Personal Care

Lonza

Consumer Care

Rômacil™ V (patent pending)

A Multifunctional Cosmetic Ingredient

INCI Name: Fragrance (Parfum)
SAP Code: 141140

Key Product Attributes

- Gentle fragrance to heighten a formulation's characteristics
- Delivers a secondary effect as a broad spectrum antimicrobial
- Has a wide range of global regulatory acceptance
- Water soluble; mixes into water-based formulas as well as water in oil emulsions
- Effective pH range of 4–7
- Non-GMO
- Compatible with key raw materials
- Patent pending

Recommended Use Level:

1.0–2.0 %

Description

Rômacil™ V multifunctional cosmetic ingredient is an innovative product that imparts a delicate fragrance to mildly enhance the attributes of a personal care product. In addition, it offers broad spectrum antimicrobial capabilities to add an additional level of protection in order to maintain the product's integrity. The material is water soluble, compatible in a diverse range of personal care products and can be used at low concentrations. Additionally, the Rômacil™ V multifunctional cosmetic ingredient has wide global approval.

Efficacy

Microbiological Challenge Studies

CTFA studies were run using different concentrations of the Rômacil™ V ingredient in various formulations to assess efficacy against various bacteria, yeast and fungi. All samples were inoculated at the beginning of the study, sampled at 24 hours, 7, 14, 21 and 28 days. Four weeks after challenge, samples were challenged again and the same sampling regime followed. Below is a summary of the results.

Makeup Remover (RD002067) – pH: 6.2

Phase	Ingredient	%
(A)	Water	43.00 %
	Propylene Glycol	2.00 %
	Glycerin	2.00 %
	PEG-8	2.00 %
	Decyl Glucoside	50.00 %
	Rômacil™ V	1.00 %
	Total	100.00 %

	Unpreserved Control				Test-Rômacil™ V (1.0 %)			
Test Organism	Initial Challenge			Rechallenge	Initial Challenge			Rechallenge
	24 hrs	1 week	28 days	28 days	24 hrs	1 week	28 days	28 days
S. aureus	<10	<10	<10	<10	<10	<10	<10	<10
P. aeruginosa + B. cepacia	10^6	10^6	10^6	10^6	<10	<10	<10	<10
K. pneumoniae + E. gergoviae	10^4	10^4	10^4	9×10^2	<10	<10	<10	10^5
C. albicans	8.4×10^2	<10	<10	<10	40	<10	<10	<10
Mixed Molds	10^4	2×10^3	10	<10	2×10^3	<10	<10	<10

Hair Conditioner (RD002068) – pH: 4.7

Phase	Ingredient	%
(A)	Water	67.35 %
	Cetyl Hydroxyethylcellulose	0.50 %
	Xanthan Gum	0.15 %
(B)	Cetrimonium Bromide & Cetearyl Alcohol	1.00 %
	Cetearyl Alcohol	3.00 %
	Steareth-21	2.50 %
	Lonzest™ SM0-20	0.50 %
	Brookswax D	2.00 %
	Lecithin	1.00 %
	Water	20.00 %
	Rômacil™ V	2.00 %
	Total	100.00 %

	Unpreserved Control				Test-Rômacil™ V (2.0 %)			
Test Organism	Initial Challenge			Rechallenge	Initial Challenge			Rechallenge
	24 hrs	1 week	28 days	28 days	24 hrs	1 week	28 days	28 days
S. aureus	10^6	10^6	10^6	10^6	<10	10	<10	<10
P. aeruginosa + B. cepacia	10^6	10^6	10^6	10^6	<10	<10	<10	<10
K. pneumoniae + E. gergoviae	10^6	10^6	10^6	10^6	<10	<10	<10	<10
C. albicans	10^5	10^5	10^5	10^5	30	<10	<10	<10
Mixed Molds	10^5	10^5	10^5	10^5	3.4×10^2	<10	<10	<10

