Certificate of Analysis

Product Name: Vitamin E Synthetic

Batch No.: 4411709

Best BeEore Date: October 2023

ITEMS	METHODS	SPECIFICATIONS	
Description	Visual	Clear, colourless slightly greenish-yellow, Viscous, liquid, Ph.Eur./USP/FCC	
Identification			
Optical rotation	Ph.Eur.2.2.7	-0.01° ~ +0.01°, Ph.Eur.	
IR	Ph.Eur.2.2.24	To conform, Ph.Eur./USP/FCC	
Color reaction	USP	To conform, USP/FCC	
Retention time	GC	To conform, USP/FCC	
Related Substances			
Impurity A	Ph.Eur.2.2.28	≤0.5%, Ph.Eur.	0.13%
Impurity B	Ph.Eur.2.2.28	≤1.5%, Ph.Eur.	0.71%
Impurity C	Ph.Eur.2.2.28	≤0.5%, Ph.Eur.	0.14%
Impurities D and E	Ph.Eur.2.2.28	≤1.0%, Ph.Eur.	<0.1%
Any other impurity	Ph.Eur.2.2.28	≤0.25%, Ph.Eur.	<0.1%
Total impurities	Ph.Eur.2.2.28	≤2.5%, Ph.Eur.	1.0%
Acidity	USP/FCC	≤1.0ml, USP/FCC	0.08mL
Residual Solvents	Ph.Eur.2.4.24 USP<467>	To conform (In-house)	Conform
Heavy metals			
Pb	AA	≤2mg/kg, FCC	<0.5mg/kg
Arsenic	ChP0822	≤1mg/kg(in-house)	<1mg/kg
Copper	ICP-MS	≤25mg/kg(in-house)	<2mg/kg
Zinc	ICP-MS	≤25mg/kg(in-house)	<2mg/kg
Palladium	AA	≤5ppm(in-house)	<1ppm
Assay			
Assay(Ph.Eur.)	Ph.Eur.2.2.28	96.5% ~ 102.0%, Ph.Eur.	98.9%
Assay(Ph.Eur.)	Ph.Eur.2.2.28	434.3mg α-tocopherol/g 459.0mg α-tocopherol/g, Ph.Eur.	445.1mg α-tocopherol/g
Assay(USP/FCC)	Ph.Eur.2.2.28	96.0% ~ 102.0%, USP/FCC	98.9%
Assay(USP/FCC)	Ph.Eur.2.2.28	432.0mg α-tocopherol/g 459.0mg α-tocopherol/g, USP/FCC	445.1mg α-tocopherol/g
Microbial limit[1]			
TAMC	USP<61> Ph.Eur.2.6.12	≤1000cfu/g, Ph.Eur./USP	<10cfu/g

ITEMS	METHODS	SPECIFICATIONS	RESULTS
TYMC	USP<61> Ph.Eur.2.6.12	≤100cfu/g, Ph.Eur./USP	<10cfu/g
Escherichia coli	USP<62> Ph.Eur.2.6.13	n.d./g, Ph.Eur./USP	n.d.
Pseudomonas aeruginosa	USP<62> Ph.Eur.2.6.13	n.d./g, Ph.Eur./USP	n.d.
Staphylococcus aureus	USP<62> Ph.Eur.2.6.13	n.d./g, Ph.Eur./USP	n.d.
Enterobacterial	USP<62> Ph.Eur.2.6.13	n.d./g, Ph.Eur./USP	n.d.
Salmonella	USP<62> Ph.Eur.2.6.13	n.d./10g, Ph.Eur./USP	n.d.

Conclusion: Conform toPh.Eur./USP/FCC

Remark: "1" Conduct every tenth batch.
"Certified"indicates data obtained by statistically designed sampling audits.
Material Code:4100102

Statement: Allergen Information

Vitamin E-Acetate (DL-alpha-tocopheryl acetate)

