



Key Characteristics

- 0∎ Wide-spectrum antimicrobial
- 0 Good water-to-oil partition coefficient
- 0 Compatible with other cosmetic ingredients
- 0∎ Effective over a wide pH range
- **0** Nontoxic, safe for human use
- 0 Environmentally safe

Wide-Spectrum Sorbic acid and potassium sorbate are excellent, safe preservatives for Antimicrobials for cosmetics and personal care products with a pH lower than 6.5. They have Maintaining good skin compatibility and are easy to use, especially potassium sorbate Freshness in salt form.

The structure for the potassium salt known as potassium sorbate (C6H7O2K) is:

CH₃—CH—CHCH—CH—C—O

OK

2,4-Hexadienoic Acid Potassium Salt CAS No. 24634-61-5

Sorbic acid was first isolated from the pressed unripened berries of the rowan or mountain ash tree by A. W. Hoffmann, a German chemist, in 1859.

The antimicrobial preservative power of sorbic acid wasn't discovered until 1939–1940. After that, the effectiveness of sorbic acid as a preservative and its physiological safety were thoroughly studied. As early as 1955, both sorbic acid and potassium sorbate were proven to be safe and innocuous. Since that time, sorbates have been approved for use as food preservatives in nearly all countries of the world. Sorbic acid has been used as a preservative in cosmetics since the early 1960s.



The following pages provide a variety of technical data to help determine whether sorbates are suitable for your particular application. The sections give property and solubility information, specific organisms inhibited by sorbates, effectiveness of sorbates under various conditions and use levels, and product safety and regulatory information.

Properties*

	Eastman Sorbic Acid	Eastman Potassium Sorbate	
INCI/CTFA Name ^b	Sorbic Acid	Potassium Sorbate	
Molecular Weight	112.13	150.22	
Water Solubility @ 20*C	0.15%	58.2%	
Solubility in Organic Compounds, % by wt @ 20°C			
Ethanol, 100%	12.9	2.0	
95%	12.6	6.5	
50%	4.9	45.3	
20%	0.29	54.6	
5%	0.16	57.4	
Ethyl Ether	5.0	0.1	
Fatty Oils	0.6-1.2	-0.1	
Propylene Glycol	5.5	20	
Glycerol	0.31	0.20	
Acetic Acid, Glacial	11.5	_	
Acetone	9.2	0.1	
Vapor Pressure, mm Hg			
@ 20"C	<0.001	NA	
120°C	10	NA	
140°C	43	NA	
Flash Point, "C ("F) (CDC, ASTM D 92)	127 (260)	none	
Ionization Constant @ 25°C	1.73 × 10-5	_	
Assay, Dry Basis	99.0%-101.0%	98.0%-101.0%	
Identification	Passes Food Chemic	als Codex Specifications	
Appearance		White to off-white, free flowing	
Melting Range	132.0"-135.0°C	Decomposes above 270°C	
Water Content	0.5% maximum	1.0% maximum	
Alkalinity/Ackity	-	1.1 mL 0.1N NaOH to 0.8 mL 0.1N HCi per 1.1 g	
Products Available	Powder, dust-free	Powder or granular	

*Properties reported here are typical of average lots. Eastman makes no representation that the material in any shipment will conform to the values given. •International Nomenclature Cosmitic Ingredient; Cosmitic, Tolkity, and Fragrance Association.

