

SCHEDA TECNICA
TECHNICAL DATA SHEET

Product	Marygold (Calendula) flower heads (capitula) dry extract >=5.0% lutein	
Botanic Name	Calendula officinalis L.	
CAS Number	84776-23-8	
Product Code	ECLNO4DR05	Date 08/04/2019
Production Site	Italy	
Extraction Solvent	Water / Ethanol (60/40 V/V)	
Excipients	Maltodextrin	
Auxiliary Substances	<= 0,5% colloidal anhydrous silica	
Tapped Density	about 0,5 g/ml	
Particle size	>= 90% - goes thru sieve nr.500 (sieve method Eur.Ph.)	

Other information	- Control is made on raw material with following limits: $< 5\text{ppb}$ aflatoxine B1 $< 10\text{ppb}$ total aflatoxin (sum of B1, B2, G1 and G2) - Residual pesticides comply to Reg.(EC) No.396/2005 and subs. amendments and updates - product gluten free and not irradiated - Product does not contain and it is not manufactured from OGM - components (EEC Reg. 1829/2003 and 1830/2003) - Storage in cool, dark and dry place The product complies to Reg.(EC) No. 1933/2015
Recommendation of usage in finished products	Extract derived from pre-treated oleoresin of Calendula officinalis flowers. The extract is suggested to be used in finished products at concentration of not more than 10.0% w/w

TEST	LIMITS	METHODS
Characters	Yellowish-orange, fine powder	Inspection
Identification	Positive (TLC may be performed on the extract or on the half-processed product or on the drug)	TLC and/or botanical identification
Content	$\geq 5.0\%$ lutein	HPLC
Drug extract ratio (DER)	8:1 (indicative)	
Loss on drying	$\leq 5\%$	105° C - 3 hours
Residual Solvents	$\leq 0,5\%$ ethanol	Gas Chromatography
Heavy Metals	$\leq 10\text{ ppm}$ (Pb $< 3\text{ ppm}$; Cd $< 1\text{ ppm}$; Hg $< 0.1\text{ ppm}$)	Atomic absorption
Antimicrobial Preservatives	Absent	
Microbial contamination		
Aerobic microorganism *	$\leq 10000\text{ cfu/g}$	as per Eur.Ph
Moulds-Yeasts *	$\leq 100\text{ cfu/g}$	as per Eur.Ph
Enterobacteriaceae	$\leq 100\text{ cfu/g}$	as per Eur.Ph
E.Coli (1 g)	Absent	
Salmonella (25g)	Absent	

* all indicated limits have to be interpreted as 5X according to Eur.Ph

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta.
Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego.
Dermolife non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati.
The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request.
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ALLERGENS FORM

Product(s) name:	Marygold (Calendula) flower heads (capitula) dry extract $\geq 5.0\%$ lutein ECLNO4DR05	
Composition (complete formulation of our products including additives and adjuvants):	– Calendula officinalis flower head (capitula) – Maltodextrin – Colloidal anhydrous silica	
MAIN ALLERGENS	PRESENCE (YES / NO)	QUANTITY (ppm) in case of presence
Sulphur dioxide and sulfites (specify quantity if higher than 10 ppm or 10 mg / kg)	< 10 ppm	
Peanut seed and derived products (including oil)	NO	
Cashew - nut (including oil)	NO	
Walnut (including oil)	NO	
Hazelnut (including oil)	NO	
Brazil nut (including oil)	NO	
Pecan nut (including oil)	NO	
Macadamia nut (including oil)	NO	
Pistachio - nut (including oil)	NO	
Pine kernel (including oil)	NO	
Almond (including oil)	NO	
Eggs and derived products	NO	
Fishes – crustaceans and derived products (including gelatin...)	NO	
Molluscs and derived products	NO	
Soya and derived products (including lecithin..)	NO	
Gluten (specify quantity) of following origin	NO	
▪ Wheat	NO	
▪ Rye	NO	

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▪ Barley	NO	
▪ rustic wheat (lat. spelta)	NO	
▪ oat	NO	
▪ Kamut®	NO	
▪ hybrid species and derived products from gluten	NO	
Milk	NO	
Dairy products including lactose (specify quantity)	NO	
Sesame seed and derived products (including oil)	NO	
Lupin (lat. lupinus) and derived products	NO	
Celery and derived products	NO	
Mustard and derived products	NO	

THERE IS NO RISK OF CROSS-CONTAMINATION IN OUR PLANTS

In case the formula is subjected to modifications or any of the conditions we have guaranteed are changed, we oblige ourselves to inform you immediately.

DATE	POSITION	SIGNATURE OF THE PERSON RESPONSIBLE
April 2019	_____	_____

PRODUCT OF VEGETAL ORIGIN: BSE/TSE FREE

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Raw Material

AGRONOMIC INFORMATION FORMAT	
Plant (Raw Material)	
Scientific (Latin) Name (Genus, species, Author's name):	Calendula officinalis L.
Regulatory reference	Drug included in the D.M. 10 August 2018
Botanical Family:	Compositae
Variety or Chemotype:	not available
Common name:	CALENDULA
English Name:	Marigold
Part used:	flower heads (capitula)
Geographical Origin:	Europe / North Africa
Growth conditions:	
- Cultivated	X
- Wild	
Harvesting conditions:	
- Manual	
- Mechanical	X
Period of harvest	Spring-summer
Primary processing	
- Washing	no
- Pressing	no
- Drying	yes
- Milling	no

* All information included in the present document are strictly in accordance to the original documentation provided by the supplier of the product

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