



## **Calendula Oil CLR**

### **Table of Contents**

### **Print Pages**

Raw Material Documentation (6 pages)

2 - 7

Product Specification (3 pages)

8 - 10

Safety Data Sheet (7 pages)

11 - 17



# Calendula Oil CLR

## Raw Material Documentation

---

- 1. Trade name:** Calendula Oil CLR
- Use:** Active for cosmetics
- Manufacturer:** Supplier:  
CLR – Chemisches Laboratorium  
Dr. Kurt Richter GmbH  
Sperenberger Staße 3  
12277 Berlin / Germany  
Tel.: +49 30 851026 – 0
- Contact for information:**  
Sales Department

- 2. Raw Material Composition**
- Chemical Name (IUPAC), Formula*  
Not applicable, as mixture.

*Characterization*

Fatty oil extract of calendula blossoms. The fatty oil used is soybean oil.

*Origin*

plant-derived

- 3. INCI Name**  
**(composition in percentages [ranges] according to FDA recommendations)**

INCI Name	EU Name	Range (FDA)
Glycine Soja (Soybean) Oil	Glycine Soja Oil	> 50 %
Calendula Officinalis Flower Extract	Calendula Officinalis Extract	1 – 5 %
Tocopherol	Tocopherol	< 0.1 %

- 4. Registration**

<i>EINECS Designation:</i> Calendula Officinalis, ext.	<i>EINECS No.:</i> 283-949-5	<i>CAS No.:</i> 84776-23-8
---	---------------------------------	-------------------------------



# Calendula Oil CLR

## Raw Material Documentation

---

### 5. Pharmacopoeial Registration

./.

### 6. Manufacturing Procedure

Calendula blossoms are gently disintegrated and extracted with stabilized soybean oil. Calendula Oil CLR finally is obtained by filtration.

### 7. Raw Material Properties

#### *Appearance, Odor*

Reddish-yellow oily liquid with aromatic herbal odor.

#### *Solubility*

Soluble in oils and fats.

#### *Recommended Use*

Emulsified and oily skin care preparations for the preventive care of normal, sensitive and dry skin (also baby skin). Especially for sun-reddened and stressed skin.

### 8. Analytical Data

#### *Quality Control*

Refractive index $n_D^{20}$	1.473 – 1.475
Density 20 °C	0.918 – 0.922 g/ml
Acid value	< 2.0
Color value (Gardner)	8 – 11
Iodine value (Hanus)	120 – 140
Colony forming units	
Total aerobic microbial count (TAMC)	< 100/ml
Total combined yeasts/moulds count (TYMC)	< 10/ml
	in absence of non conforming organisms

### 9. Methods of Identification

Total of quality control data



# Calendula Oil CLR

## Raw Material Documentation

### 10. Contaminants/Reaction Intermediates occurring in the Raw Material or its Production Process:

Contaminants	not to be expected	Concentrations	Methods
Formaldehyde	x		
Nitrosamines	x		
1,4-Dioxane	x		
Free ethylene oxide	x		
Monochloroacetic acid	x		
Dichloroacetic acid	x		
Monomers	x		
Halogenous organic compounds	*		
Polycyclic aromatic hydrocarbons	*		
Pesticides	*		
Heavy metals			
As		< 0.15 ppm	ICP-OES** ***
Cd		< 0.01 ppm	"
Pb		< 0.2 ppm	"
Hg		< 0.2 ppm	"
Allergenic substances (acc. to 2003/15/EU)			
24 allergens		< 1 mg/kg	GC/MS**
Oakmoss and Treemoss		< 10 mg/kg	"
Others	./.		
* no data available	**spot-checked	***(DIN EN ISO 11885-E22)	

### 11. Stabilizing Additives

Antioxidant: 0.1 % Mixed Tocopherol Concentrate

### 12. Microbiology

Colony forming units (the total of aerobic, anaerobic and fungal colonies): < 100/ml. Check for absence of characteristic pathogenic germs (*Aspergillus niger*, *Candida albicans*, *Staphylococcus aureus*, *E. coli*, *Pseudomonas aeruginosa*) is done using a sample of 0.1 ml.

