

## Technical data | TRlstat ECO

### 1. INCI composition

---

*Benzyl Alcohol*  
*Glyceryl Caprylate*  
*Glyceryl Undecylenate*

### 2. General description

---

*TRlstat ECO* is a broad spectrum preservative blend based on nature identical and nature-derived ingredients for the protection of natural and traditional cosmetics in a wide pH range. It is a synergistic combination of benzyl alcohol with glyceryl monoesters that boost the preservative action and add emolliency. *TRlstat ECO* is gentle to the skin and is active against bacteria, yeasts & molds. Colorless, with very mild odor, it is effective in the pH range of 4 to 8. *TRlstat ECO* is globally approved and suitable for a wide range of personal care products (rinse-off & leave-on). It is permitted for the preservation of natural & organic cosmetics according to the major certification standards (Ecocert, BDIH, Soil Association, ICEA, COSMOS Standard, Natrue, and NPA).

### 3. Specification data

---

|                               |                            |
|-------------------------------|----------------------------|
| <b>Appearance:</b>            | Clear pale yellow liquid   |
| <b>Odor:</b>                  | Slight characteristic      |
| <b>Benzyl alcohol:</b>        | 43.0-47.0%                 |
| <b>Glyceryl monoesters:</b>   | 38% min                    |
| <b>Density(@20C)</b>          | 1.032-1.035 g/ml           |
| <b>Refractive Index(@20C)</b> | 1.4820-1.5020              |
| <b>Heavy Metals:</b>          | 10 ppm max                 |
| <b>Shelf Life</b>             | 1 year in original packing |

#### 4. *Other properties*

---

|                                |               |
|--------------------------------|---------------|
| pH (0.5% in water dispersion): | Approx. 5     |
| Freezing point:                | Less than 0°C |

#### 5. *Properties*

---

**TRIstat ECO** is an innovative preserving system that combines the well-established and nature identical cosmetic preservative Benzyl alcohol with two high purity monoesters that are 100% naturally derived.

Glyceryl caprylate and Glyceryl undecylenate possess antibacterial and antifungal activity respectively, and enhance the activity of benzyl alcohol. As a result, TRIstat ECO is a synergistic preservative system with broad spectrum activity suitable for the control of microbial growth in cosmetics without the use of additional preservatives.

**Benzyl alcohol** is an aromatic alcohol with a mild and sweet odor; it is a natural constituent of some essential oils (jasmine, hyacinth, ylang-ylang), many edible fruits and green/black tea. It is largely used as a preservative in cosmetics, foods and pharmaceuticals, as a component of fragrances, and as a local anesthetic.

Benzyl alcohol is active primarily against bacteria and molds. The mechanism of action is the disruption of the cell membrane barrier by solubilization of lipids, the enhancement of the permeability of microbial cells to other antimicrobials and the inhibition of essential enzymes involved in the Krebs's cycle.

It is globally approved and mainly used in combination with other preservatives to create a broad spectrum preservative system.

**Glyceryl caprylate and Glyceryl undecylenate** are monoesters obtained from the reaction of glycerol with caprylic acid and undecylenic acid respectively and are both from 100 % vegetal origin.

Glyceryl esters are present in natural oils and in the metabolism of living systems. They are widely used in cosmetics, foods & pharmaceuticals and possess multiple beneficial properties as co-emulsifiers, emollients, wetting agents and solubilizers.

Additionally esters of medium chain fatty acids with C8 to C12 chain length like glyceryl caprylate, glyceryl caprate, glyceryl undecylenate & glyceryl laurate have antimicrobial activity.<sup>2</sup> These C8-C12 esters have the suitable length to enter, destabilize the microbial membrane and destroy microbial cells<sup>3</sup>

It is also known that the high purity monoesters, which have higher levels of monoglycerides, have greater biocidal activity<sup>4</sup>. Glyceryl monoesters are ideal examples of multi-functional ingredients which act as coemulsifiers, humectants, refatting agents and skin-feel enhancers. They also exert antimicrobial action and act as preservative boosters that allow preservatives to enter the microbial cell more effectively. Therefore glyceryl esters, when used as part of the preservative system can help reduce preservative requirements.

As a synergistic combination of an alcohol & glyceryl esters, TRIstat ECO is a new interesting option in cosmetic preservation. It is an efficient antimicrobial system that is not pH dependent and has a low irritation potential. TRIstat ECO is synergistic with other

ingredients of formulations like chelating agents, antioxidants, surfactants and organic acids.

This synergism further reduces the use level in the finished cosmetic.

The multiple benefits of *TRIstat ECO* allow formulators to create safe self-preserving cosmetics with reduced content of traditional preservatives according to the “hurdle technology”<sup>5</sup>. This is a modern holistic approach to preservation, largely used in foods, making use of several hurdles that create a hostile environment to microorganisms and inhibit microbial metabolism and reproduction.

