

Commercial Name	Vitamin C Tetra E
INCI name	Ascorbyl tetraisopalmitate

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RECOMMENDATIONS

All recommendations for the use of the mentioned raw materials are given to the best of our knowledge at the date they are established. Our clients should themselves verify that the content and the properties of our raw materials are compatible with the required end result and end-product labelling requirements.

1. RAW MATERIAL DESCRIPTION

- Trade name: Vitamin C TetraE
- Product code: VCTE001
- Manufacturer: EPHYLA
- INCI Europe: Ascorbyl Tetraisopalmitate

2. GEOGRAPHIC ORIGIN

The above mentioned raw materials are sourced from France

3. MANUFACTURING PROCESS

Available on demand

4. DEBACTERIZING TREATMENT

We hereby certify that the above mentioned raw materials are NOT decontaminated by gamma-rays.

5. COMPOSITION

Ing.	%	INCI NAME (EU)	INCI name China (IECIC 2015)	O (**)	CAS (***)	N° EINECS (***)
1	>96 (*)	Ascorbyl Tetraisopalmitate	Ascorbyl Tetraisopalmitate	S	183476-82-6	NA

(*) Purity is normally higher than 98% according to HPLC measures. The missing 2% are traces of unreacted ester of isopalmitic acid.

(**) Origin:

- (P) plant; also included biotechnological origin from vegetal substrates
- (AD) derived from animals
- (AH) harvested from animals
- (MO) micro-organism / fungal
- (MI) mineral
- (S) synthesis,

(***) CAS# & N° EINECS: the usual reference for CAS# & N° EINECS is COSING

<http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.results>

NOTE: As it is written in the Nomenclature conventions of INCI, the conventions used to determine INCI names for cosmetic ingredients states that:

"11. Water, ethyl alcohol, and other diluents or solvents contained in commercially available raw materials, except extracts, as not normally identified as part of the INCI name. See labeling reminders, for additional information on the labeling of solvents and/or diluents that may be present in raw materials".

6. REACH EUROPE

In accordance with Article 24 of the Reach Regulation, our product is notified under Directive 67/548 / EEC, it is considered already registered under the Reach Regulation, to the relevant tonnage band. Our laboratory is currently requesting its own number.

7. LEGISLATION

Any legislation which restricts or prohibits the use of this raw materials in the following territories:

Territories	Yes/No	Applicable Legislation & Usage Levels
EU	NO	
Turkey		
Russia		
SASO (Saudi Arabian Standards Organization)		
South Africa		
USA	NO	
Canada	NO	
South America		
China	NO	
Japan	NO	3% quasi drug status
ASEAN (Indonesia, Malaysia, Philippines, Singapore, Vietnam, Burma, Cambodia, Thailand, Laos, Brunei)		
Korea	NO	2% whitening status
Australia (NICNAS – Cosmetics)		<p>Assessment available on demand</p> <p>the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:</p> <p>Under Section 64(1) of the Act; if</p> <ul style="list-style-type: none"> – the importation volume exceeds one tonne per annum notified chemical; – the concentration of the notified chemical exceeds or is intended to exceed 10% in cosmetic products

Australia (TGA – Therapeutics)		
New Zealand		
<i>Other</i>		

8. COSMETIC REGULATION N°1223/2009

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials do not contain any forbidden or regulated substances by the annexes II, III, IV, V and VI of the European regulation n°1223/2009 and their adaptations.

9. SAFETY

Based on our actual knowledge, we certify that no incident following of the above mentioned raw materials that can be interpreted as being a sign of toxicity has been brought to our attention. In light of our experience acquired by the sale of this ingredient, we declare that it is not harmful in normal concentrations and normal conditions of use.

10. NOAEL

We certify that the mentioned raw materials hereafter have not been experimented for measuring a NOAEL (no observed adverse effect level).

11. BOVINE SPONGIFORM ENCEPHALOPATHY (BSE/TSE)

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials do not contain any substance from bovine, ovine and caprine origin (Annexe II, n°1223/2009).

12. GENETICALLY MODIFIED ORGANISM (GMO)

EC Directives 1829/2003 and 1830/2003

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials do not contain any ingredients from genetically modified organism (GMO).

13. RESIDUAL SOLVENT

ICH guideline Q3C (R5)

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials comply to limits of residual solvent listed in ICH Guideline.

Class 1: Comply

Class 2: Comply

Class 3: Comply

14. GLYCOL ETHERS

Regulation EC 1223/2009, Annexe II

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials do not include the following 10 glycol ethers:

- DEGBE Annex II / No 187, Regulation 1223/2009
- EGBE Annex II / No 188, Regulation 1223/2009
- EGME Annex II / No 665, Regulation 1223/2009
- EGMEA Annex II / No 665, Regulation 1223/2009
- EGEE Annex II / No 666, Regulation 1223/2009
- EGEEA Annex II / No 666, Regulation 1223/2009
- DEDGME Annex II / No 676, Regulation 1223/2009
- DEGME Annex II / No 1000, Regulation 1223/2009
- TEGDME Annex II / No 1147, Regulation 1223/2009
- DEGEE

15. PROPOSITION 65

Californian Safe drinking water and toxic enforcement act of 1986

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials do not contain any substance of the list of Chemicals known to the state to cause cancer or reproductive to toxicity.

