amenities Instant Unscented Hand Sanitizer with Aloe Vera Advanced	74949-002-20 74949-002-25 74949-002-49 74949-002-60	FDA tested product; contains methanol; product retained at the border; FDA recommended a recall on all other potential products on the market on 6/29/2020
DDI Multinacional SA de CV (Mexico)	07/08/2020	Hand Sanitizer Agavespa Skincare	77415-000-00	Product purported to be made at the same facility; FDA recommended a recall on other all potential products on the market on 6/29/2020
DDI Multinacional SA de CV (Mexico)	07/08/2020	Vidanos Easy Cleaning Rentals Hand Sanitizer Agavespa Skincare	77056-000-01	Product purported to be made at the same facility; FDA recommended a recall on all other potential products on the market on 6/29/2020
Eskbiochem SA de CV (Mexico)	*07/02/2020	All-Clean Hand Sanitizer	74589-002-01	Product purported to be made at the same facility; product voluntarily recalled by ITECH 361
Eskbiochem SA de CV (Mexico)	*07/02/2020	Esk Biochem Hand Sanitizer	74589-007-01	Product purported to be made at the same facility
Eskbiochem SA de CV (Mexico)	*07/02/2020	Lavar 70 Gel Hand Sanitizer	74589-006-01	FDA tested product; contains methanol
Eskbiochem SA de CV (Mexico)	*07/02/2020	The Good Gel Antibacterial Gel	74589-010-10	Product purported to be made at the same facility

Hand Sanitizer

		riana Gamazor		
Eskbiochem SA de CV (Mexico)	*07/02/2020	CleanCare NoGerm Advanced Hand Sanitizer 80% Alcohol	74589-005-03	Product purported to be made at the same facility
Eskbiochem SA de CV (Mexico)	*07/02/2020	CleanCare NoGerm Advanced Hand Sanitizer 75% Alcohol	74589-009-01	FDA tested product; contains methanol
Eskbiochem SA de CV (Mexico)	*07/02/2020	CleanCare NoGerm Advanced Hand Sanitizer 80% Alcohol	74589-003-01	Product purported to be made at the same facility
Eskbiochem SA de CV (Mexico)	*07/02/2020	Saniderm Advanced Hand Sanitizer	74589-001-01	Product purported to be made at the same facility; product recalled by Saniderm Products and UVT Inc.
Grupo Insoma, S.A.P.I de CV (Mexico)	07/02/2020	Hand sanitizer Gel Unscented 70% Alcohol	75744-0200-3 75744-0200-4 75744-0201-5 75744-0202-1 75744-0250-1 75744-0250-2 75744-0500-1 75744-1000-1 75744-1000-3 75744-1001-1	FDA tested product; contains methanol; FDA recommended a recall on 07/01/2020
Limpo Quimicos SA de CV (Mexico)	07/08/2020	Andy's Best	73755-120-01 73755-120-02 73755-120-04	FDA tested product; contains methanol; FDA recommended a recall on 07/08/2020
Limpo Quimicos SA de CV (Mexico)	07/08/2020	Andy's	73755-110-01 73755-130-02	Product purported to be made at the same facility; FDA recommended a recall on 07/08/2020
Limpo Quimicos SA de CV (Mexico)	07/08/2020	Gelclor	73755-140-01	Product purported to be made at the same facility; FDA recommended a recall on 07/08/2020
Limpo Quimicos SA de CV (Mexico)	07/08/2020	NeoNatural	73755-200-01 73755-200-02	Product purported to be made at the same facility; FDA recommended a recall on 07/08/2020
Limpo Quimicos SA de CV (Mexico)	07/08/2020	Plus Advanced	73755-300-01	Product purported to be made at the same facility; FDA recommended a recall on 07/08/2020

Liqesa Exportacion or Liq-E-S.A. de CV (Mexico)	07/08/2020	Optimus Lubricants Instant Hand Sanitizer	75416-004-01 75416-005-01	FDA tested product; contains methanol; FDA recommended a recall on 07/07/2020; company is not registered with FDA; additional products may be on the market
Maquiladora Miniara, SA de CV (Mexico)	07/10/2020	Shine and Clean Hand Sanitizer	76753-001-01 76753-001-02 76753-001-03	FDA tested product; contains methanol; FDA recommended a recall on 07/09/2020
Maquiladora Miniara, SA de CV (Mexico)	07/10/2020	Selecto Hand Sanitizer	76753-002-01	Product purported to be made at the same facility; FDA recommended a recall on 07/10/2020
Mystic International SA de CV (Mexico)	07/02/2020	Mystic Shield Protection hand sanitizer	75477-435-02 75477-435-10 75477-435-12 75477-435-25 75477-435-50 75477-534-10	Contains methanol; product voluntarily recalled by Transliquid Technologies LLC
Soluciones Cosmeticas SA de CV (Mexico)	07/02/2020	Bersih Hand Sanitizer Gel Fragrance Free	75165-000-01 75165-001-01 75165-003-02 75165-004-01 75165-005-01 75165-008-01 75165-250-01 75165-600-01	FDA tested product; contains methanol; FDA recommended a recall on 07/01/2020
Soluciones Cosmeticas SA de CV (Mexico)	07/02/2020	Antiseptic Alcohol 70% Topical Solution hand sanitizer	Not listed	FDA tested product; contains methanol; FDA recommended a recall on 07/01/2020
Soluciones Cosmeticas SA de CV (Mexico)	07/10/2020	Hand sanitizer (labeled with Wet Look Janitorial and Gardening Corp.)	79095-000-01 79095-001-01 79095-002-01 79095-003-01 79095-004-01 79095-005-01 79095-006-01	Product purported to be made at the same facility; FDA recommended a recall on 07/01/2020
Tropicosmeticos SA de CV (Mexico)	07/02/2020	Britz Hand Sanitizer Ethyl Alcohol 70%	76676-402-01 77676-402-02 77676-402-03 77676-402-04 77676-402-05 77676-402-06 77676-402-07 77676-402-08	FDA tested product; contains methanol; FDA recommended a recall on 07/01/2020