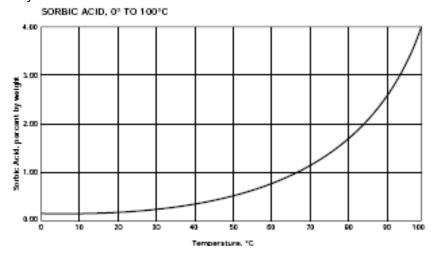
NA-Not Applicable



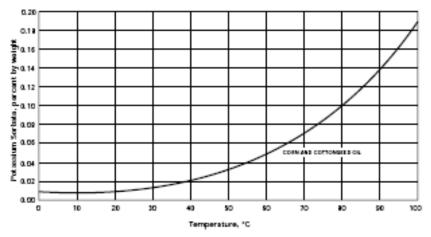


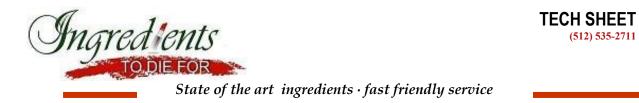
sorbic acid and potassium sorbate are highly refined, white to off-white, freeflowing powders or granules. Sorbic acid provides greater antimicrobial potency than potassium sorbate. However, in water, sorbic acid is barely soluble while potassium sorbate is extremely soluble. Therefore, potassium sorbate is usually chosen as a preservative for cosmetic products. The potency of the salt on an equivalent weight basis to the acid is 74%. Thus, for equal preservative power, four parts of potassium salt must be used to equal three parts sorbic acid.

Solubility in Water

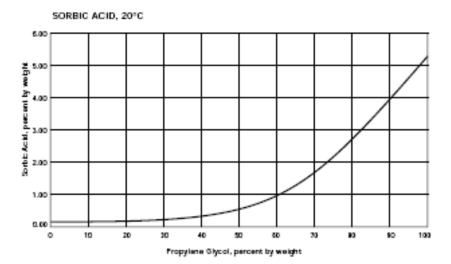


POTASSIUM SORBATE, 0° TO 100°C

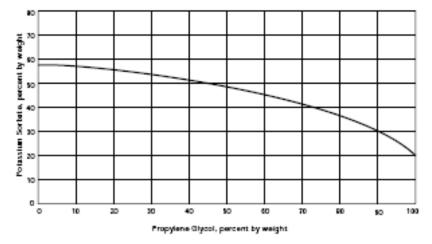




Solubility in Corn and Cottonseed Oils











Above about 60°C (140°F), sorbic acid begins to sublime. This volatility should be considered when sorbate is to be added prior to a heating step in the existing process.

Sorbates have a relatively high water-to-oil partition coefficient. A high water-to-oil partition coefficient means a high concentration of sorbates in the aqueous phase and a low concentration in the oil phase. As the pH of the formulation increases (approaching pH = 7) and sorbic acid converts to the salt form, the partition coefficient increases. A high partition coefficient is favorable because microorganisms reproduce in the aqueous phase and, in the case of an emulsion, at the interface between the aqueous and oil phase. Therefore, a balance is achieved. Even though the potassium sorbate has less antimicrobial potency than sorbic acid, it offers better solubility in water where antimicrobial effectiveness is most needed.

Sorbates are compatible with other cosmetic ingredients. Unlike the phydroxybenzoic acid esters (parabens), sorbic acid remains active when used with nonionic emulsifiers. Sorbates do have an antagonistic effect on chlorhexidin digluconate, which is inactivated by the potassium ion. However, chlorhexidin digluconate and sorbates are not normally used in the same products. Sorbates are used in leave-on or rinse-off products and chlorhexidin digluconate is used in oral hygiene products. Several other cosmetic preservatives are also antagonistic to chlorhexidin digluconate.

Under certain conditions, sorbic acid may oxidize and cause slight color changes in the cosmetic product. This can normally be prevented by adding 0.1%–0.3% citric acid to the product. Citric acid may already be added to cosmetics to obtain a skin-neutral pH. Highly concentrated solutions of sorbic acid and potassium sorbate may oxidize and become discolored during prolonged storage, especially when exposed to sunlight. Therefore, sorbate stock solutions should be used up as soon as possible.

Antimicrobial Effectiveness Most cosmetics have great potential for microbial contamination and growth, especially creams and lotions that are packed in jars, opened frequently, and applied to the skin with the fingers. Brushes that are used to apply makeup around the eyes or other parts of the face touch the skin and the cosmetic repeatedly. Each use increases the chance for contamination. Several cases of eye ulceration and partial or complete blindness have been attributed to mascaras contaminated with pseudomonas. Cosmetic contamination may also occur because consumers leave the containers open for a period of time. Moreover, most cosmetics are stored at room temperature and the warm temperatures stimulate the growth of microorganisms. In addition, the ingredients in cosmetics contain all the things microorganisms like—water, oils, peptides, and a variety of carbohydrates.