### 13. Physiological Safety

*Acute Toxicity*

LD<sub>50</sub> oral: > 20 ml/kg body weight (rat):  
non-toxic



# Calendula Oil CLR

---

## Raw Material Documentation

### *Skin tolerance*

An OW cream containing 10% Calendula Oil CLR was applied on 50 volunteers for 48 hours in a patch test. The score concerning erythema, fissures and scaling was always zero. Calendula Oil CLR can be classified as harmless as regards the possibility of skin irritation.

### *Experienced Skin Tolerance under Use Conditions*

Product has been used in cosmetics for many years; negative effects have not been reported.

### *Eye irritation potential*

Calendula Oil CLR has undergone the Draize test. There is no objection to the application of Calendula Oil CLR in the vicinity of the eyes.

### *Sensitization*

Sensitization test/guinea-pig/DGF method:  
non-sensitizing

## **14. Information on Percutaneous Permeation**

no data available

## **15. Genotoxicity**

### *Bacterial Testing*

no data available

### *Non-Bacterial Testing*

no data available

## **16. Human Experience (as far as available)**

Product has been used in cosmetics for many years; negative effects have not been reported.

## **17. Other Information**

### *Chronic Toxicity*

no data available



# Calendula Oil CLR

---

## Raw Material Documentation

### *Subchronic Toxicity*

no data available

### *Teratogenicity*

no data available

### *Toxicokinetics*

no data available

### *Additional Genotoxicological Tests (as far as required)*

no data available

### *Mutagenicity*

no data available

### *BSE Hazard*

No BSE risk analysis required because Calendula Oil CLR is purely plant-derived.

## **18. Potential Risks presented by UV Exposure and on Inhalation**

### *Phototoxicity*

no data available

### *Photosensitization*

no data available

### *Toxicity on Inhalation*

no data available



# Calendula Oil CLR

Raw Material Documentation

---

## 19. Ecology

### *Biodegradability*

As soybean oil based herbal extract, Calendula Oil CLR is non-toxic and easily biodegradable.

### *Acute Aquatic Toxicity*

- Bacteria
  - Algae
  - Daphnia
  - Fish
- } no data available

### *Water Pollution Hazard Class:*

Product presents no water pollution hazard  
(self-classification)

authorized by:

W. Reinhold  
(Director Quality Assurance)  
– valid without signature –



# Calendula Oil CLR

## Product Specification

### Characteristics

Calendula Oil CLR contains the lipid-soluble constituents of calendula blossoms in a vegetable oil medium. The calendula blossoms used are gently disintegrated using a special technique and extracted with soybean oil.

Natural tocopherol is used to stabilize Calendula Oil CLR against rancidity.

INCI Name	CAS No.	EINECS No.
Glycine Soja (Soybean) Oil (EU Name: Glycine Soja Oil)	8001-22-7	232-274-4
Calendula Officinalis Flower Extract (EU Name: Calendula Officinalis Extract)	84776-23-8	283-949-5
Tocopherol	1406-18-4	215-798-8

### Analytical Data

Ratio of the extract to actual drug: 10 parts of Calendula Oil correspond to 1 part of calendula blossoms.

Refractive index $n_D^{20}$	1.473 – 1.475
Density 20 °C	0.918 – 0.922 g/ml
Acid value	< 2,0
Color value (Gardner)	8 – 11
Iodine value (Hanus)	120 – 140
Colony forming units	
Total aerobic microbial count (TAMC)	< 100/ml
Total combined yeasts/moulds count (TYMC)	< 10/ml
	in absence of non conforming organisms

### Physiological Safety

#### *Acute oral toxicity*

LD<sub>50</sub> oral: > 20 ml per kg bodyweight (rat).

Calendula Oil CLR is hence to be designated as non-toxic.

#### *Eye irritation potential*

Calendula Oil CLR has undergone the Draize test. There is no objection to the application of Calendula Oil CLR in the vicinity of the eyes.





# Calendula Oil CLR

---

## Product Specification

### *Skin tolerance*

An O/W cream containing 10% Calendula Oil CLR was applied on 50 volunteers for 48 hours in a patch test. The score concerning erythema, fissures and scaling was always zero. Calendula Oil CLR can be classified as harmless as regards the possibility of skin irritation.