## 6. Solubility

---

*TRIstat ECO* is very soluble in alcohol, glycerin, glycols and polar oils, very slightly soluble in water. The solubility of *TRIstat ECO* at 20°C in common cosmetic solvents is showed below (expressed as weight in grams of *TRIstat ECO* dissolved in 100 g of solution):

| <b>Solvent</b>       | <b>%w/w</b> |
|----------------------|-------------|
| Water                | <0.1%       |
| Ethanol              | >50         |
| Glycerin             | >50         |
| Propylene glycol     | >50         |
| Ethylhexyl palmitate | >50         |
| Octyldodecanol       | >50         |
| Mineral Oil          | 1.2         |

## 7. Stability

---

*TRIstat ECO* may tolerate process heating to 80°C for approx. 30 minutes, exposure to prolonged high thermal exposure is not recommended and the use of the lowest possible temperature is suggested.

It should be stored in the tightly closed original container at room temperature (25°C) and protected from direct sunlight and frost. The product is stable to temperature near 0°C.

## 8. Antimicrobial activity

---

The activity of *TRIstat ECO* against microbial contaminants was determined following the Minimum Inhibitory Concentration (MIC) and Minimum Biocidal Concentration (MBC) method<sup>6</sup>.

The test was conducted using the standard panel of microorganisms (bacteria and fungi) used in pharmacopeia tests. Microbial suspensions of microorganisms derived from ATCC were prepared in suitable nutrient broths. Serial dilutions of the preservative were carried out aseptically in micro titer plates. Each well was inoculated with a single culture to the

concentration of 10<sup>5</sup>-10<sup>6</sup> cells/mL. The plates were incubated at 35°C for 48 hours for bacteria and at 25°C for 5 days for fungi.

The minimum inhibitory concentration (MIC) provides the bacteriostatic/fungi static activity, which is the ability to inhibit the reproduction of microorganisms. The MIC value is the lowest concentration which inhibits the visible growth of test organisms after 48 hours for bacteria, 72 hours for yeasts and 5 days for molds.

The minimum biocidal concentration (MBC) gives the bactericidal/fungicidal activity, which defines the ability to kill microorganisms after a contact time of 48 hours with the antimicrobial. This is obtained by plating an aliquot of each dilution without visible growth into a suitable solid nutrient media.

The MBC value is the lowest concentration of preservative that kills more than 99.9% of the initial concentrations of microorganisms.

**Tab 6.1: Inhibitory (MIC) and biocidal (MBC) activity of Kem Nat in ppm**

| <b>Test organisms</b><br>( $\cong 10^6$ CFU/mL) | <b>Minimum inhibitory concentration</b> | <b>Minimum biocidal concentration</b> |
|---|---|---------------------------------------|
| <b>Gram-negative bacteria</b>                   |   |                                       |
| <i>Escherichia coli</i> ATCC 8739               | <b>3000</b>                             | <b>4000</b>                           |
| <i>Pseudomonas aeruginosa</i> ATCC 9027         | <b>3000</b>                             | <b>5000</b>                           |
| <b>Gram-positive bacteria</b>                   |   |                                       |
| <i>Staphylococcus aureus</i> ATCC 6538          | <b>2500</b>                             | <b>3500</b>                           |
| <b>Yeasts</b>                                   |   |                                       |
| <i>Candida albicans</i> ATCC 10231              | <b>1000</b>                             | <b>4000</b>                           |
| <b>Molds</b>                                    |   |                                       |
| <i>Aspergillus niger</i> ATCC 16404             | <b>2500</b>                             | <b>10000</b>                          |

TRIstat ECO has bacteriostatic and fungistatic effect at levels of 0.3%. Additionally it is bactericidal at 0.5%, fungicidal against the yeast *C. albicans* at 0.4% and fungicidal against the molds *A. Niger* at 1.0%.

TRIstat ECO is also effective in reducing and inhibiting the growth of *P. acnes* at concentration as low as 0.1%.

NOTE: The above MIC/MBC values estimate the antimicrobial activity of preservatives in culture media. The optimal use levels to be used in cosmetic products should be determined by challenge testing. On demand, our microbiological laboratory may provide the appropriate support.

## 9. Challenge Tests

---

The antimicrobial activity of TRlstat ECO in different cosmetic formulations was evaluated by challenge testing, using a modified European Pharmacopoeia method (5.1.3 Efficacy of antimicrobial preservation). The tests were performed using the following microorganisms:

- E. coli ATCC 8739
- P. aeruginosa ATCC 9027
- S. aureus ATCC 6538
- C. albicans ATCC 10231
- A. brasiliensis (niger) ATCC 16404.