Water in Oil Lotion (RD002069) – pH: N/A

Phase	Ingredient	%
(A)	Water	73.00 %
	Glycerin	3.00 %
	Sodium Chloride	1.00 %
(B)	Cyclopentasiloxane and PEG/PPG-20/15 Dimethicone	10.00 %
	Cyclomethicone	8.50 %
	Gel Base BSM-PT HV	2.50 %
	Rômacil™ V	1.00 %
	Total	100.00 %

	Unpreserved Control				Test-Rômacil™ V (2.0 %)			
Test Organism	Initial Challenge			Rechallenge	Initial Challenge			Rechallenge
	24 hrs	1 week	28 days	28 days	24 hrs	1 week	28 days	28 days
S. aureus	4×10^3	10^3	10	9×10^2	<10	<10	<10	<10
P. aeruginosa + B. cepacia	10^6	10^4	10^4	9×10^2	<10	<10	<10	<10
K. pneumoniae + E. gergoviae	10^4	2×10^2	9×10^2	1×10^3	<10	<10	<10	<10
C. albicans	8×10^3	3×10^3	10^4	10^5	6.7×10^2	<10	<10	<10
Mixed Molds	10^4	10^4	10^5	10^5	2.3×10^2	<10	<10	<10

Mouthwash (RD0020178-2) – pH: 4.4

Phase	Ingredient	%
(A)	Water	80.55 %
	Glycerin	10.00 %
	Polyglyceryl 10 Oleate (10-1-0)	0.25 %
	Sorbitol	7.50 %
	Peppermint Oil	0.20 %
	Sodium Lauryl Sulfate (30 %)	0.50 %
	Rômacil™ V	1.00 %
	Total	100.00 %

	Unpreserved Control				Test-Rômacil™ V (1.0 %)			
Test Organism	Initial Challenge			Rechallenge	Initial Challenge			Rechallenge
	24 hrs	1 week	28 days	28 days	24 hrs	1 week	28 days	28 days
S. aureus	60	<10	<10	<10	<10	<10	<10	<10
P. aeruginosa + B. cepacia	5×10^3	<10	<10	<10	<10	<10	<10	<10
K. pneumoniae + E. gergoviae	10^4	10	<10	<10	<10	<10	<10	<10
C. albicans	6.7×10^2	<10	<10	<10	30	<10	<10	<10
Mixed Molds	10^4	3×10^3	9×10^2	7×10^2	70	<10	<10	<10

Oil in Water – pH: 6.7

Phase	Ingredient	%
(A)	Water	60.20 %
	Glycerin	4.00 %
	Urea	1.00 %
(B)	Sorbitan Monostearate	2.00 %
	Capric/Caprylic Triglyceride	20.00 %
	PEG 100 Stearate and Glyceryl Stearate	1.50 %
	Glyceryl Monostearate	2.00 %
	Decaglyceryl Decaoleate	5.00 %
(C)	Octyl Methoxycinnamate	2.00 %
	Acylates/Acrylamide Copolymer and Mineral Oil and Polysorbate-85	0.30 %
	Rômacil™ V	2.00 %
	Total	100.00 %

	Unpreserved Control				Test-Rômacil™ V (2.0 %)			
Test Organism	Initial Challenge			Rechallenge	Initial Challenge			Rechallenge
	24 hrs	1 week	28 days	28 days	24 hrs	1 week	28 days	28 days
S. aureus	10^6	10^4	<10	10^6	1.2×10^3	<10	<10	<10
P. aeruginosa + B. cepacia	10^6	10^6	10^6	10^6	1×10^2	<10	<10	<10
K. pneumoniae + E. gergoviae	10^6	10^6	10^5	10^6	<10	<10	<10	<10
C. albicans	10^5	10^5	10^5	10^5	4×10^2	<10	<10	<10
Mixed Molds	10^5	10^5	10^5	10^5	2.7×10^2	<10	<10	<10

Wet Wipes Efficacy Test

An assay was performed to determine the efficacy of Rômacil™ V in wet wipes. The protocol followed was "Antimicrobial Preservative Effectiveness Challenge Test Method for Nonwoven Substrates" (USAD-34226 Version: 4.0) with the exception of a smaller group of microorganisms and no re-challenge was performed. The substrate used was an unpreserved Suominen SPC™ Nonwoven Wipe. Product code MI44015050.

