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facts

Sustainable preservation concepts with L(+)-Lactic Acid for home and personal care products

Introduction – Changes in preservation chemistry

Sustainability has evolved to become a key driver in the field of home and personal care products. An increasing number of consumers demand greener, uncontroversial products that match the quality as well as shelf-life requirements of more traditional products. This affects, among others, products containing major preservation agents like parabens and isothiazolinones. Growing concerns about potential allergenic and sensitising effects have led to regulatory pressure and a strong decline in their usage for home and personal care products. One prominent example is the re-classification of methylisothiazolinone in May 2020 as allergenic in any concentration above 15 ppm.[1] Similar restrictions, stricter classifications and bans of common synthetic preservatives are observed on a global level. This not only affects home and personal care products but also other goods including paints, inks and coatings. Among the non-food applications, the cosmetics industry is often the first to introduce changes and therefore, an early indicator of trends and developments that are likely to spread to other market segments. Currently, this industry is increasingly turning to ingredients derived from natural processes such as fermentation or directly via plant extraction.

Jungbunzlauer's L(+)-lactic acid is one such ingredient: it is bio-based and produced by fermentation of renewable resources. It is liquid under ambient conditions, easy to handle and to dose for home and personal care formulations. Lactic acid is non-allergenic and non-sensitising. It is well known in the cleaning industry for its descaling and disinfectant properties, which represent additional benefits when it is used as a preservation agent in home care and personal care products.[2]

In this overview, recommendations for L(+)-lactic acid itself and for combinations with other additives are made in order to achieve the best results possible in terms of preservation for home and personal care formulations. A particular focus will lie on the preservation efficacy of formulations with a pH range from 2.0 to 5.5. Furthermore, the successful testing of a wet wipe formulation and a skin cream formulation for personal care are reported.

Results – Preservation tests with L(+)-Lactic Acid and mixtures

Analysis of antimicrobial preservation efficacy

To assess the preservation efficacy, tests according to European Pharmacopoeia (Ph. Eur.) 5.1.3. were conducted.[3] This guideline describes a protocol to determine the microbiological stability of a given product. Originally designed for topical preparations (cosmetic/pharmaceutical), it is widely used for other applications as it is considered one of the strictest tests in the area of preservation. According to Ph. Eur. 5.1.3., the respective sample is inoculated with 10^5 to 10^6 colony forming units (CFU) of selected microorganisms per millilitre. The microorganisms comprise *Staphylococcus aureus* (gram-positive coccus), *Pseudomonas aeruginosa* (gram-negative bacillus), *Escherichia coli* (gram-negative bacillus), *Candida albicans* (yeast), and *Aspergillus brasiliensis* (mould). The prepared samples are stored at room temperature away from light and the concentration of CFU/ml is determined after predefined times (2, 7, 14 and 28 days). Depending on the observed logarithmic decline of the microbial count and the potential re-occurrence of growth, the test is graded as pass or fail based on the acceptance criteria A and B as described in table 1.

Table 1: Criteria of acceptance for tests according to Ph. Eur. 5.1.3.

	Test criteria	Log reduction, NI = no increase vs. previous sampling			
		2 d	7 d	14 d	28 d
Bacteria	A	2	3	-	NI
	B	-	-	3	NI
Fungi	A	-	-	2	NI
	B	-	-	1	NI

The recommended criterion is A. However, this is often achieved using harsher substances, for example from the industrial cleaning market, or with undesirably high preservative concentrations. For gentler formulations with neutral or close to neutral pH values, criterion B is more applicable. Here, the required logarithmic reduction of the inoculum is either lower than with criterion A or is tested at a later point in time.

Antimicrobial preservation efficacy tests for L(+)-Lactic Acid at different pH values

In a first step, the basic preservation efficacy of L(+)-lactic acid in simple aqueous surfactant solutions was analysed dependent on the pH value. The solutions consisted of 3% sodium lauryl ether sulfate (SLES) and 0.9% L(+)-lactic acid (active concentration). The concentration of lactic acid was set below 1% to avoid the hazard labelling of the final formulation. The pH was adjusted to desired values with 30% sodium hydroxide solution.

The test results according to Ph. Eur. 5.1.3. are displayed in table 2. As expected, the antimicrobial performance of lactic acid is better at lower pH values, as only the protonated species is sufficiently able to permeate the cell membrane of the microorganisms. Up to a pH of 3.5, L(+)-lactic acid is sufficiently effective to keep the system microbiologically stable. At pH 4.0, the test for preservation activity against mould failed. Nevertheless, with efficacy proven for up to pH 3.5, it is still possible to target a broad range of acidic home care formulations.