Cosmetic samples with different levels of preservative were challenged with mixed inocula of bacteria and fungi separately, to reach microbial levels of not less than 106 cfu/g for bacteria and 105 cfu/g for fungi. These samples were tested for microbial count at 0, 2, 7, 14, 21, 28 days.

Microbial counts were performed on 1 g of test sample serially diluted and plated in suitable solid media; plates are incubated at 35°C for bacteria and at 25°C for fungi, then the number of colonies per gram (cfu/g) are counted.

The products tested are judged adequately preserved when bacteria are reduced by more than 99% (2 Log) after 2 days and more than 99.9% (3 Log) after 7 days. Yeasts and molds should be reduced by more than 99% (2 Log) after 14 days.

The composition of the formulations tested (natural o/w emulsion and mild shower bath) as well as the results obtained are showed in following tables and graphs.

### *Natural O/W emulsion*

| <u><i>INCI name</i></u>             | <u><i>Weight %</i></u> |             |             |             |
|-------------------------------------|------------------------|-------------|-------------|-------------|
| <i>Arachidyl glucoside,</i>         |                        |             |             |             |
| <i>Arachidyl alcohol</i>            |                        |             |             |             |
| <i>Behenyl alcohol</i>              | 5.0                    | <i>idem</i> | <i>idem</i> | <i>idem</i> |
| <i>Caprylic/capric triglyceride</i> | 4.0                    | <i>idem</i> | <i>idem</i> | <i>idem</i> |
| <i>Cetyl alcohol</i>                | 4.0                    | <i>idem</i> | <i>idem</i> | <i>idem</i> |
| <i>Glycerin</i>                     | 4.0                    | <i>idem</i> | <i>idem</i> | <i>idem</i> |
| <i>Octyl palmitate</i>              | 3.0                    | <i>idem</i> | <i>idem</i> | <i>idem</i> |
| <i>Allantoin</i>                    | 0.3                    | <i>idem</i> | <i>idem</i> | <i>idem</i> |
| <i>Sodium phytate</i>               | 0.1                    | <i>idem</i> | <i>idem</i> | 0.2         |
| <i>Sodium hydroxide 10%</i>         | <i>q. s.</i>           | <i>idem</i> | <i>idem</i> | <i>idem</i> |
| <i>Water</i>                        | <i>to 100</i>          | <i>idem</i> | <i>idem</i> | <i>idem</i> |
| <b>TRlstat ECO</b>                  | 0                      | 1.4         | 1.5         | 1.4         |

Final pH 6.0

**Results:**

The unpreserved emulsion resulted susceptible to bacterial and fungal contamination and supported very high levels of viable organisms for all the test period.

The formulation with 1.4% TRlstat ECO decreased the bacterial inocula by more than 2 Log (>99%) in 2 days and fully inactivated them in 7 days.

C. albicans was fully inactivated within 7days.

A. niger was reduced by 1 Log (90%) in 14 days, by more than 2 Log in 21 days and more than 3 Log (>99.9%) at the end of the test.

The formulation with 1.4% TRlstat ECO was judged, according to the Ph. Eur criteria of acceptance, poorly preserved against A. niger and adequately preserved against bacteria and C. albicans.

The formulation with 1.5% TRlstat ECO totally inactivated bacteria and C. albicans in 2 days.

A. niger was reduced by more than 2 Log (>99%) in 7 days, more than 3 Log in 14 days and fully inactivated in 21 days.

The formulation with 1.5% TRlstat ECO was judged adequately preserved against all test organisms.

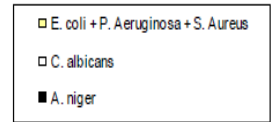
The formulation with 1.4% TRlstat ECO + 0.2% Sodium phytate showed greater than 4 Log (>99.99%) reduction of bacteria and complete inactivation of inocula in 7 days.

C. albicans was fully inactivated within 2 days.

A. niger was reduced by more than 2 Log in 7 days, more than 3 log in 14 days and completely inactivated in 21 days.

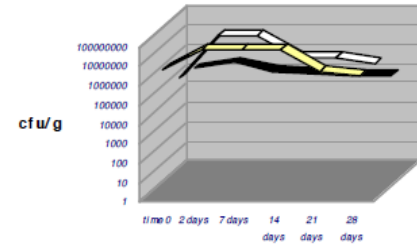
The formulation with 1.4% TRlstat ECO + 0.2% Sodium phytate was judged adequately preserved against all tested organisms.

To summarize, a use level of 1.5% TRlstat ECO provided satisfactory and broad spectrum coverage to a typical o/w emulsion, according to the Ph. Eur. requirements. Interestingly the combination of 1.4% TRlstat ECO with the chelating agent Sodium phytate at 0.2% significantly increases the antimicrobial activity and proves the synergistic effect with chelating agents, useful to reduce the final use levels of TRlstat ECO in cosmetics.