All of these factors mean that good preservatives are essential for cosmetics. In fact, cosmetics need better preservation than foods normally stored in cooler temperatures and consumed quickly. Cosmetic preservatives must be strong, but they must also be nonirritating to skin. Sorbates fit both of these criteria. Sorbic acid is effective against small populations of common micro-organisms in cosmetics. Cosmetic preservatives are not intended to combat extremely high counts of bacteria. They are intended to control small populations that would normally be present in products manufactured under clean, sanitary conditions. Sorbic acid can be metabolized by some species of organisms when they are present in extremely high concentrations. However, this situation should not occur when good manufacturing practices are employed. When selecting a preservative and establishing a use level, two factors are particularly important: the type of microorganisms that can potentially grow and the pH of the product. Other factors to consider include water content, storage temperature, shelf life expectancy, and potential for abuse in distribution and use. Generally higher sorbate levels are required when the water content is higher and storage temperatures are warmer.

Factors That Influence the Effectiveness of Preservatives

Initial Contamination Level

- 0 Raw materials
- 0∎ Water supply
- 0 Processing sanitation—equipment and premises

Composition of Cosmetic/Personal Care Product

- 0∎ pH of the product
- 0∎ Water content
- 0 Antimicrobial effects of other ingredients

Distribution and Use

- 0∎ Packaging
- **0** Storage temperature
- 0∎ Shelf life expectancy
- **0** Potential for contamination by consumer



Microorganisms Inhibited by Sorbates

not necessarily found in cosmetics.

Molds

Alternaria citria Alternaria tenuis^b Alternaria spp.^c Ascochyta cucumis^b Ascochvta sp.^b Aspergillus clavatus^a Aspergillus elegans^b Aspergillus flavus^b Aspergillus fumigatus^b Aspergillus glaucus^c Aspergillus niger^{b,c} Aspergillus ocraceus^a Aspergillus parasiticus^a Aspergillus sydowib Aspergillus terreus^b Aspergillus unguis^b Aspergillus versicolor^b Botrytis cinerea^a Cephalosporium sp.^b Cercospora sp.^b Chaetomium globosum^b Cladosporium cladosporiodes^b Colletotrichum lagenarium^b Cunninghamella echinulata^b Curvularia trifoliib Fusarium episphaeria^b Fusarium moniliforme^{b,c} Fusarium oxysporum^{b,c} Fusarium roseum^c Fusarium rubrum^a Fusarium solani^{b,c} Fusarium tricinctum^a Geotrichum candidum^a Geotrichum sp.^b (2 strains tested) Gliocladium roseum^b Helminthosporium sp.^b (2 strains tested) Rosellinia sp.^b Heterosporium terrestre^b Humicola fusco-atra.^b Mucor silvaticus^b Mucor spp.^{b,c} (5 strains tested) Myrothecium roridum^b Myrothecium verrucaria^b

Myrothecium sp.^b Papularia arundinis^b Penicillium atromentosum^b Penicillium chermesinum^b Penicillium chrvsogenum^c Penicillium citrinum^a Penicillium digitatum^a Penicillium duclauxi^b Penicillium expansum^b Penicillium frequentans^b Penicillium funiculosum^b Penicillium gladiolib Penicillium herquei^b Penicillium implicatum^b Penicillium italicum^a Penicillium janthinellum^b Penicillium notatum^c Penicillium oxalicum^{b,c} Penicillium patulum Penicillium piscarium^b Penicillium purpurogenum^a Penicillium restrictum^b Penicillium roquefortiic Penicillium rugulosum^b Penicillium sublateritium^b Penicillium thomiib Penicillium urticae^b Penicillium variabile^b Penicillium spp.^{b,c} (2 strains tested) Pestolotiopsis macrotricha sp.^b Phoma sp.^b Pullularia pullulans^{b,c} Rhizoctonia solania Rhizopus arrhizus^b Rhizopus nigricans^{b,c} Sporotrichum pruinosum^b Stagonospora sp.^b Stysanus sp.^b Thielavia basicolab Trichoderma viride^b Truncatella sp.^b

The following charts list the most common microorganisms inhibited by sorbates. These organisms are

^aEastman Chemical Company unpublished data.