Date: 28 Mar. 2019

PRD 30041054

Allergen list[1,2,3,4,5,6,7,8]	Product ingredient (Y/N)	Details about the ingredient and labelling requirements*	Allergen used on production line** (Y/N/ n/a)	Allergen used or stored in production facility** (Y/N/ n/a)	Material on production line/in production facility	Allergen cross contact risk under control** (Y/N/n/a)
Cereals containing gluten namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof	N		N	N		n/a
Celery and products thereof	N		N	N		n/a
Crustaceans and products thereof	N		N	N		n/a
Eggs and products thereof	N		N	N		n/a
Fish and products thereof	N		N	N		n/a
Lupin and products thereof	N		N	N		n/a
Milk and products thereof (including lactose)	N		N	N		n/a
Molluscs and products thereof	N		N	N		n/a
Mustard and products thereof	N		N	N		n/a
Peanuts and products thereof	N		N	N		n/a
Sesame seeds and products thereof	N		N	N		n/a
Soybeans and products thereof	N		N	Y	Soybean oil	Y

Statement: Allergen Information

Vitamin E-Acetate (DL-alpha-tocopheryl acetate)

Date: 28 Mar. 2019

PRD 30041054

Allergen list[1,2,3,4,5,6,7,8]	Product ingredient (Y/N)	Details about the ingredient and labelling requirements*	Allergen used on production line** (Y/N/ n/a)	Allergen used or stored in production facility** (Y/N/ n/a)	Material on production line/in production facility	Allergen cross contact risk under control** (Y/N/n/a)
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO^2	N		N	N		n/a
(Tree-) Nuts and products thereof (namely almond, Brazil nut/para nut, cashew, hazelnut, macadamia/Queensland nut, pecan nut, pistachio nut, walnut; and additionally: beechnut, butternut, chestnut, chinquapin, coconut, gingko nut, hickory nut, lychee nut, pili nut, pine nut, sheanut)	N		N	Y	MCT (medium chain triglycerides) obtained by esterification of fractionated fatty acids derived from coconut and/or palm/palm kernel oil with glycerol	Y
Natural latex	N		N	N		n/a
Tartrazine	N		N	N		n/a
Buckwheat and products thereof	N		N	N		n/a
Fruits, namely apples, bananas, kiwi fruits, oranges, peaches and mango, tomato and products thereof	N		N	N		n/a
Beef and products thereof	N		N	N		n/a
Chicken and products thereof	N		N	N		n/a
Pork and products thereof	N		N	Y	Pork gelatine	Y
Matsutake mushrooms and products thereof	N		N	N		n/a
Yams and products thereof	N		N	N		n/a
Gelatine	N		N	Y	Pork gelatine	Y

Statement: Allergen Information

Vitamin E-Acetate (DL-alpha-tocopheryl acetate)

Date: 28 Mar. 2019

PRD 30041054

*Above mentioned labelling requirements are given according to the below mentioned legislations. For further regions the labelling requirements have not been evaluated. Further information is available on request.

[1]Australian New Zealand Food Standards Code (Standard 1.2.3)
[2]Regulation (EU) No 1169/2011 as amended
[3]US Food Allergen Labelling and Consumer Protection Act (FALCPA)
[4]Health Canada 2011 Amendments of Food Allergen Labelling Regulation
[5]Argentina CODIGO ALIMENTARIO ARGENTINO Resolución Conjunta 11-E/2017
[6]Brazil RESOLUTION - RDC No. 26, dated July 02, 2015 and updated September 23, 2016
[7]Japan Japan Food Labelling Act - Guidelines for Labelling of food containing allergens issued by Consumer Affairs Agency (CAA), Government of Japan, dated March 20, 2015
[8]China GB 7718-2011 National food safety standard on General Rules for the Labelling of Pre-packaged foods,dated April 20, 2011

**In order to minimize the risk of a potential cross contamination with allergens that are used on the same production line respectively used or stored in the production facility the following protective measures/procedures are in place:

- Avoidance of materials derived from potential allergens where applicable
- Allergen information and statements available for all raw materials used in production where relevant
- Approved HACCP concept in place including product related allergen risk evaluation
- Validated cleaning procedures
- Traceability on every step
- Separated storage of different products and raw materials wherever applicable
- Crosscheck before handling and filling of raw materials
- Specific training on allergens for production staff established
- Food quality standards like e.g. FSSC 22000/ ISO 22000 and/or GMP Food/Pharma certification

We therefore conclude that there will be no risk of cross contamination with the above mentioned materials and therefore labelling is not required.

If you have any further questions or need additional support, please contact your BASF sales representative.