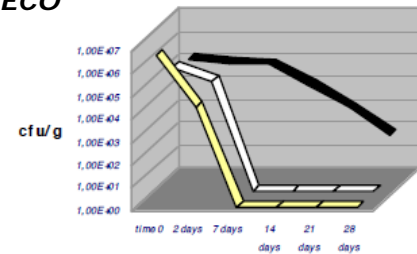
**Preservation efficacy on natural o/w emulsion unpreserved**

| Strains              | time 0           | 2 days           | 7 days           | 14 days          | 21 days          | 28 days          | Results |
|----------------------|------------------|------------------|------------------|------------------|------------------|------------------|---------|
| <i>E. coli</i>       |                  |                  |                  |                  |                  |                  |         |
| <i>P. aeruginosa</i> | $4.6 \cdot 10^6$ | $>10^7$          | $>10^7$          | $>10^7$          | $3.6 \cdot 10^6$ | $2.2 \cdot 10^6$ | Failed  |
| <i>S. aureus</i>     |                  |                  |                  |                  |                  |                  |         |
| <i>C. albicans</i>   | $2.8 \cdot 10^5$ | $>10^7$          | $>10^7$          | $6.5 \cdot 10^6$ | $3.4 \cdot 10^6$ | $1.7 \cdot 10^6$ | Failed  |
| <i>A. niger</i>      | $1.7 \cdot 10^5$ | $3.5 \cdot 10^5$ | $1.2 \cdot 10^5$ | $8.8 \cdot 10^4$ | $7.8 \cdot 10^4$ | $7.5 \cdot 10^4$ | Failed  |



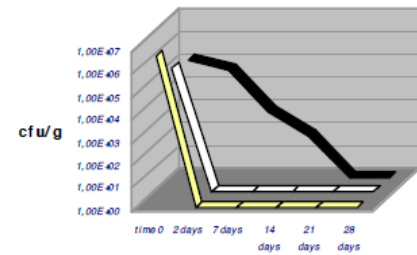
**Preservation efficacy on natural o/w emulsion with 1.4% TRIstat ECO**

| Strains              | time 0           | 2 days           | 7 days           | 14 days          | 21 days          | 28 days | Results |
|----------------------|------------------|------------------|------------------|------------------|------------------|---------|---------|
| <i>E. coli</i>       |                  |                  |                  |                  |                  |         |         |
| <i>P. aeruginosa</i> | $4.6 \cdot 10^6$ | $2.3 \cdot 10^4$ | $<10$            | $<10$            | $<10$            | $<10$   | Passed  |
| <i>S. aureus</i>     |                  |                  |                  |                  |                  |         |         |
| <i>C. albicans</i>   | $2.8 \cdot 10^5$ | $6.7 \cdot 10^4$ | $<10$            | $<10$            | $<10$            | $<10$   | Passed  |
| <i>A. niger</i>      | $1.7 \cdot 10^5$ | $1.1 \cdot 10^5$ | $9.4 \cdot 10^4$ | $1.2 \cdot 10^4$ | $1.1 \cdot 10^3$ | 70      | Failed  |



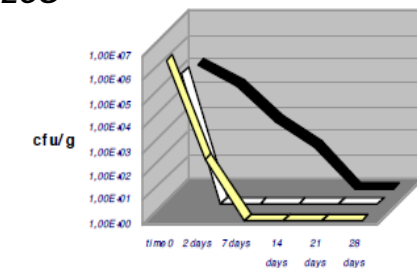
**Preservation efficacy on natural o/w emulsion with 1.5% TRIstat ECO**

| Strains              | time 0           | 2 days           | 7 days           | 14 days | 21 days | 28 days | Results |
|----------------------|------------------|------------------|------------------|---------|---------|---------|---------|
| <i>E. coli</i>       |                  |                  |                  |         |         |         |         |
| <i>P. aeruginosa</i> | $4.6 \cdot 10^6$ | $<10$            | $<10$            | $<10$   | $<10$   | $<10$   | Passed  |
| <i>S. aureus</i>     |                  |                  |                  |         |         |         |         |
| <i>C. albicans</i>   | $2.8 \cdot 10^5$ | $<10$            | $<10$            | $<10$   | $<10$   | $<10$   | Passed  |
| <i>A. niger</i>      | $1.7 \cdot 10^5$ | $5.4 \cdot 10^4$ | $7.9 \cdot 10^2$ | 70      | $<10$   | $<10$   | Passed  |