^bBell, T. A., Etchells, J. L., and Borg, A. F., J. Bacteriology 77 573 (1959). ^cYork, G. K., Dissertation, University of California Davis (1960).



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Yeasts

Brettanomyces clauseniic Brettanomyces versatilis^b Candida albicans^{b,c} Candida krusei^{b,c} Candida tropicalis^c Candida mycoderma^c Cryptococcus terreus^c Cryptococcus neoformans^b Cryptococcus sp.^c Debaryomyces membranaefaciens^c Debaryomyces membranaefaciens var. hollandicus^b Debaryomyces spp.^c Endomycopsis ohmeri^b Hansenula anomala^c Hansenula saturnus^c Hansenula subpelliculosa^{b,c} Oospora sp.^c Pichia alcoholophila^b Pichia membranaefaciens^c Pichia polymorpha^c Pichia silvestris^c Pichia sp.^b

Rhodotorula flava^b Rhodotorula glutinis^b Rhodotorula rubra^{b,c} Rhodotorula spp.^b Saccharomyces cerevisiae^{b,c} Saccharomyces cerevisiae var.

ellipsoideus^c Saccharomyces carlsbergensis Saccharomyces fragilis^{b,c} Saccharomyces rouxii^c Saccharomyces delbrueckii^b Saccharomyces lactis^b

Schizosaccharomyces octosporus^c Sporobolomyces sp.^c Torulaspora rosei^{b,c}

Torulopsis candida^b Torulopsis caroliniana^b Torulopsis minor^b Torulopsis polcherrima^c Torulopsis versitalis lipofera^b

Zygosaccharomyces globiformis^b Zygosaccharomyces halomembranis^b

Bacteria

Acetobacter aceti^c Acetobacter xylinum^c Achromobacter sp.^c Alcaligenes faecalis^c Azotobacter agilis^c Bacillus coagulans^c Bacillus cereus^c Bacillus poymyxa^c Bacillus stearothermophilus^c Bacillus subtilis^c Clostridium perfringens^a Clostridium sporogenes^a Clostridium tetani^d Enterobacter aerogenes^c Escherichia coli^c Escherichia freundii^c Klebsiella species^d Lactobacillus brevis^a Micrococcus sp.^c Propionibacterium zeae^c Propionibacterium freundenreichii Proteus vulgaris^c

Pseudomonas aeruginosa^d Pseudomonas fragi^c Pseudomonas fluorescens^a Pseudomonas sp.^c Salmonella heidelberg^a Salmonella montevideo^a Salmonella typhimurium^c Salmonella enteritidis^c Sarcina lutea^c

Serratia marcescens^c Staphylococcus aureus^c Streptococcus pyogenes^d Vibrio parahaemolyticus^a

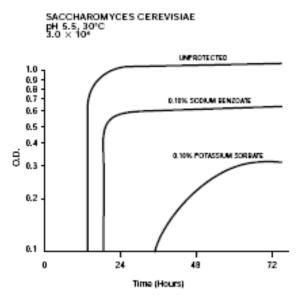
^aEastman Chemical Company unpublished data.

^bBell, T. A., Etchells, J. L., and Borg, A. F., J. Bacteriology 77 573 (1959). ^cYork, G. K., Dissertation, University of California Davis (1960).
^dJager, M., Preservatech Conference Proceedings, pp 39–50 (1995).

Antimicrobial Effectiveness

Relationship of pH to the antimicrobial potency of all commercial cosmetic preservatives is pH-dependent. Sorbates are more effective at higher pH ranges than other organic acids used as preservatives. Sorbates are effective up to 6.5, whereas benzoates are effective to only 4.5. These preservative compounds can be used in either the acid or salt form. Their antimicrobial activity is mainly due to the undissociated acid molecule. Sorbates are most effective when used below pH 6.0. They function up to pH 6.5, but are relatively ineffective above pH 7.0.

> The graph shows the relative inhibition of yeast by equal concentrations of sorbate and benzoate at pH 5.5 and 30°C when a broth is inoculated with 3 3 10⁴ organisms/mL. Growth is measured by the optical density of the broth. Sorbate significantly delays growth, and the amount of ultimate growth at 72 hours is far less.