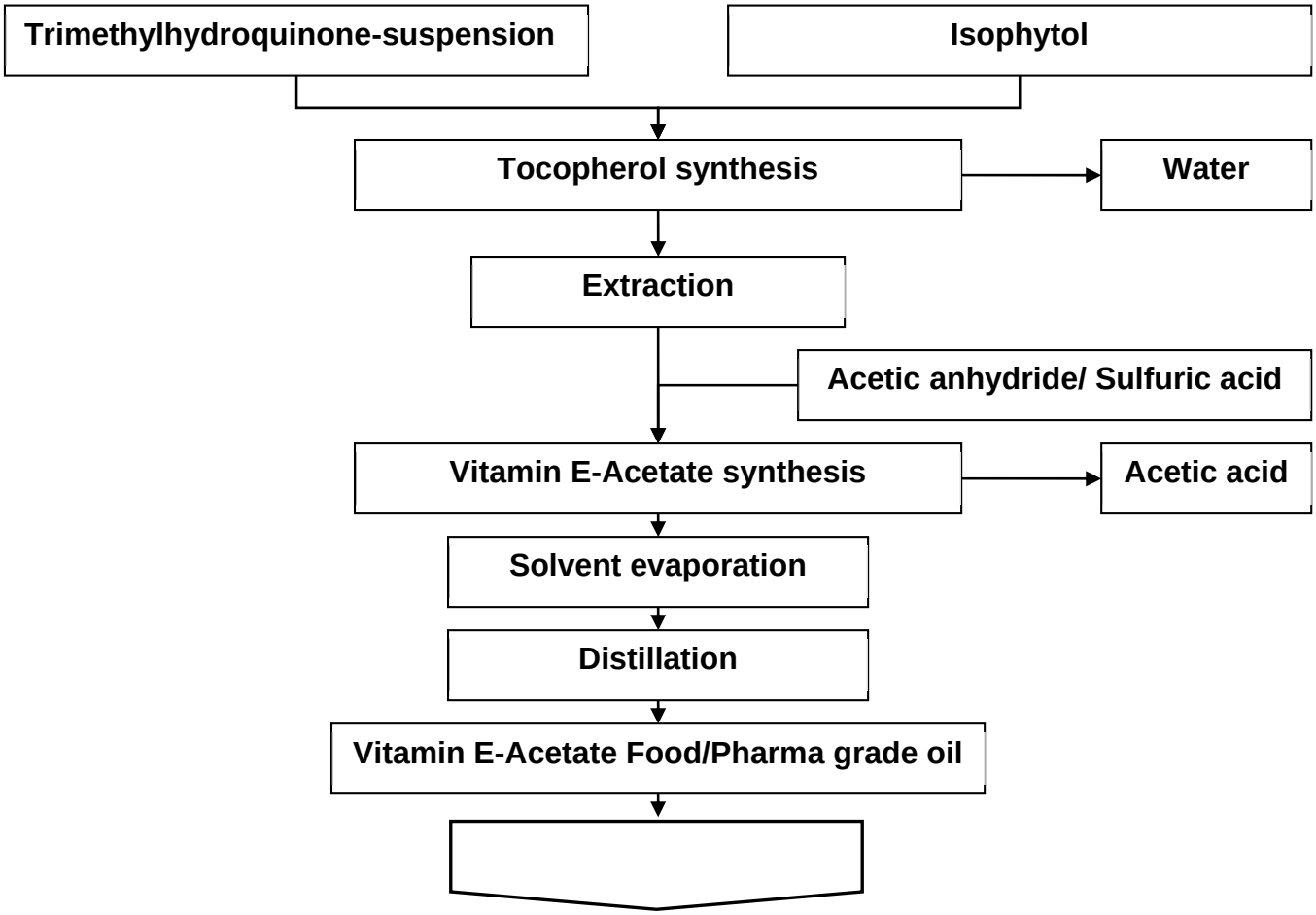
This is a computer generated document. It is valid without signature.