**Preservation efficacy on natural o/w emulsion with 1.4% TRIstat ECO + 0.2% Sodium Phytate**

| Strains              | time 0           | 2 days           | 7 days           | 14 days | 21 days | 28 days | Results |
|----------------------|------------------|------------------|------------------|---------|---------|---------|---------|
| <i>E. coli</i>       |                  |                  |                  |         |         |         |         |
| <i>P. aeruginosa</i> | $4.6 \cdot 10^6$ | $3.1 \cdot 10^2$ | $<10$            | $<10$   | $<10$   | $<10$   | Passed  |
| <i>S. aureus</i>     |                  |                  |                  |         |         |         |         |
| <i>C. albicans</i>   | $2.8 \cdot 10^5$ | $<10$            | $<10$            | $<10$   | $<10$   | $<10$   | Passed  |
| <i>A. niger</i>      | $1.7 \cdot 10^5$ | $2.1 \cdot 10^4$ | $6.6 \cdot 10^2$ | 60      | $<10$   | $<10$   | Passed  |



NOTE: Value <10 is the limit of detection of plate count method and indicates the absence of microbial growth.

### Mild shower Bath

| <u>INCI name</u>               | <u>Weight %</u> |      |      |      |
|--------------------------------|-----------------|------|------|------|
| Capryl/caprylyl glucoside 64%  | 20.0            | idem | idem | idem |
| Sodium lauroyl sarcosinate 30% | 15.0            | idem | idem | idem |
| Cocamidopropyl betaine 30%     | 8.0             | idem | idem | idem |
| Glycerin                       | 3.0             | idem | idem | idem |
| Sodium Chloride                | 0.9             | idem | idem | idem |
| Allantoin                      | 0.2             | idem | idem | idem |
| Phytic acid                    | 0.1             | idem | idem | idem |
| Citric acid                    | q. s.           | idem | idem | idem |
| Water                          | to 100          | idem | idem | idem |
| <b>TRIstat ECO</b>             | 0               | 1.2  | 1.4  | 1.6  |

Final pH 5.0

idem : From Latin (“the same”).

#### Results:

The unpreserved mild shower bath was susceptible to bacterial as well as fungal contamination and supported microbial growth for all the test period.

The formulation with 1.2% TRIstat ECO inactivated bacteria and *C. albicans* within 2 days with no further increase.

*A. niger* was reduced by >1 Log (>90%) in 2 days, >2 Log (>99%) in 7 days and was completely inactivated in 21 days.

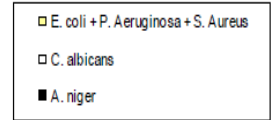
The formulation with 1.2% TRIstat ECO can be considered as adequately preserved against all test organisms, according to Ph. Eur. criteria of acceptance.

The formulation with 1.4% TRIstat ECO showed further reduction of *A. niger* by more than 2 Log in 2 days.

The formulation with 1.6% TRIstat ECO totally inactivated *A. niger* in 14 days.

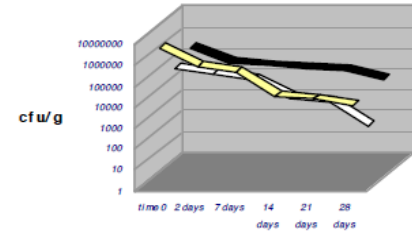
On the basis of the above results, the use level of 1.2% TRIstat ECO can provide satisfactory and broad spectrum coverage to a typical surf and 1.6% showed higher inactivation rate of *A. Niger*. actant-based cosmetic according to the Ph. Eur requirements. Concentrations of 1.4





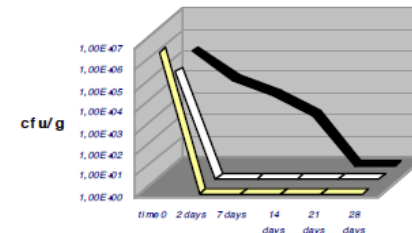
**Preservation efficacy on mild shower bath unpreserved**

| Strains              | time 0           | 2 days           | 7 days           | 14 days          | 21 days          | 28 days          | Results |
|----------------------|------------------|------------------|------------------|------------------|------------------|------------------|---------|
| <i>E. coli</i>       |                  |                  |                  |                  |                  |                  |         |
| <i>P. aeruginosa</i> | $4.6 \cdot 10^6$ | $5.5 \cdot 10^5$ | $3.4 \cdot 10^5$ | $2.1 \cdot 10^4$ | $1.6 \cdot 10^4$ | $7.9 \cdot 10^3$ | Failed  |
| <i>S. aureus</i>     |                  |                  |                  |                  |                  |                  |         |
| <i>C. albicans</i>   | $1.2 \cdot 10^5$ | $6.7 \cdot 10^4$ | $3.2 \cdot 10^4$ | $4.5 \cdot 10^3$ | $3.0 \cdot 10^3$ | $2.1 \cdot 10^2$ | Failed  |
| <i>A. niger</i>      | $2.6 \cdot 10^5$ | $5.4 \cdot 10^4$ | $3.7 \cdot 10^4$ | $2.8 \cdot 10^4$ | $2.1 \cdot 10^4$ | $8.5 \cdot 10^3$ | Failed  |