Table 2: Preservation efficacy of L(+)-Lactic Acid (LA) in Sodium Lauryl Ether Sulfate (SLES) solution at varying pH values.

	0.9% LA + 3% SLES			
Test germ	**pH 2.0**	**pH 3.0**	**pH 3.5**	**pH 4.0**
E. coli	A	A	A	A
P. aeruginosa	A	A	A	A
S. aureus	A	A	A	A
C. albicans	A	A	A	A
A. brasiliensis	A	A	A	F
Total test results	**A**	**A**	**A**	**F**

Antimicrobial preservation efficacy tests of L(+)-Lactic Acid in combination with other additives/boosters

To protect the natural acid mantle of human skin, the pH value of typical personal care formulations is set to about 5.5. At this level, preservation against fungi is no longer possible with only L(+)-lactic acid, as indicated above. Hence, a combination with boosters, preferably long-chained organic acids or 1,2-alkanediols, is crucial to achieve efficacy in the desired pH range. To reflect the pH level of representative home and personal care formulations, the surfactant concentration was adjusted correspondingly.

For tests according to Ph. Eur. 5.1.3., aqueous solutions with 10% SLES, 2.9% L(+)-lactic acid (active concentration) and various boosters were prepared at a pH of 5.5. A representative number of boosters of synthetic and of natural origin was tested: Anisic acid, dehydroacetic acid, caprylhydroxamic acid, caprylic acid, and 1,2-hexanediol.[4] The results depicted in table 3 show a very uniform picture: Whereas almost all reference test formulations without L(+)-lactic acid failed, all combinations of booster with L(+)-lactic acid passed the tests. In case of the combination of caprylhydroxamic acid and L(+)-lactic acid, the criterion was improved from B to A. With this synergistic effect between L(+)-lactic acid and a booster, home and personal care formulations at a pH of 5.5 can successfully be stabilised with a bio-based and consumer-friendly preservation system.

Table 3: Preservation efficacy of aqueous surfactant solutions of different synthetic or natural boosters alone and in combination with 2.9% L(+)-Lactic Acid (LA) compared to a booster-free blend of 2.9% LA/Sodium L(+)-Lactate (SL) at pH 5.5.

	Formulation of booster with or without 2.9% LA (active concentration) at pH 5.5										
Booster →		0.3% Anisic Acid[a,b]		0.01% Dehydro-acetic Acid[b]		0.8% Caprylhydro-xamic Acid[b]		0.4% Caprylic Acid[a,b]		1% 1,2-Hexanediol[b]	
Test germ ↓	**2.9% LA/SL**		**+ LA**		**+ LA**		**+ LA**		**+ LA**		**+ LA**
E. coli	A	F	A	A	A	B	A	F	B	F	B
P. aeruginosa	A	A	A	F	A	A	A	F	A	F	A
S. aureus	B	A	B	A	A	A	A	B	A	A	A
C. albicans	A	A	A	A	A	A	A	A	A	A	A
A. brasiliensis	F	A	A	A	A	B	A	A	A	F	A
Total test results	**F**	**F**	**B**	**F**	**A**	**B**	**A**	**F**	**B**	**F**	**B**

[a] natural origin available, [b] synthetic origin available

Antimicrobial preservation efficacy of wet wipe and skin cream formulations

To demonstrate the applicability of the previous results with regard to commercial products, the findings were transferred to a realistic scenario, in which selected combinations of L(+)-lactic acid and booster were tested in an actual wet wipe formulation as well as in a skin cream formulation for personal care applications.

The formulation for the wet wipe presented in table 4 only varies with regard to the booster used. An unpreserved formulation without the combination of L(+)-lactic acid and booster was tested as a control sample, as well as a formulation based on L(+)-lactic acid alone as a preservation agent without any added booster. For all formulations, the pH was set to 4.0.

Table 4: Formulation for a wet wipe soaking solution for personal care applications at pH 4.0.