Manufacturing Flow Chart with CCP

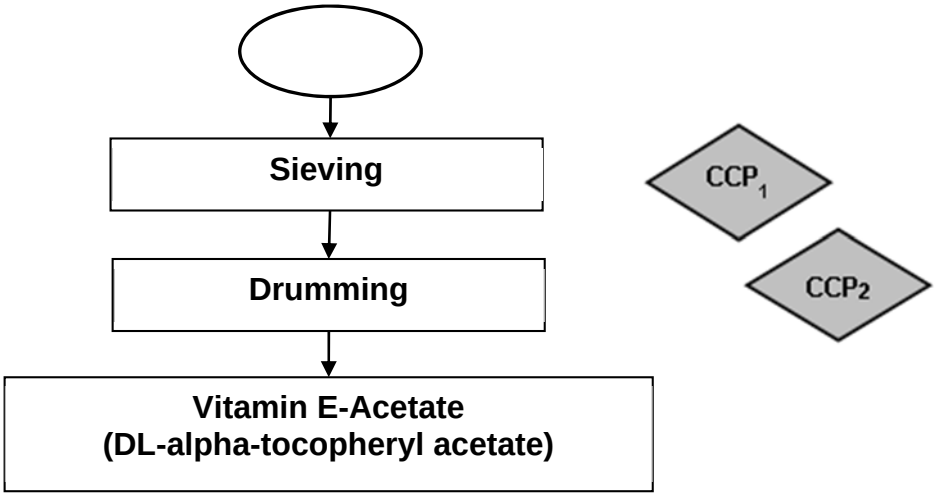
Version 5, 10.2015

Vitamin E-Acetate (DL-alpha-tocopheryl acetate)

PRD no. 30041054
Manufacturing site: Ludwigshafen, Germany



BiOrigins, 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK
Tel: 01425 655555 Email: technical@madarcorporation.co.uk



CCP_1: Visual inspection of sieve(s) (includes check of loose and missing parts in filling equipment)
CCP_2: Check of label and inspection of label printer

BiOrigins, 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK
Tel: 01425 655555 Email: technical@madarcorporation.co.uk

GMO Statement

PRODUCT NAME: Vitamin E Synthetic

MADAR Corporation Limited can confirm that the above listed product is GMO Free.

05/08/2019

Safety data sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Vitamin E-Acetate (DL-alpha-tocopheryl acetate)

Chemical name: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate
CAS Number: 7695-91-2

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: feed additive(s), food additive(s)

1.3. Details of the supplier of the safety data sheet

Company:

Madar Corporation Limited

Contact address:
19 - 20 Sandleheath Industrial Estate
Fordingbridge
SP6 1PA

Telephone: +44 1425 655 555
E-mail address: technical@madarcorporation.co.uk

1.4. Emergency telephone number

Telephone: +44 1425 655 555

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

According to Regulation (EC) No 1272/2008 [CLP]

No need for classification according to GHS criteria for this product.

2.2. Label elements

Globally Harmonized System, EU (GHS)

The product does not require a hazard warning label in accordance with GHS criteria.

2.3. Other hazards

According to Regulation (EC) No 1272/2008 [CLP]

The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Mop up spills with non-flammable adsorbents (e.g. vermiculite, spill mats). Soiled textiles / cleaning rags / adsorbents and Silica are capable of self ignition and should be wetted with water and must be disposed of in a safe manner. High risk of slipping due to leakage/spillage of product.

SECTION 3: Composition/Information on Ingredients

3.1. Substances

Chemical nature

3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate
CAS Number: 7695-91-2
EC-Number: 231-710-0

3.2. Mixtures

Not applicable

SECTION 4: First-Aid Measures

4.1. Description of first aid measures

Remove contaminated clothing.

If inhaled:
Keep patient calm, remove to fresh air.

On skin contact:
Wash thoroughly with soap and water.

On contact with eyes:

Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion:
Rinse mouth and then drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms: No significant reaction of the human body to the product known.

4.3. Indication of any immediate medical attention and special treatment needed
Treatment: Symptomatic treatment (decontamination, vital functions).

SECTION 5: Fire-Fighting Measures

5.1. Extinguishing media
Suitable extinguishing media:
water spray, carbon dioxide, dry powder, alcohol-resistant foam

Unsuitable extinguishing media for safety reasons:
water jet

5.2. Special hazards arising from the substance or mixture
acrylaldehyde; acrolein; prop-2-enal, harmful vapours, carbon oxides
Evolution of fumes/fog. The substances/groups of substances mentioned can be released in case of fire. Burning produces harmful and toxic fumes.

5.3. Advice for fire-fighters
Special protective equipment:
Wear a self-contained breathing apparatus.

Further information:
Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.
Cool endangered containers with water-spray.