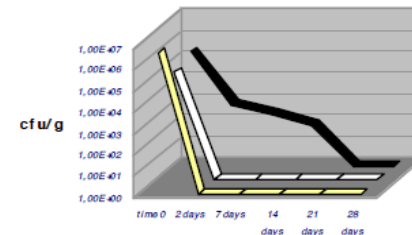
**Preservation efficacy on mild shower bath with 1.2% TRIstat ECO**

| Strains              | time 0           | 2 days           | 7 days           | 14 days          | 21 days | 28 days | Results |
|----------------------|------------------|------------------|------------------|------------------|---------|---------|---------|
| <i>E. coli</i>       |                  |                  |                  |                  |         |         |         |
| <i>P. aeruginosa</i> | $4.6 \cdot 10^6$ | <10              | <10              | <10              | <10     | <10     | Passed  |
| <i>S. aureus</i>     |                  |                  |                  |                  |         |         |         |
| <i>C. albicans</i>   | $1.2 \cdot 10^5$ | <10              | <10              | <10              | <10     | <10     | Passed  |
| <i>A. niger</i>      | $2.6 \cdot 10^5$ | $1.1 \cdot 10^4$ | $2.4 \cdot 10^3$ | $2.3 \cdot 10^2$ | <10     | <10     | Passed  |



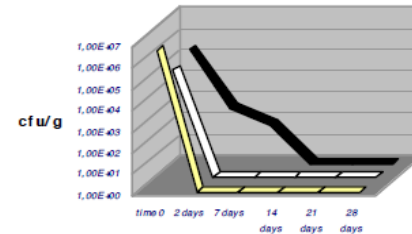
**Preservation efficacy on mild shower bath with 1.4% TRIstat ECO**

| Strains              | time 0           | 2 days           | 7 days           | 14 days | 21 days | 28 days | Results |
|----------------------|------------------|------------------|------------------|---------|---------|---------|---------|
| <i>E. coli</i>       |                  |                  |                  |         |         |         |         |
| <i>P. aeruginosa</i> | $4.6 \cdot 10^6$ | <10              | <10              | <10     | <10     | <10     | Passed  |
| <i>S. aureus</i>     |                  |                  |                  |         |         |         |         |
| <i>C. albicans</i>   | $1.2 \cdot 10^5$ | <10              | <10              | <10     | <10     | <10     | Passed  |
| <i>A. niger</i>      | $2.6 \cdot 10^5$ | $8.7 \cdot 10^2$ | $2.9 \cdot 10^2$ | 90      | <10     | <10     | Passed  |



**Preservation efficacy on mild shower bath with 1.6% TRIstat ECO**

| Strains              | time 0           | 2 days           | 7 days | 14 days | 21 days | 28 days | Results |
|----------------------|------------------|------------------|--------|---------|---------|---------|---------|
| <i>E. coli</i>       |                  |                  |        |         |         |         |         |
| <i>P. aeruginosa</i> | $4.6 \cdot 10^6$ | $2.7 \cdot 10^2$ | <10    | <10     | <10     | <10     | Passed  |
| <i>S. aureus</i>     |                  |                  |        |         |         |         |         |
| <i>C. albicans</i>   | $1.2 \cdot 10^5$ | <10              | <10    | <10     | <10     | <10     | Passed  |
| <i>A. niger</i>      | $2.6 \cdot 10^5$ | $4.7 \cdot 10^2$ | 70     | <10     | <10     | <10     | Passed  |



## 10. Applications

---

TRIstat ECO is a preservative system with broad spectrum activity for the protection of natural & organic cosmetics as well as standard and in particular high quality skin care cosmetics. The components of TRIstat ECO are natural-compliant cosmetic ingredients permitted in any cosmetic applications that meets the requirements of the major standards for the certification of natural & organic cosmetics like Ecocert (France), Soil Association (UK), BDIH (Germany), ICEA (Italy), COSMOS (EU), NPA (US) and NaTrue.

TRIstat ECO is effective in the pH range from 4.0 to 8.0, a considerably broad pH range that overcomes the lack of activity in neutral and slightly alkaline formulations of other preservatives like organic acids.

TRIstat ECO is a clear colorless liquid, with little pleasant odor, that does not change the organoleptic properties of cosmetics. It is compatible with most cosmetic ingredients and is fully effective in anionic, non-ionic and cationic systems.

