



RAW MATERIAL SPECIFICATION VENDOR AGREEMENT

Oterra material number:	712366	Document ID: RMS-712366
Oterra material description:	OR Deodourised Lutein\17KG	Version: 02
Vendor/Manufacturer:	10931 Synthite Industries Private Limited/ Synthite Harihar	Date: 12/02/2025
Vendor/Manufacturer item number/name:	Oleoresin Marigold (4010001026)	

Issued by: (Electronic signature)

Manufacturer approval: (Name of the signer, manufacturer, date and signature)

CoA is reviewed and aligned with RMS:

(Alignment is verified after manufacture comments & approval of RMS and final CoA at date indicated)

Our raw materials are crucial to ensure the safety and quality of Oterra's final products. Therefore, vendors must be approved according to Oterra's vendor management system prior to delivery. Major changes, such as change of production site, manufacturer, country of origin, way of manufacturing, declarations on allergens, environmental and occupational health classification, food safety, HACCP, packaging (dimensions and pack type) and compliance to this specification must be notified to Oterra in 3 months advance to such change.

General description

This raw material is produced from *Tagetes erecta* L. (Family: Compositae). Produced by solvent extraction using hexane of the dried flowers followed by deodourisation using methanol. Product is Oleoresin marigold and not purified lutein, so the product belongs to N1 according to the NatCol categories. The raw material must be food grade and comply with the current editions of the monographs and other regulations mentioned below. The raw material is intended for the manufacturing of ingredients to be used in food.

Legal requirements

Compliance with EU legislation:

Comply with the current editions of;

EU reg 231/2012, E161b Lutein

Compliance with Codex:

JECFA INS 161b(iii) Lutein ester from
Tagetes erecta

Country of manufacture

Manufactured in:

India

Ingredient breakdown

Oleoresin maricold

Content

100%

Material source and Country of manufacture

Tagetes erecta L. CoM: India

Primary characteristic

Product source (Primary ingredient):

Acceptance criteria

Natural - *Tagetes erecta* L. (Family: Compositae)

Identity

CAS number:

127-40-2 (Lutein)

Chemical formula:

$C_{40}H_{56}O_2$

Chemical name:

3,3'-dihydroxy-d-carotene

Einecs number:

204-840-0

Regulatory reference or methods

Sensory properties

Appearance

Acceptance criteria

Orange brown waxy semisolid

Odor

Relatively odourless

Texture/consistency

Waxy semisolid

Color

Orange brown

Regulatory reference or methods

Chemical / physical

Acceptance criteria

Regulatory reference or methods



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Assay (as lutein esters)*	≥ 75 % total carotenoid esters	JECFA
Xanthophyll content, free lutein *	≥ 25 %	(Quality parameter)
Zeaxanthin (of total carotenoids)**	≤ 10 %	JECFA
Ash**	≤ 1 %	JECFA
Waxes**	≤ 25 %	JECFA
Solubility	Insolubility in water, soluble in hexane	JECFA
Solvents used:	Hexane, Methanol	
Residual solvents**	Complies	231/2012/EC and 32/2009/EC as amended
Hexane solvent residue*	≤ 25 mg/kg	231/2012/EC, JECFA
Methanol solvent residue*	≤ 10 mg/kg	231/2012/EC, JECFA
Moisture**	≤ 1,00 %	
Heavy metals		
Arsenic (As)*	≤ 3 mg/kg	231/2012/EC
Lead (Pb)*	≤ 2 mg/kg	231/2012/EC, JECFA
Mercury (Hg)*	≤ 1 mg/kg	231/2012/EC
Cadmium (Cd)*	≤ 1 mg/kg	231/2012/EC
Aflatoxin B1**	≤ 5,0 µg/kg	1881/2016/EC (2.1.14)
Aflatoxin B1+B2+G1+G2**	≤ 10,0 µg/kg	1881/2016/EC (2.1.14)
Chemical/environmental contaminants**	Complies	EU regulation 915/2023 as amended, CODEX standard 193-1995
Pesticides residues**	Complies	EU regulation 396/2005/EC as amended
Illegal dyes**	Complies	Specification for all illegal dyes listed in "Appendix 1: CH Illegal Dyes Limits". And Commission Regulation (EC) no 669/2009, stating that illegal dyes shall not be present in the materials i.e. any traces found of illegal dye of any LOQ or LOD is not accepted.



