nVH Italia srl ®
Herbal extracts manufacturers

Product	Calendula flower heads (capitula) mother tincture D/E 1:10 (66°)
Botanic Name	Calendula officinalis L.
CAS Number	84776-23-8
Product Code	ECLNO4TM66
Production site	Italy
Antimicrobial preservatives	Absent

Date 08/04/2019

Other information

Control is made on raw material with following limits: <5 ppb aflatoxin B1
<10 ppb total aflatoxins (sum of B1,B2,G1,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 fro GMO components (EEC Regg. 1829/2003 and 1830/2003)
-Storage in a cool, dark and dry place

The product complies to Reg.(EC) No. 1933/2015

TEST	LIMITS	METHODS
Characters	From Yellowish to brownish, liquid	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		
Ethanol content (%V/V)	62.0 - 66.0	
Density (g/ml)	0.900 - 0.930	
Dry residue (m/m)	<= 5.00%	105°C, 3 hours
Heavy metals	<= 10 ppm (Pb <3 ppm; Cd <1 ppm; Hg <0.1 ppm)	Atomic absorption
Microbial contamination		
Aerobic microrganisms*	<= 10000 c.f.u./g	as per Eur.Ph.
Mould-Yeasts*	<= 100 c.f.u./g	as per Eur.Ph.
Enterobacteriaceae	<= 100 c.f.u./g	as per Eur.Ph.
E.coli (1 g)	Absent	as per Eur.Ph.
Salmonella (25 g)	Absent	as per Eur.Ph.
		as per Eur.Ph.
*	all indicated limits have tobe interpreted as 5X according to Eur.Ph.	

ALLERGENS FORM		
Product(s) name:	**Calendula flower heads (capitula) mother tincture D/E 1:10 (66°)** **ECLNO4TM66**	
Composition (complete formulation of our products including additives and coadjuvants):	– *Calendula officinalis* flower heads (capitula) – Water – Ethanol	
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)	NO	
Peanut seed and derived products (including oil)	NO	
Cashew - nut (including oil)	NO	
Walnut (including oil)	NO	
Hazelnut (includine 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	
▪ 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	

COPY CONFORMING TO THE ORIGINAL, VALID ALTHOUGH NOT SIGNED

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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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*
Veriety 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*

Rev. 00 March 2019