SECTION 6: Accidental Release Measures

High risk of slipping due to leakage/spillage of product.

6.1. Personal precautions, protective equipment and emergency procedures
Use personal protective clothing. Information regarding personal protective measures see, section 8.

6.2. Environmental precautions
Do not discharge into drains/surface waters/groundwater.

6.3. Methods and material for containment and cleaning up
For small amounts: Contain with absorbent material (e.g. sand, silica gel, acid binder, general purpose binder, sawdust).

For large amounts: Dike spillage. Pump off product.
Mop up spills with non-flammable adsorbents (e.g. vermiculite, spill mats). Soiled textiles / cleaning rags / adsorbents and Silica are capable of self ignition and should be wetted with water and must be disposed of in a safe manner. Dispose of absorbed material in accordance with regulations.

6.4. Reference to other sections
Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling
No special measures necessary provided product is used correctly.

Protection against fire and explosion:
Take precautionary measures against static discharges. Avoid all sources of ignition: heat, sparks, open flame. Soiled textiles / cleaning rags / adsorbents and Silica are capable of self ignition and should be wetted with water and must be disposed of in a safe manner.

7.2. Conditions for safe storage, including any incompatibilities
Further information on storage conditions: Containers should be stored tightly sealed in a dry place. Protect against heat.

Storage stability:
Storage temperature: <= 25 °C

7.3. Specific end use(s)
For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

Components with occupational exposure limits

No occupational exposure limits known.

PNEC
freshwater: 0.27 mg/l

marine water: 0.027 mg/l

intermittent release: 0.27 mg/l

sediment (freshwater): 212000 mg/kg

sediment (marine water): 21200 mg/kg

soil: 74800 mg/kg

STP: 100 mg/l

DNEL
worker:
Long-term exposure- systemic effects, Inhalation: 73.5 mg/m3

worker:
Long-term exposure- systemic effects, dermal: 416.6 mg/kg

consumer:
Long-term exposure- systemic effects, Inhalation: 21.7 mg/m3

consumer:
Long-term exposure- systemic effects, dermal: 250 mg/kg

consumer:
Long-term exposure- systemic effects, oral: 12.5 mg/kg

8.2. Exposure controls

Personal protective equipment

Respiratory protection:
Respiratory protection in case of vapour/aerosol release. Particle filter with medium efficiency for solid and liquid particles (e.g. EN 143 or 149, Type P2 or FFP2)

Hand protection:
Chemical resistant protective gloves (EN 374)

Eye protection:
Safety glasses with side-shields (frame goggles) (e.g. EN 166)

Body protection:
Body protection must be chosen based on level of activity and exposure.

General safety and hygiene measures
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Form:	oily	
Colour:	colourless to amber	
Odour:	almost odourless	
Odour threshold:	not determined	
pH value:	not applicable	
Freezing point:	< -20 °C	
Boiling point:	> 300 °C	
Flash point:	257 °C	(DIN EN 22719; ISO 2719, closed cup)
Evaporation rate:	Value can be approximated from Henry's Law Constant or vapor pressure.	
Flammability:	hardly combustible	
Lower explosion limit:	For liquids not relevant for classification and labelling.	
Upper explosion limit:	For liquids not relevant for classification and labelling.	
Ignition temperature:	382 °C	(DIN EN 14522)
Vapour pressure:	< 0.000001 hPa (25 °C)	(calculated)
Density:	0.98 g/cm3 (20 °C) Literature data.	
Relative vapour density (air):	No data available.	
Solubility in water:	sparingly soluble < 0.8 mg/l (20 °C)	(OECD Guideline 105)
Partitioning coefficient n-octanol/water (log Kow):	12.25 (25 °C)	(calculated)
Self ignition:	Risk of self-ignition when a large surface area is produced due to fine dispersion.	
Thermal decomposition:	430 °C	
Viscosity, kinematic:	5,706 mm2/s (20 °C)	(OECD 114)
	701 mm2/s (40 °C)	(OECD 114)
Explosion hazard:	Based on the chemical structure there is no indicating of explosive properties.	
Fire promoting properties:	Based on its structural properties the product is not classified as oxidizing.	

9.2. Other information

Other Information:
If necessary, information on other physical and chemical parameters is indicated in this section., No further information available.