Microorganisms Tested

Bacteria

- *Staphylococcus aureus* ATCC 6538
- *Pseudomonas aeruginosa* ATCC 9027
- *Escherichia coli* ATCC 8739

Fungi

- *Candida albicans* ATCC 10231
- *Aspergillus brasiliensis* ATCC 16404

Bacterial Pool Inoculum = 3.5×10^7 CFU/wipe

Fungal Pool Inoculum = 1.4×10^6 CFU/wipe

Wet Wipe Juice

Ingredient	%
Water	97.35 %
Decyl Glucoside	0.25 %
Polysorbate 20	0.30 %
Disodium EDTA	0.10 %
Rômacil™ V	2.00 %
Total	100.00 %

	Unpreserved Control					Test-Rômacil™ V (2.0 %)				
Test Organism	**Initial Challenge**					**Initial Challenge**				
	Day 0	**Day 7**	**Day 14**	**Day 21**	**Day 28**	**Day 0**	**Day 7**	**Day 14**	**Day 21**	**Day 28**
Bacterial Pool	$>3\times10^7$	$>3\times10^7$	$>3\times10^7$	$>3\times10^7$	6.9×10^6	8.3×10^6	<100	<100	<100	<100
Fungal Pool	6.3×10^5	1.9×10^6	$>3\times10^6$	$>3\times10^6$	$>3\times10^6$	4.8×10^5	<100	<100	<100	<100

Formulation Recommendations

In certain formulations, different external environments or additives may impact the color of a finished product. Lonza offers suggestions to help minimize this potential effect.

Add while the batch is below 40 °C

- Efficacy is seen between pH of 4-7; for formulations that may be impacted by color, keeping the pH below 6 throughout formulation can reduce discoloration.
- Addition of a chelator such as citric acid, or an antioxidant, is recommended prior to addition of Rômacil™ V ingredient in formulations that are affected by color.
- Certain emollients cause more discoloration than others, but this is formulation dependent. An emollient may have an impact in one formulation but not in another; testing is recommended.
- In formulations that develop discoloration due to an emollient, testing has shown that the following emollients limit color, in order starting with the best: Shea Butter, Coconut Oil, Sunflower Oil, Olive Oil.

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Chemical Compound Breakdown	CAS No.	EINECS No.
1, 5 Pentanediol	111-29-5	203-854-4
Polyglyceryl-10 Oleate	9007-48-1	279-230-0
Vanillin	121-33-5	204-465-2
Caprylic Acid	124-07-2	204-677-5

Applications

- Baby care
- Baby wipes
- Body butter
- Body wash
- Conditioner
- Cream
- Eye creams/gels
- Face lotion
- Face wipes
- Facial cream
- Foundation
- Hair gel
- Hand soap
- Lotion
- Make up remover
- Mascara
- Oil in water products
- Shampoo
- Suncare
- Toner
- Water in oil products

Typical Properties

Spec	Parameter
Appearance	Yellow to dark amber viscous liquid
pH (5 % solution in neutral distilled water @25 °C)	4.40–4.70
Spec. Gravity (as is @25 °C)	1.05–1.09
Odor	Pleasant vanilla odor
Gardner	6–14
Assay	IR: matches spec
Solubility	Water soluble

Europe Japan US ROW

- No regulatory restrictions on concentration levels of any components of Rômacil™ V ingredient
- China compliant (IECSC & INCI)

General

- All components REACH pre-registered.
- In the EU, Vanillin has been identified as one of a large range of potential allergens by SCCS
- Future legislation will require this to be listed as one of the ingredients on the product label

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