The addition to emulsions can cause a reduction of viscosity, thus the stability should be checked and adjusted with thickening agents or waxes if needed.

It is synergistic with organic acids (citric acid, lactic acid), chelating agents (phytic acid trisodium ethylenediamine disuccinate, tetrasodium glutamate diacetate), antioxidants (tocopherol), essential oils and fragrances, therefore represents an ideal multifunctional system to develop safe self-preserving cosmetics with reduced preservative content, according to the principles of Hurdle technology. This is a system approach that makes an intelligent use of preservation factors (hurdles) including low pH, low water activity, multifunctional agents and protective packaging to achieve mid preservation<sup>5</sup>.

TRIstat ECO is effective in reducing and inhibiting the growth of *P. acnes*, consequently can be a useful addition in anti-acne products, and in general in tonics, shampoos, creams & lotions cosmetics for the treatment of greasy & impure skin.

TRIstat ECO can be used in wide range of cosmetics for rinse-off and leave-on. Due to its miscibility in alcohols and oils it can be easily incorporated in surfactant-based products, emulsions and oils.

It is practically not soluble in water, but it is dispersible in aqueous systems where it can be dissolved with the addition of solubilizing agents.

Even if heating to 80°C is tolerated, the prolonged exposure to high heating process is not suggested and the use of the lowest possible manufacturing temperature is recommended.

TRIstat ECO can be incorporated in aqueous & hydroalcoholic formulations and clear gels with the addition of solubilizers upon stirring at room temperature or with gentle heating to accelerate the dissolution.

In surfactant-based systems can be easily incorporated at room temperature into the surfactant blends before the addition of the other components.

In emulsions can be added in the oil phase, in the water phase or after the emulsification, preferably during the cooling stage at temperature below 50°C.

It is compatible and freely soluble in oil-based formulations.

The typical recommended use levels are within 1.0-1.6%, which can be increased to 2.0% in more complex and contaminable formulations.

| <b>Vehicle form</b>                  | <b>Applications</b>  | <b>% use levels</b> |
|--------------------------------------|--|---------------------|
| <i>Aqueous formulations</i>          | hair lotions & gels<br>skin serums<br>tonics<br>shaving gels<br>aftersun gels<br>body & foot gels<br>baby lotions  | 1.2-1.8             |
| <i>Surfactant-based formulations</i> | shower gels<br>bubble baths<br>shampoos<br>hair conditioners<br>shave foams<br>hand cleaners<br>intimates  | 1.0-1.6             |
| <i>Emulsions</i>                     | body lotions & creams<br>face lotions & creams<br>suncare lotions & creams<br>shaving lotions & creams<br>antiacne lotions & creams<br>hand & foot creams<br>foundations | 1.2-2.0             |
| <i>Oil-based formulations</i>        | body oils<br>massage oils  | 0.8-1.2             |
| <i>Powders</i>                       | bath powders<br>make-up powders  | 0.8-1.4             |
| <i>Raw materials</i>                 | surfactants blends<br>vegetal extracts   | 0.8-1.8             |

NOTE: The above use levels are only general indications. The exact use concentration is related to many factors including raw materials quality, manufacturing hygiene, formula composition and final packaging. The optimal amount of preservative should be determined by challenge testing in the specific products.

## **11. Toxicological Information**

---

The components of TRIstat ECO are well established cosmetic ingredients, recognized as safe for any personal care application and permitted at use levels of up to 2.2% according to the EU cosmetic regulation.

The safety of all the ingredients of Tristat ECO for cosmetic use was reviewed by the Expert Panel of the US Cosmetic Ingredient Review (CIR).

Benzyl alcohol<sup>7</sup> is widely used in cosmetics as a fragrance, solvent and preservative. In the EU, its use as a preservative is restricted to the maximum concentration of 1%, while it is not restricted in Japan. It is classified as a fragrance allergen. Benzyl alcohol is approved as food & pharma additive.

Glyceryl caprylate<sup>8</sup> and glyceryl undecylenate<sup>5</sup> are well-established cosmetic raw materials and are generally considered to present no special hazards.

Based on these assessments, TRlstat ECO is considered a safe cosmetic additive at the recommended use concentrations.

## **12. Regulatory Status**

---

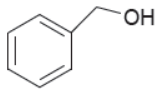
TRlstat ECO is approved as cosmetic preservatives in the EU, USA, Brazil & ASEAN countries with a maximum concentration of 2.2% in all type of cosmetics.

## **13. Storage**

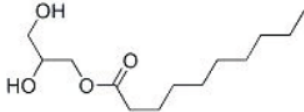
---

TRlstat ECO should be stored in the well closed original container at temperature below 25°C, protected from direct sunlight and frost. Containers once opened should be firmly re-closed. At these conditions its minimum shelf-life is one year from the manufacturing date.

