



We create chemistry

19 Dec 2016
E-EMC/QR - J 550
Ellen Pfrommer
Tel.: +49 621 60-72163
Fax: +49 621 60-6672163
ellen.pfrommer@basf.com

To whom it may concern

Dear Valued Customer:

Due to increasing regulatory requirements, BASF SE receives a significant amount of questionnaires and surveys from our customers regarding our products that essentially address the same issues. Unfortunately we are unable to individually complete each customer's specific form.

In order to respond to these requests in a timely and efficient manner, we have established a standardized Quality & Regulatory Product Information package (Q&R PI) to facilitate the exchange of standard regulatory, quality and safety information with our customers.

By responding to surveys, questionnaires and other requests for information in this manner, we can respond more quickly and efficiently to all requests as well as ensure that consistent information is provided in all cases.

We are convinced that this is an improvement in information management for both sides and we will do our best to provide our customers also in future with excellent service. Thank you for your continued interest in our products.

Sincerely,

BASF SE
Head of Product Stewardship & EHS Master Data Personal Care

A handwritten signature in black ink, appearing to read "Pfrommer".

i. V. Pfrommer

Quality & Regulatory Product Information

Vitamin E-Acetate Care

1. Identity and Registrations

INCI Name

Tocopheryl Acetate

Colorants identifier

☐ Color Index No.:

Chemical description

☒ Refer to attached Technical Information / Data Sheet

Composition

☒ Refer to attached Composition Sheet

Compliance with Chemical Inventories

Compliance with the European Union's Chemicals Legislation (REACH),
Regulation (EC) 1907/2006

☒ Refer to attached statement

Compliance with Global Chemical Inventories

☒ Refer to attached statement

Approval for cosmetic uses

Compliance with European Union cosmetics legislation

☒ We hereby confirm that the cosmetic raw material marketed by the BASF Care Chemicals Division conforms with the requirements relevant to cosmetic ingredients of the Cosmetics Regulation (EC) 1223/2009 and its amendments as currently in force.

Specific approvals

☐ UV-Filters Refer to attached statement

☐ Colorants Refer to attached statement

2. Product specification

☒ Refer to attached specification

3. Manufacturing and raw materials

Type of manufacturing process

☒ Chemical reaction

☐ By purification of a natural product

Quality & Regulatory Product Information

Vitamin E-Acetate Care

- ☐ Other:
- ☐ Brief description of manufacturing process:

Radioactive material

- ☒ Based on information concerning the raw materials, production process, and equipment used radioactive material is not expected to be present and no irradiation has been used.

Raw materials

Based on our actual knowledge, the raw materials are:

- ☐ Of vegetable origin
- ☐ Derived from non-genetically modified plant.
- ☐ GMO-free (not containing genetically modified DNA)
- ☐ Of animal origin
- ☐ BSE classification:
- ☒ Of mineral oil/natural gas origin
- ☐ Inorganic

4. Quality standards

- ☒ Certified according to ISO 9001/2008
- ☒ Kosher
- ☒ Other: Halal

5. Storage and handling

Retest period (if appropriate storage conditions are maintained) 36 months if the storage conditions below are maintained

Storage temperature	15 - 25°C
Storage conditions	Carefully reseal the container after opening
Additional information	

6. Stabilization of the product

The following substances are added to the product (during or after manufacture) for purposes of stabilization:

- ☐ Preservatives:
- ☐ Antioxidants / Stabilizers:
- ☐ Sequestering / complexing agents:
- ☐ Others:

Quality & Regulatory Product Information

Vitamin E-Acetate Care

7. By-products and impurities

a) Residual solvents

- ☐ Based on our actual knowledge of our production process, raw materials and equipment used, no solvent is used in the manufacturing process or, if used, is removed in a final step of the manufacturing process.
- ☒ Refer to attached statement on residual solvents
- ☐ Refer to attached statement on solvent components

b) Heavy metals

- ☐ Effect pigments: Refer to product specification
- ☒ Heavy metals in sum (as Pb) max. 10 ppm
- ☒ Refer to attached statement

c) Pesticides

- ☒ Based on information concerning the raw materials, production process, and equipment used, pesticides are not likely to be present.
- ☐ Based on information concerning the raw materials, production process, and equipment used, pesticides are expected to conform with concentration limits of the European Pharmacopoeia; Section 2.8.13 "Pesticide residues", Table 2.8.13.-1
- ☐ Refer to attached statement

d) Aflatoxin/Mycotoxin

- ☒ Based on information concerning the raw materials, production process, and equipment used Aflatoxin/Mycotoxin are not likely to be present .
- ☐ Based on information concerning the raw materials, production process, and equipment used Aflatoxin/Mycotoxin are expected to conform with the concentration limits of Regulation (EC) 1881/2006 Annex, Section 2.1.5
Aflatoxins B1: max. 2.0 µg/kg; Sum of Aflatoxins B1, B2, G1 and G2: max. 4.0 µg/kg