Name	INCI	Function	Supplier	Quantity
Water demin.	Aqua			Qs to 100%
Potassium L(+)-Lactate 60% personal care grade	Potassium Lactate	Moisturiser	**Jungbunzlauer**	3.00%
Plantacare® 818 UP	Coco-Glucoside	Surfactant	BASF	2.00%
L(+)-Lactic Acid 90% heat stable personal care grade	Lactic Acid	Antimicrobial substance	**Jungbunzlauer**	3.22%
Booster	Anisic Acid, Dehydroacetic Acid, Caprylic Acid	Antimicrobial substance	Various	0.01–1.00%

Regarding the preservation efficacy, the results of the simple surfactant solutions of L(+)-lactic acid and of L(+)-lactic acid plus respective boosters (see table 3) could be reproduced using a conventional personal care formulation (see table 5). Whereas the control sample without any antimicrobial agents as well as the solution containing only 2.9% L(+)-lactic acid (active concentration) failed the preservation test against fungi, both combinations of L(+)-lactic acid plus respective booster passed the test successfully with criterion A.

Table 5: Results of wet wipe soaking solution according to Ph. Eur. 5.1.3.

	Wet wipe formulation, pH 4.0			
Test germ	**Blank**	**2.9% LA**	**2.9% LA + 0.3% Anisic Acid**	**2.9% LA + 0.4% Caprylic Acid**
E. coli	A	A	A	A
P. aeruginosa	A	A	A	A
S. aureus	A	A	A	A
C. albicans	F	A	A	A
A. brasiliensis	F	F	A	A
Total test results	**F**	**F**	**A**	**A**

Accordingly, the preservation efficacy was also assessed for a conventional skin cream formulation (pH 5.5), whose composition is shown in table 6. The results for the preservation efficacy test are illustrated in table 7. The preservation test for the skin cream formulation without any preservative failed, whereas the combination of L(+)-lactic acid with caprylic acid as booster resulted in passing the test with criterion B.

Table 6: Formulation for a skin cream at pH 5.5.

Phase	Name	INCI	Function	Supplier	Quantity
A	Water demin.	Aqua	Solubiliser		Qs. to 100
	Glycerine	Glycerine	Moisturiser		3.00%
	Xanthan Gum FNCSP-PC	Xanthan Gum	Thickener	**Jungbunzlauer**	0.40%
B	Axol® C 62 Pellets	Glyceryl Stearate Citrate	Emulsifier	Evonik	4.00%
	Lanette® O	Cetearyl Alcohol	Co-Emulsifier	BASF	1.00%
	dermofeel® sensolv	Isoamyl Laurate	Emollient	Evonik	4.00%
	Tegosoft® AC MB	Isoamyl Cocoate	Emollient	Evonik	4.00%
C	L(+)-Lactic Acid 90% heat stable personal care grade	Lactic Acid	Antimicrobial substance	**Jungbunzlauer**	3.22%
	Booster	Caprylic Acid	Antimicrobial substance	Various	0.40%

Table 7: Results of skin cream formulation test according to Ph. Eur. 5.1.3.

	Skin cream formulation, pH 5.5	
Test germ	**Blank without LA**	**2.9% LA + 0.4% Caprylic Acid**
E. coli	F	B
P. aeruginosa	F	A
S. aureus	F	B
C. albicans	F	A
A. brasiliensis	F	B
Total test results	**F**	**B**

Summary

Global trends point towards the replacement of synthetic and potentially hazardous chemicals by safe and bio-based ingredients. In particular, preservatives such as parabens and isothiazolinones are facing increasing regulatory pressure regarding possible allergenic and sensitising effects. This article provides evidence that L(+)-lactic acid, on its own or in combination with other additives, offers an efficient and sustainable alternative preservation system for personal and home care formulations. It was successfully demonstrated that the results reported in this paper can be applied to conventional formulations including skin creams and soaking solutions for wet wipes. While L(+)-lactic acid *per se* is a suitable preservation agent for acidic home care formulations, its combination with an effective booster yields a highly efficient preservation system that perfectly fits into the field of personal care applications, where a skin friendly pH is desired. Therefore, the use of preservation agent combinations as described above is recommended as a starting point for formulation developments in the field of home and personal care.

References

[1] Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776.

[2] K. von Nessen, F. Weiher, M. Neubauer, Jungbunzlauer Facts 2020.

[3] European Pharmacopeia (7th ed.), 5.1.3. Efficacy of antimicrobial preservation.

[4] K. von Nessen, F. Weiher, M. Neubauer, T. Kerl, J. Preusche, SOFW Journal 2020, 146, 22-25.

About Jungbunzlauer

Jungbunzlauer is one of the world's leading producers of biodegradable ingredients of natural origin. We enable our customers to manufacture healthier, safer, tastier and more sustainable products. Thanks to continuous investment, state-of-the-art manufacturing processes and comprehensive quality management, we are able to provide outstanding product quality.

Our mission "From nature to ingredients®" commits us to protecting people and their environment.

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