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Allergens

This raw material does not trigger allergen labelling according to EU-regulation 1169/2011 with later amendments or US Food Allergen Labeling and Consumer Protection Act of 2004 and 21CFR5130.9

Microbiology

	Acceptance criteria	Regulatory reference or methods
Aerobic Viable Count, 30°C*	<1000 cfu/g	ISO 4833-2
Yeast*	<100 cfu/g	ISO 21527-1
Mold*	<100 cfu/g	ISO 21527-1
(total Y&M <100 cfu/g)		
Enterobacteriaceae*	<10 cfu/g	ISO 21528-2
Aerobic bacterial spores**	<100 cfu/g	heating 12min@80°C, then ISO 4833-2
Sulphite reducing Clostridia spores**	<10 cfu/g	ISO15213
Salmonella**	Not detected in 25g	ISO 6579
Listeria**	Not detected in 25g	ISO 11290-1
E. coli**	Not detected in 1g	ISO 16649-2
Coagulase-positive <i>Staphylococci</i> **	Not detected in 1g	ISO 6888-3

Other requirements

Kosher	Certified
Halal	Certified
GMO	This raw material does not trigger GMO labeling according to EU regulations 1829/2003 and 1830/2003 when used for manufacturing of food or feed products
BSE/TSE	None of the materials used for manufacturing of this raw material are of animal origin. Therefore, there is no risk in relation bovine spongiform encephalopathies (BSE) or any other transmissible spongiform encephalopathies (TSE)
Irradiation	This raw material or its constituents has not been treated by ionising radiation
Radioactivity	Neither the raw material nor any of its components have been exposed to radiological hazards at any point during the manufacturing process
REACH	This raw material does not need to be registered or pre-registered as it a naturally occurring and not chemically modified substance and therefore exempted according to annex V in accordance with EU regulation 1907/2006



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Packaging, delivery and storage

Total shelf life	24 months from the date of manufacture at the recommended storage conditions
Remaining shelf life at delivery	Minimum 75% of total shelf life is acceptable. Less can be accepted for specific deliveries but only after prior agreement with Oterra in writing
Recommended storage conditions	Ambient temperature in original packaging (Optimal: 4-8 °C)
Net content	17 kg per unit
Primary packaging materials	Materials in direct contact with the raw material must comply with relevant food contact regulations
Primary packing type and material	PPCP material
Secondary packaging materials	The units must be delivered on a shrink wrapped and heat treated pallet with a slip sheet
Sealing	Each unit must have tamper evident sealing
Certificate of analysis	Parameters with * in this specification must be specified for each delivery. Manufacturers site, lot/batch number and manufacturing date must specified on each certificate
Surveillance system	Parameters with ** in this specification must be a part of an internal surveillance system at the manufacturers site. Declaration showing conformance must be sent to Oterra when required.
Pre-shipment sample	Please forward pre-shipment samples by courier ASAP upon order confirmation. Pre-shipment samples should be sent in a heat resistant packaging (small steel container).
Traceability	The manufacturers lot/batch number and manufacturing date must be appear on each unit of the delivered goods. In addition, a reference to our purchase order must be available at delivery (on delivery note, certificate, the goods or similar)
Good distribution practice	This raw material must be distributed to Oterra in accordance with relevant regulations and guidelines

For Synthite Industries Private Limited

Manjula Venugopal
AGM - QA, Regulatory & Certifications