SECTION 10: Stability and Reactivity

10.1. Reactivity
No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals: No corrosive effect on metal.

10.2. Chemical stability
The product is stable if stored and handled as prescribed/indicated.

10.3. Possibility of hazardous reactions
When finely distributed, self-ignition is possible.

10.4. Conditions to avoid
Avoid direct sunlight. Avoid heat.

10.5. Incompatible materials

Substances to avoid:
strong alkalies, strong oxidizing agents

10.6. Hazardous decomposition products

Hazardous decomposition products:
No hazardous decomposition products if stored and handled as prescribed/indicated.

SECTION 11: Toxicological Information

11.1. Information on toxicological effects

Acute toxicity

Assessment of acute toxicity:
Virtually nontoxic after a single ingestion. Virtually nontoxic after a single skin contact.

Experimental/calculated data:
LD50 rat (oral): > 10,000 mg/kg (BASF-Test)

LD50 rat (dermal): > 3,000 mg/kg

Irritation

Assessment of irritating effects:
Not irritating to the skin. Not irritating to the eyes.

Experimental/calculated data:
Skin corrosion/irritation rabbit: non-irritant (OECD Guideline 404)

Serious eye damage/irritation rabbit: non-irritant (OECD Guideline 405)

Respiratory/Skin sensitization

Assessment of sensitization:
Skin sensitizing effects were not observed in animal studies.

Experimental/calculated data:
photo-allergy test guinea pig: Non-sensitizing.

Germ cell mutagenicity

Assessment of mutagenicity:
No mutagenic effect was found in various tests with bacteria and mammals.

Carcinogenicity

Assessment of carcinogenicity:
In long-term animal studies in which the substance was given in high doses by feed, a carcinogenic effect was not observed.

Reproductive toxicity

Assessment of reproduction toxicity:
The results of animal studies gave no indication of a fertility impairing effect.

Developmental toxicity

Assessment of teratogenicity:
No indications of a developmental toxic / teratogenic effect were seen in animal studies.

Specific target organ toxicity (single exposure)

Assessment of STOT single:
Based on available Data, the classification criteria are not met.

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity:
Repeated oral uptake of the substance did not cause substance-related effects.

Aspiration hazard

no classification possible (no data available)

SECTION 12: Ecological Information

12.1. Toxicity

Assessment of aquatic toxicity:
The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish:
LC50 (96 h) > 11 mg/l, Oncorhynchus mykiss (OECD Guideline 203, static)
The statement of the toxic effect relates to the analytically determined concentration. No toxic effects occur within the range of solubility.

Aquatic invertebrates:
EC50 (48 h) > 20.6 mg/l, Daphnia magna (OECD Guideline 202, part 1, static)
The statement of the toxic effect relates to the analytically determined concentration. No toxic effects occur within the range of solubility.

Aquatic plants:
EC50 (72 h) > 27.8 mg/l (growth rate), Pseudokirchneriella subcapitata (OECD Guideline 201, static)
The statement of the toxic effect relates to the analytically determined concentration. No toxic effects occur within the range of solubility.

Chronic toxicity to fish:
No observed effect concentration (28 d) > 100 mg/l, Oncorhynchus mykiss (OECD Guideline 215, semistatic)

12.2. Persistence and degradability

Assessment biodegradation and elimination (H2O):
Moderately/partially biodegradable. Not readily biodegradable (by OECD criteria). The product is virtually insoluble in water and can thus be separated from water mechanically in suitable effluent treatment plants.

Elimination information:
30 - 40 % BOD of the ThOD (28 d) (OECD 301F; ISO 9408; 92/69/EEC, C.4-D) (aerobic, activated sludge, domestic)

Assessment of stability in water:
In contact with water the substance will hydrolyse slowly.

12.3. Bioaccumulative potential

Assessment bioaccumulation potential:
Accumulation in organisms is not to be expected.

12.4. Mobility in soil

Assessment transport between environmental compartments:
Volatility: The substance will slowly evaporate into the atmosphere from the water surface.
Adsorption in soil: Adsorption to solid soil phase is expected.

12.5. Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): The product does not fulfill the criteria for PBT (Persistent/bioaccumulative/toxic) and vPvB (very persistent/very bioaccumulative). Self classification

12.6. Other adverse effects

The substance is not listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods

The UK Environmental Protection (Duty of Care) Regulations (EP) and amendments should be noted (United Kingdom).