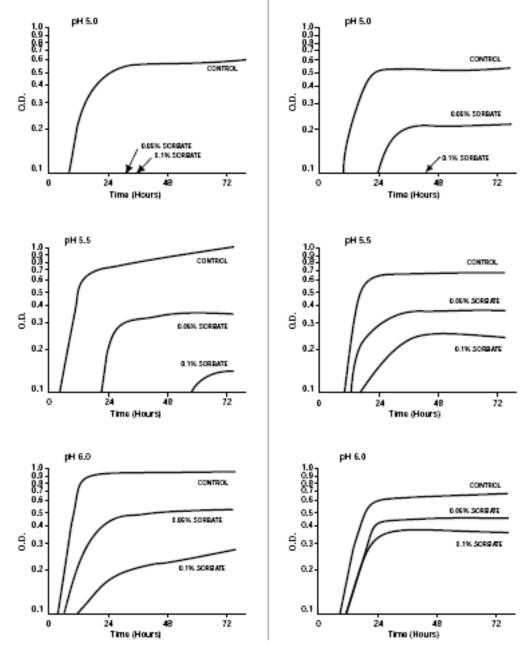
The following graphs show the effectiveness of sorbate at pH 5.0, 5.5, 6.0, and 6.5

ESCHERICHIA COLI

SACCHAROMYCES CEREVISIAE

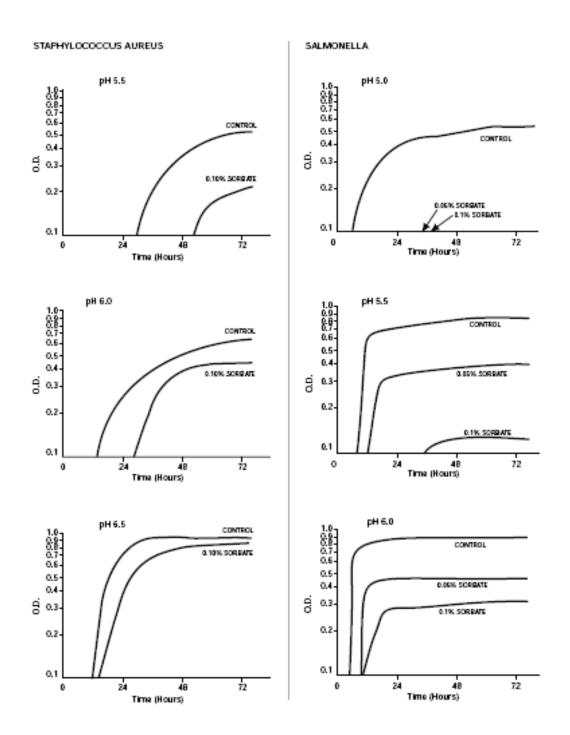
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Sorbate Use Levels

Normally, sorbic acid and potassium sorbate are effective in a concentration range of 0.05% to 0.3% by weight. Generally, the higher the sorbate level, the longer the microbial growth will be inhibited. Increasing the potential of exposure to microbial contamination (e.g., cosmetic containers that are opened frequently, contents that last beyond a single use, or a product that is particularly susceptible to attack) requires the use of a higher level of preservative.

In a study done on a rinse-off product, potassium sorbate was very effective in combating microorganisms. The product was inoculated with Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Aspergillus niger, and Candida albicans. When the rinse-off product (pH 5.5) contained 0.4% potassium sorbate, fewer than 10 microorganisms remained in the product after both one week and one month even though the initial concentration had been as high as 6.5 **3** 10⁵. For most of the microorganisms tested, 0.4% potassium sorbate in combination with 0.1% citric acid reduced the microorganism counts faster than potassium sorbate alone.

Another study showed that 0.05% to 0.2% sorbates are required to combat gram positive bacteria such as Staphylococcus aureus, Streptococcus pyrogenes, and Clostridium perfringens. Greater than 0.4% sorbates are required to fight Clostridium tetani.