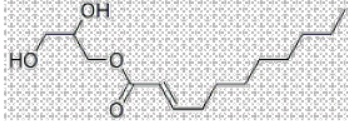
## 14. Description of Single Ingredients

|   |   |
|---|---|
|  | <b>INCI name:</b> <i>Benzyl Alcohol</i> |
| <b>Empirical formula:</b> C <sub>7</sub> H <sub>8</sub> O                         | <b>CAS number:</b> 100-51-6             |
| <b>Molecular weight:</b> 108.1  | <b>EINECS name:</b> Benzyl alcohol      |
|   | <b>EINECS number:</b> 202-859-9         |

|   |  |
|---|--|
|  | <b>INCI name:</b> <i>Glyceryl caprylate</i>                          |
| <b>Empirical formula:</b> C <sub>11</sub> H <sub>22</sub> O <sub>4</sub>          | <b>CAS number:</b> 26402-26-6  |
| <b>Molecular weight:</b> 218.29   | <b>EINECS name:</b> Octanoic acid, monoester with 1,2,3-propanetriol |
|   | <b>EINECS number:</b> 247-668-1                                      |

|   |   |
|---|---|
|  | <b>INCI name:</b> <i>Glyceryl undecylenate</i>                          |
| <b>Empirical formula:</b> C <sub>14</sub> H <sub>26</sub> O <sub>4</sub>          | <b>CAS number:</b> 65684-27-7   |
| <b>Molecular weight:</b> 258.35   | <b>EINECS name:</b> Undecylenic acid, monoester with 1,2,3-propanetriol |
|   | <b>EINECS number:</b> 236-935-8   |

## 15. References

- 1 D. K. Brannan (1997) *Cosmetic microbiology. A practical handbook.* CRC Press. pp. 167-168.
- 2 D. Smith, W. Pedersen (2000) The self-preserving challenge. *Cosmetic & toiletries*, 115 (5), pp. 67-74
- 3 G. Bergsson (1998) In vitro inactivation of *Chlamidia trachomatis* by fatty acids and monoglycerides. *Antimicrobial agents and chemotherapy*, 42 (9), pp. 2290-2294.
- 4 J. Kabara (1997) Fatty acid and esters as multifunctional components. In "Preservative-free ad self preserving cosmetics and drugs. Principles and practice". *Cosmetic science and technology series.* Vol. 16, pp. 123-131, Marcel Dekker
- 5 D.S. Orth (2010) Using Hurdle technology to reduce preservatives requirements. In "Insights into cosmetic microbiology" pp. 89-96. Allured Books.
- 6 E. W. Koneman (1992). *Diagnostic Microbiology* 4 ed., J. B. Lippincott Company, Philadelphia, p. 559.
- 7 *Cosmetic Ingredient Review* (2001) Final report on the safety assessment of benzyl alcohol, benzoic acid and sodium benzoate. *International Journal of toxicology*; 20 (3), pp. 23-50.
- 8 *Cosmetic Ingredient Review* (2004) Final report of the amended safety assessment of Glyceryl Laurate, Glyceryl Laurate SE, Glyceryl Laurate/Oleate, Glyceryl Adipate, Glyceryl Alginate, Glyceryl Arachidate, Glyceryl Arachidonate, Glyceryl Behenate, Glyceryl Caprate, Glyceryl Caprylate, Glyceryl Caprylate/Caprata, Glyceryl Citrate/Lactate/Linoleate/Oleate, Glyceryl Cocoate, Glyceryl Collagenate, Glyceryl Erucate, Glyceryl Hydrogenated Rosinate, Glyceryl Hydrogenated Soyate, Glyceryl Hydroxystearate, Glyceryl Isopalmitate, Glyceryl Isostearate, Glyceryl Isostearate/Myristate, Glyceryl Isostearates, Glyceryl Lanolate, Glyceryl Linoleate, Glyceryl Linolenate, Glyceryl Montanate, Glyceryl Myristate, Glyceryl Isotridecanoate/Stearate/Adipate, Glyceryl Oleate SE, Glyceryl Oleate/Elaidate, Glyceryl Palmitate, Glyceryl Palmitate/Stearate, Glyceryl Palmitoleate, Glyceryl Pentadecanoate, Glyceryl Polyacrylate, Glyceryl Rosinate, Glyceryl Sesquioleate, Glyceryl/Sorbitol Oleate/Hydroxystearate, Glyceryl Stearate/Acetate, Glyceryl Stearate/Maleate, Glyceryl Tallowate, Glyceryl Thiopropionate, and Glyceryl Undecylenate. *International Journal of Toxicology*; 23, pp. 55-94.