SECTION 14: Transport Information

Land transport

ADR

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

RID

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for	None known

user

Inland waterway transport

ADN

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user:	None known

Transport in inland waterway vessel

Not evaluated

Sea transport

IMDG

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

Air transport

IATA/ICAO

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

14.1. UN number

See corresponding entries for “UN number” for the respective regulations in the tables above.

14.2. UN proper shipping name
See corresponding entries for “UN proper shipping name” for the respective regulations in the tables above.

14.3. Transport hazard class(es)
See corresponding entries for “Transport hazard class(es)” for the respective regulations in the tables above.

14.4. Packing group
See corresponding entries for “Packing group” for the respective regulations in the tables above.

14.5. Environmental hazards
See corresponding entries for “Environmental hazards” for the respective regulations in the tables above.

14.6. Special precautions for user
See corresponding entries for “Special precautions for user” for the respective regulations in the tables above.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Regulation:	Not evaluated
Shipment approved:	Not evaluated
Pollution name:	Not evaluated
Pollution category:	Not evaluated
Ship Type:	Not evaluated

SECTION 15: Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

The data should be considered when making any assessment under the Control of Substances Hazardous to Health Regulations (COSHH), and related guidance, for example, 'COSHH Essentials' (United Kingdom).

If other regulatory information applies that is not already provided elsewhere in this safety data sheet, then it is described in this subsection.

15.2. Chemical Safety Assessment

Chemical Safety Assessment not required

SECTION 16: Other Information

Assessment of the hazard classes according to UN GHS criteria (most recent version)

Any other intended applications should be discussed with the manufacturer. Corresponding occupational protection measurements must be followed.

If you have any queries relating to this MSDS, it's contents or any other product safety related questions, please write to the following e-mail address: technical@madarcorporation.co.uk

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. The data do not describe the product's properties (product specification). Neither should any agreed property nor the suitability of the product for any specific purpose be deduced from the data contained in the safety data sheet. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

Vertical lines in the left hand margin indicate an amendment from the previous version.

Vitamin E-Acetate (DL-alpha-tocopheryl acetate)

PRD-No. 30041054

120559 **Revision 7**

NOT FOR REGULATORY PURPOSES

Test parameter	Requirement	Test method
Assay		
DL-alpha-Tocopheryl acetate (GC)	96.5 to 102.0 g/100g	Ph. Eur.
DL-alpha-Tocopheryl acetate (GC)	96.0 to 102.0 g/100g	PM0827 (USP)
DL-alpha-Tocopheryl acetate (GC)	960 to 1020 I.U./g	USP
Characters		
Appearance	Viscous, light yellow oil	Visual
Identification (1)		
Identification	Must comply	Ph. Eur.
Tests		
Impurity A	≤ 0.5 % (area)	Ph. Eur.
Impurity B	≤ 1.5 % (area)	Ph. Eur.
Impurity C	≤ 0.5 % (area)	Ph. Eur.
Sum of impurity D and E	≤ 1.0 % (area)	Ph. Eur.
Any other impurity, each	≤ 0.25 % (area)	Ph. Eur.
Total impurities	≤ 2.5 % (area)	Ph. Eur.
Optical rotation	-0.01 to +0.01 °	Ph. Eur.
Acidity	Must comply	USP
Lead(*)	≤ 2 mg/kg	PM01683
Cadmium(*)	≤ 1 mg/kg	PM01683
Mercury(*)	≤ 0.1 mg/kg	PM00934
Arsenic(*)	≤ 1 mg/kg	PM01683
Zinc(*)	≤ 10 mg/kg	PM01683
Heavy metals(*)	≤ 10 mg/kg	PM01683
Methanol (residual solvent class 2)(*)	≤ 3000 mg/kg	PM00544
Heptane (residual solvent class 3)(*)	≤ 0.5 g/100g	PM00544

(1) May also be determined by other means/methods (General Notices Ph. Eur./USP)

(*) ensured by quality assurance measures and therefore tested randomly only.

The product meets the requirements of this specification.

The product meets the specification of current monographs:

"all-rac-alpha-tocopheryl acetate" of Ph. Eur.
"Vitamin E" of USP
"all-rac-alpha-tocopheryl acetate of FCC
"Tocopheryl-Acetate" of IP

This document is valid without signature.