### **Mode of action**

Topically applied calendula extracts help fissured and injured skin. Extracts from calendula blossoms are bacteriostatic and suppress both inflammation and leucocyte infiltration (5). These anti-inflammatory effects are produced by triterpenoids (1, 2). Through their stimulating effect on the metabolism of glycoproteins, nucleoproteins and collagen, calendula extracts help stimulate skin regeneration and epithelialization, thus improving wound healing (4). In vitro, calendula extracts were even found to have anti-HIV activity (3).

### **Application**

As fatty oil extract from calendula blossoms with properties generally beneficial to the skin, Calendula Oil CLR is suitable for preventive care of normal, dry or sensitive skin (inc. baby skin).

Preparations with Calendula Oil CLR are especially suitable for application to rough, brittle, chapped or otherwise slightly damaged skin (worn hands, sunburn).

It can be used in emulsified and oily skin care products.

### **Dosage**

3.0 % - 10.0 %

### **Appearance/Odor**

Reddish-yellow oil. Herbal odor.

### **Solubility**

Soluble in fats and oils.

### **Processing**

Due to the natural character of the product slight turbidity might occur at temperatures below approx. 20 °C.



# Calendula Oil CLR

---

## Product Specification

Calendula Oil CLR tolerates short heating to the temperatures required for the manufacture of emulsified preparations. Cosmetics with Calendula Oil CLR have a yellowish (skin oils) to ivory (creams, liquid emulsions) tinge.

Cosmetics with Calendula Oil CLR can be perfumed without difficulty.

### Storage

Storage at cellar to room temperature (15 - 25° C), in well closed containers, protected from light. Product packs should be fully used once opened. Under these conditions Calendula Oil CLR is stable for at least 1 year.

### Packing

Pack size: 5 kg; 25 kg

Sample size: 50 g

### References

1. Akihisa, T., K. Yasukawa, H. Oinuma, Y. Kasahara, S. Yamanouchi, M. Takido, K. Kumaki, and T. Tamura. 1996. Triterpene alcohols from the flowers of compositae and their anti-inflammatory effects. *Phytochemistry*. 43:1255-1260.
2. Della Loggia, R., A. Tubaro, S. Sosa, H. Becker, S. Saar, and O. Isaac. 1994. The role of triterpenoids in the topical anti-inflammatory activity of *Calendula officinalis* flowers. *Planta Med.* 60:516-520.
3. Kalvatchev, Z., R. Walder, and D. Garzaro. 1997. Anti-HIV activity of extracts from *Calendula officinalis* flowers. *Biomed Pharmacother.* 51:176-180.
4. Klouček-Popova, E., A. Popov, N. Pavlova, and S. Krusteva. 1982. Influence of the physiological regeneration and epithelialization using fractions isolated from *Calendula officinalis*. *Acta Physiol Pharmacol Bulg.* 8:63-67.
5. Shipochliev, T., A. Dimitrov, and E. Aleksandrova. 1981. Anti-inflammatory action of a group of plant extracts. *Vet Med Nauki.* 18:87-94.

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Calendula Oil CLR  
Revision date : 27.06.2016  
Print date : 15.03.2017

Version (Revision) : 3.3.0 (3.2.0)

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

### 1.1 Product identifier

Calendula Oil CLR (140)

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

#### Relevant identified uses

Cosmetics, personal care products

#### Uses advised against

No information available.

#### Remark

The product is intended for professional use.

### 1.3 Details of the supplier of the safety data sheet

#### Supplier (manufacturer/importer/only representative/downstream user/distributor)

CLR Chemisches Laboratorium  
Dr. Kurt Richter GmbH

**Street :** Sperenberger Strasse 3

**Postal code/city :** D-12277 Berlin

**Telephone :** +49 30 851026-0

**Telefax :** +49 30 851026-85

**Information contact :** Info@clr-berlin.com

### 1.4 Emergency telephone number

+49 30 851026-0 (Available at: Mon.-Thu. 8.00 am - 4.30 pm; Fri. 8.00 am - 3.30 pm)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008 [CLP]

None

### 2.2 Label elements

According to EC directives or the corresponding national regulations the product does not have to be labelled.

### 2.3 Other hazards

None

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Description

Fatty oil extract from calendula blossoms. The fatty oil used for extraction is soybean oil.