16. CMR SUBSTANCES

European regulation 1272/2008, Annexe VI, part 3

Based on our actual knowledge of our production process and ingredients used we hereby certify that

the above mentioned raw materials do not contain any substance classified as CMR category 1A, 1B, 2 (carcinogenic, mutagen or toxic for reproduction) according to the 1272/2008 (EC) regulation and adaptations.

17. SVHC (SUBSTANCES OF VERY HIGH CONCERN)

Article 57 of Regulation (EC) n° 1907/2006

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials do not contain any substances of very high concern listed in the candidate list of substances as describe by the European Chemicals Agency. The candidate list of such substances is available at the following address:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

18. VOCS SUBSTANCES

Based on our actual knowledge of our production process, we hereby certify that the above mentioned raw materials is free of VOCS substances

19. HEAVY METALS

Heavy metals content as detected by ICP-MS:

ANTIMONY	< 3 mg/kg
ARSENIC	< 3 mg/kg
CADMIUM	< 3 mg/kg
LEAD	< 3 mg/kg
MERCURY	< 3 mg/kg
NICKEL	< 3 mg/kg

20. FOOD ALLERGENS

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials do not contain the allergens listed below as defined by current European food regulation:

- Crustaceans and products thereof
- Eggs and products thereof
- Peanuts and products thereof
- Soybean and products thereof

- Milk and products thereof including lactose
- Celery and products thereof
- Mustards and products thereof
- Sesame and products thereof
- Lupine and products thereof
- Mollusks and products thereof
- Fish and products thereof

21. GLUTEN

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials are not expected to contain gluten.

22. VEGETARIAN

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials is suitable for vegetarians.

23. VEGAN

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials is suitable for vegans.

24. COSMETIC ALLERGENS

Regulation EC 1223/2009, Annex III modified by Regulation EC 2023/1545

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above-mentioned raw materials do not contain any of the 80 allergens described by the European regulation 1223/2009 modified by European regulation 2023/1545

25. QUESTIONABLE CHEMICALS

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials are free of the following chemicals:

- Lanolin (& derivatives)
- Rosin (& derivatives)

- Camphor (& derivatives)
- Mineral oil

26. IMPURITIES

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials do not contain any of the following impurities:

- Acetone
- Acrylamide
- Antibiotics
- Asbestos
- Chloracetic acid
- 1,4 – Dioxane
- Diglycol
- Ethylacetate
- Ethylene oxide
- Formaldehyde
- Hydroquinone
- Hydroquinone dimethyl ether
- Methylbenzene
- Monomers, including acrylamide monomer, etc.
- Nitrosamines
- Phenol
- Resorcinol
- Secondary alkyl and alkanolamines and their salts
- Triethanolamine
- HICC
- Atranol
- Chloroatranol
- Furfural
- Phtalates

27. PRESERVATIVES

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials are free of preservatives

28. PESTICIDES

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the pesticides residue levels of the above mentioned raw materials comply to European regulation 396/2005.

29. SULPHUR DIOXIDE AND SULFITES

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials do not contain Sulphur dioxide and sulfite.

30. BISPHENOL A / PHTHALATES

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials are not expected to contain Bisphenol A or Phthalates.

31. PALM OIL AND DERIVATIVES

Based on our actual knowledge of our production process and ingredients used, the above mentioned raw materials does not contain palm oil derivatives (palmitic acid). The name "palmitic" derived from the use of 16 carbons (C16) but it is not linear chain like palmitic acid, it is branched. This acid is obtained by biotechnology (derived natural).

32. LATEX

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials do not contain latex.

33. NANOPARTICULES

European cosmetic regulation 1223/2009, article 2 k) / French Environmental Code

Based on our actual knowledge of our production process and ingredients used we hereby certify that the above mentioned raw materials are free of ingredients containing nanoparticules as defined in article 2, point k) of European regulation 1223/2009 or article R523-12 of French environmental code.

34. ANIMAL TESTING

European regulation 1223/2009, Article 18

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials and the ingredients

- does not contain any product of animal origin and has not been in contact with any material of animal origin during the manufacture and storage
- have not been tested on animals for cosmetic purposes by or on behalf of the company since January 1st 2000.

35. CITES CERTIFICATE

European Regulation 338/97

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials, we hereby declare that the above mentioned raw materials are not listed in CITES regulation.

36. ORGANIC

This material is non organic.

37. KOSHER

Based on our actual knowledge of our production process and ingredients used, we hereby certify that the above mentioned raw materials do not contain Non-Kosher ingredients and is manufactured only with herbal raw botanicals

38. HALAL

We hereby declare that for the production of the above raw material all ingredients used are non-animal based or do not contain any animal impurity. Following ingredients have been explicitly excluded during the complete production process:

- Swine/Pork and its by-product, or ingredients based on Swine/Pork.
- Animals improperly slaughtered or dead before slaughtering.
- Animals killed in the name of anyone else than Allah.
- Ethanol (Alcohol) or drugs.
- Carnivorous animals.
- Birds of prey.
- Land animals without external ears.

	CERTIFICATE OF COMPLIANCE	Date of issue: 05/07/2017
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Blood, blood by products and blood derived ingredients.

39. STATEMENT MICROPLASTICS

Based on our actual knowledge of the production process and raw materials used, we hereby certify that this ingredient does not contain any microplastic materials (non-biodegradable polymers).