Product Specification	*FINAL*	Effective from	Jun 9, 2014

Vitamin E-Acetate (DL-alpha-tocopheryl acetate)

PRD-No. 30041054

120559 **Revision 7**

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. SELLER MAKES NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, BY FACT OR LAW, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The statements under the heading “Characters” are not to be interpreted in a strict sense and are not requirements.

Vitamin E Acetate

(DL-alpha-tocopheryl acetate)

Chemical names of active ingredient
all-rac-α-tocopheryl acetate, DL-α-tocopheryl acetate, DL-alpha-tocopherol acetate, all-rac-alpha-tocopherol acetic acid ester, racemic 5,7,8-trimethyltocol acetate

CAS-No. 7695-91-2

EINECS-No. 231-710-0

PRD-No.
30041054*

* The product is kosher and halal.

Articles

55434595	4 x 5 kg plastic can
55434171	25 kg plastic bucket

Country of origin
Germany

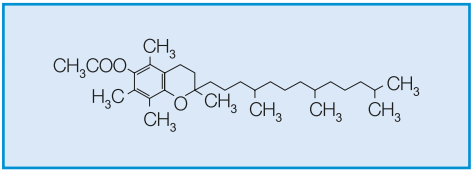
Units
1 mg DL (= all-rac)-α-tocopheryl acetate
= 0.455 mg D (=RRR)-α-tocopherol equivalent
= 1 International Unit (IU)

Description
Light-yellow, viscous, virtually odorless oil.

Solubility
Soluble in hydrocarbons, alcohols, fats, and oils; insoluble in water.

Specification

Assay min. 96.0%* DL (=all-rac)-α-tocopheryl acetate (= 960 mg/g vitamin E)
max. 102.0%* DL (=all-rac)-α-tocopheryl acetate (= 1020 mg/g vitamin E)
*USP



$C_{31}H_{52}O_3$ Molar mass 472.8 g/mol

For information see separate document: “Standard Specification” (not for regulatory purposes) available via BASF’s WorldAccount: https://worldaccount.basf.com (registered access).

Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

Monographs
The product complies with the current “All-rac-α-tocopheryl acetate” Ph. Eur., “Vitamin E” USP, “All-rac-alpha-tocopheryl acetate” FCC and “Tocopheryl acetate” IP monographs.
A grade complying with the requirements of the JP and CP, respectively, is available upon request.

Regulations
The product meets the regulatory requirements for a vitamin E source in most countries. However, regulations on the product in the respective countries and for its intended use have to be checked.

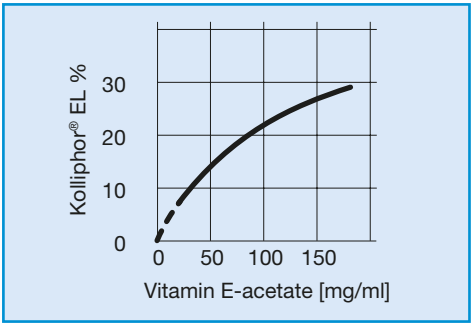
Stability
In contrast to vitamin E-alcohol, vitamin E-acetate is resistant to heat and oxygen. It is not resistant to strong oxidizing agents or to alkalis because it undergoes saponification. Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

Storage/Handling
The product should be stored tightly sealed in a cool, dry place.

Applications
Pharmaceutical products:
Suitable for use in pharmaceutical applications, where a European ASMF and CEP is accepted.

Dietary supplements:
Suitable for use in dietary supplements with a lipophilic base, e.g., ointments, creams, oils, soft gelatin capsules, as well as in aqueous preparations, e.g., syrups, drops, tonics, and solubilizates in conjunction with a solubilizing agent, such as Kolliphor® EL, Kolliphor® RH 40, or Kolliphor® HS 15.

Food products:
Suitable for the fortification of fats, e.g., in regular and low-fat margarine as well as in oils and fat-containing foods, such as cakes, biscuits, and dairy products.



Note
Vitamin E Acetate must be handled in accordance with the Safety Data Sheet.

Vegetarian & Vegan Suitability Statement

PRODUCT NAME: Vitamin E Synthetic

MADAR Corporation Limited can confirm that the above listed product has not been tested in animals and does not contain dairy or any other animal product, by product or derivative and is therefore suitable for vegetarian and vegan use.

05/08/2019