e) Polycyclic aromatic hydrocarbons

- ☒ Based on information concerning the raw materials, production process, and equipment used, polycyclic aromatic hydrocarbons are not likely to be present.
- ☐ Based on information concerning the raw materials, production process, and equipment used , polycyclic aromatic hydrocarbons are expected to conform to concentration limits of Regulation (EC) 1881/2006 Annex, Section 6.1.1 for benzo(a)pyrene: < 2 µg/kg

f) Residual monomers

- ☒ Not relevant
- ☐ Total residual monomers content (sum):
- ☐ The following residual monomers may be present

Quality & Regulatory Product Information
Vitamin E-Acetate Care

g) Other impurities

- ☐ 1,4-Dioxane:
- ☐ Diethylene glycol (sum of ethylene glycol and diethylene glycol)
- ☐ Nitrosamines:
- ☒ Others:
Residual reactant: max 1% Tocopherol

h) Allergens

Fragrance allergens

- ☒ Based on information concerning the raw materials, production process, and equipment used fragrance allergens as of EU Regulation 1223/2009 Annex III, No. 67-92 are not likely to be present.
- ☐ Refer to attached statement

Food allergens

- ☒ Based on information concerning the raw materials, production process, and equipment used food allergens as of EU Directive 2000/13/EC (as amended), Annex IIIa, and Regulation (EU) 1169/2011, Annex II are not likely to be present.
- ☐ May contain the following substances:
- ☐ Refer to attached statement.

i) Phthalates

- ☒ Based on information concerning the raw materials, production process, and equipment used phthalates listed in EU Regulation 1223/2009 Annex II are not likely to be present.

j) CMR substances

- ☒ Based on information concerning the raw materials, production process, and equipment used CMR substances according to Annex VI of the CLP Regulation (EC) 1272/2008 are not likely to be present.
- ☐ May contain the following CMR substances:

k) Proposition 65

- ☐ Based on information concerning the raw materials, production process, and equipment used substances listed in The Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") are not likely to be present.
- ☒ Refer to attached statement.

l) Glycol ethers

- ☒ Based on information concerning the raw materials, production process, and equipment used the following glycol ethers are not likely to be present:
 - Butyldiglycol (CAS No 112-34-5)
 - Ethyldiglycol (CAS No 111-90-0)
 - 2-Butoxyethanol (CAS No 111-76-2)

8. Nanomaterials

- ☒ Concerning new requirements for nanomaterials in cosmetic products, laid down in the Cosmetics Regulation (EC) 1223/2009, the following definition is provided in Article 2, 1 (k) of Regulation (EC) 1223/2009: *'Nanomaterial' means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm'*
The product is not considered as a nanomaterial under this definition.

Quality & Regulatory Product Information
Vitamin E-Acetate Care

9. Microbiological information

- ☒ Based on our current knowledge of our production process, raw materials, and equipment used we do not expect microbiological contamination.
- ☐ Refer to attached specification
- ☐ Refer to attached statement.

10. Safety and Environment

- ☒ BASF Sustainability policy:
http://www.basf.com/group/sustainability_en/index
<http://www.basf.com/group/corporate/en/sustainability/our%2Dvalues/index>
- ☒ Current EU Safety Data Sheet available upon request
- ☒ Toxicological information available upon request
- ☒ Ecotoxicological information: Refer to Safety Data Sheet
- ☒ Information on animal testing: Refer to attached statement

This questionnaire has been produced electronically and is valid without signature.

This document including all the attachments is not intended for regulatory submissions. There is no automatic updating service. For regulatory support, please contact your BASF Sales representative.

Note:

This document, or any answers or information provided herein by BASF, does not constitute a legally binding obligation of BASF. While the descriptions, designs, data and information contained herein are presented in good faith and believed to be accurate, it is provided for your guidance only. Because many factors may affect processing or application/use, we recommend that you make tests to determine the suitability of a product for your particular purpose prior to use. It does not relieve our customers from the obligation to perform a full inspection of the products upon delivery or any other obligation. NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE MADE REGARDING PRODUCTS DESCRIBED OR DESIGNS, DATA OR INFORMATION SET FORTH, OR THAT THE PRODUCTS, DESIGNS, DATA OR INFORMATION MAY BE USED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS. IN NO CASE SHALL THE DESCRIPTIONS, INFORMATION, DATA OR DESIGNS PROVIDED BE CONSIDERED A PART OF OUR TERMS AND CONDITIONS OF SALE.