It also showed that 0.05% to 0.2% sorbates are required to combat gram negative bacteria such as Pseudomonas aeruginosa and Klebsiella species. 0.2% to 0.4% sorbates are required to fight Pseudomonas fluorescens.

Molds such as Candida albicans, Candida parapsilosis, Aspergillus species, Penicillum species, Fusarium species, Geotrichum candidum, Rhizopus nigricans, Pullularia pullulans, Rhodotorula rubra, and Alternaria species are kept in check by 0.05% to 0.2% sorbates.

Use Levels of Sorbic Acid and Potassium Sorbate in Cosmetics Market Survey, 1995 (According to M. Jager, 1995 Preservatech Conference Proceedings)





Used w/				
Product	Chelating Ager	nt pH-Value	Concentration% ^a	
Shampoo	Yes	4.8-5.6	0.15–0.3	
Shower Gel	Yes	4.8–5.6	0.15–0.35	
Body Lotion	Yes	5.0-6.0	0.1–0.2	
Sun Lotion	Yes	5.2-5.6	0.1–0.2 ^b	
Cleansing Lotion	No	5.8–6.2	0.1–0.2 ^b	
Toning Lotion	Yes	5.8	<0.1 ^b	
Artificial Tanning Lotion	Yes	4.9	<0.1 ^b	
Oral Hygiene Products	No	6.5–6.6	0.15	
Moist Tissues	Yes	5.5–5.9	0.1–0.15	

^aConcentrations are calculated as sorbic acid, although potassium sorbate is more commonly used.

bSorbic acid used in combination with other preservatives.





Safety and Regulatory Status Sorbic acid is a naturally occurring fatty acid similar in structure to corn oil's linoleic acid and margarine's oleic acid. Because sorbates are commonly used as preservatives for foods, they have been subjected to repeated toxi-cological testing. In acute oral toxicity studies, sorbic acid and potassium sorbate were practically nontoxic to mice and rats.

Sorbates do not irritate the skin. At concentrations up to 10%, sorbic acid and potassium sorbate were practically nonirritating to rabbits' eyes. Very few allergic reactions to sorbic acid have been demonstrated. As a result, sorbates are often used in baby-care products and creams and lotions.

Sorbic acid and potassium sorbate have been tested for mutagenic and other genotoxic effects using a variety of tests. The sorbates were at most weakly genotoxic in some of the tests.

Sorbates are nonphotosensitizing, so they are also appropriate as preservatives for sun care products.

Sorbates are environmentally safe. Even though they function as antimi-crobials, they are rapidly and completely broken down in biological wastewater treatment plants. Sorbic acid is classified in the lowest water hazard class (0) by the German government and does not harm aquatic life. Many other cosmetic preservatives are classified in water hazard class 1 or 2. A few are even classified as a 3, the highest water-hazard class.

Sorbic acid and potassium sorbate have general acceptance as preservatives for almost all types of foods and are accepted for use in cosmetics in accordance with the International Cosmetic Ingredient Dictionary and Handbook, CTFA.¹

- 0■ The CTFA Cosmetic Ingredient Review (CIR) panel has concluded that sorbic acid and potassium sorbate are safe as cosmetic ingredients in the present practices of use and concentration—up to 1.0%.
- 0■ The European Commission Cosmetic Directive has approved the use of sorbic acid without restrictions or warning labels at levels up to 0.6%. This is equal to 0.8% potassium sorbate.
- 0■ The Japanese Ministry of Health and Welfare has approved sorbic acid and potassium sorbate for use in hair-care products and cleansing, makeup, suntan and sunscreen, lip, eyeliner, and bath preparations at levels up to 0.5%. This level of sorbic acid is equal to 0.67% potassium sorbate.
- 0 Sorbates have been approved as cosmetic preservatives in China and Australia.

¹Cosmetic, Toiletry, and Fragrance Association.





Storage and Handling

sorbic acid and potassium sorbate are shipped and stored in boxes that have a moisture-barrier inner liner. The compounds deteriorate when exposed to heat or light for prolonged periods of time. Boxes should be kept closed as much as possible. Storage areas should be cool and dry. In order to minimize exposure to elevated temperatures, boxes should not be stored next to steam lines or directly under space heaters.

Aruba aloe Internet site.

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