#### Hazardous ingredients

None

**This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH**

None

**This mixture contains the following substances of very high concern (SVHC) which are subject to authorisation according to Annex XIV of REACH**

None

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Calendula Oil CLR  
Revision date : 27.06.2016  
Print date : 15.03.2017

Version (Revision) : 3.3.0 (3.2.0)

## Additional information

All ingredients of this mixture are (pre)registered according to REACH regulation.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### Following inhalation

Provide fresh air.

#### In case of skin contact

Water and soap

#### After eye contact

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

#### After ingestion

Do NOT induce vomiting.

### 4.2 Most important symptoms and effects, both acute and delayed

No information available.

### 4.3 Indication of any immediate medical attention and special treatment needed

None

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Foam Carbon dioxide (CO<sub>2</sub>) Dry extinguishing powder

#### Unsuitable extinguishing media

Water

### 5.2 Special hazards arising from the substance or mixture

#### Hazardous combustion products

Carbon dioxide (CO<sub>2</sub>) Carbon monoxide Acrolein

### 5.3 Advice for firefighters

Do not inhale explosion and combustion gases.

### 5.4 Additional information

Do not allow run-off from fire-fighting to enter drains or water courses.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

No special measures are necessary.

### 6.2 Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

### 6.4 Reference to other sections

None

## SECTION 7: Handling and storage

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Calendula Oil CLR  
Revision date : 27.06.2016  
Print date : 15.03.2017

Version (Revision) : 3.3.0 (3.2.0)

## 7.1 Precautions for safe handling

### Protective measures

#### Measures to prevent fire

Take precautionary measures against static discharges.

## 7.2 Conditions for safe storage, including any incompatibilities

### Hints on joint storage

Storage class : 10

Storage class (TRGS 510) : 10

### Further information on storage conditions

Protect against : Contact with air/oxygen. UV-radiation/sunlight

Storage temperature : 15 - 25 °C (59 - 77 °F)

## 7.3 Specific end use(s)

None

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### DNEL/DMEL and PNEC values

##### DNEL/DMEL

No substance related limit value derivable.

##### PNEC

No substance related limit value derivable.

### 8.2 Exposure controls

#### Personal protection equipment



#### Eye/face protection

##### Suitable eye protection

Eye glasses with side protection

#### Skin protection

##### Hand protection

Suitable gloves type : Disposable gloves.

Suitable material : PE (polyethylene) NR (natural rubber, natural latex) NBR (Nitrile rubber)

Thickness of the glove material : > 0.1 mm

#### Respiratory protection

Usually no personal respirative protection necessary.

#### General health and safety measures

When using do not eat, drink, smoke, sniff. Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Calendula Oil CLR  
Revision date : 27.06.2016  
Print date : 15.03.2017

Version (Revision) : 3.3.0 (3.2.0)

Physical state : liquid  
Colour : yellow yellow-orange

## Odour

characteristic

## Safety relevant basis data

Initial boiling point and boiling range :	( 1013 hPa )	No data available
Flash point :	approx.	320 °C
Vapour pressure :	( 50 °C )	No data available
Density :	( 20 °C )	0,918 - 0,922 g/cm <sup>3</sup>
Solvent separation test :	( 20 °C )	No data available
Water solubility :	( 20 °C )	insoluble
pH :		not applicable
Viscosity :	( 20 °C )	approx. 60 mPa.s

## 9.2 Other information

None

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No information available.

### 10.2 Chemical stability

No information available.

### 10.3 Possibility of hazardous reactions

No information available.

### 10.4 Conditions to avoid

No information available.

### 10.5 Incompatible materials

No information available.

### 10.6 Hazardous decomposition products

No information available.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute effects

##### Acute oral toxicity

Parameter :	LD50
Exposure route :	Oral
Species :	Rat
Effective dose :	> 20 mL/kg

#### Irritant and corrosive effects

##### Primary irritation to the skin

Parameter :	Primary irritation to the skin
Species :	Rabbit
Result :	Not irritant
Method :	Draize test (10 % in liquid paraffin):

##### Irritation to eyes

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Calendula Oil CLR  
Revision date : 27.06.2016  
Print date : 15.03.2017

Version (Revision) : 3.3.0 (3.2.0)

Parameter : Irritation to eyes  
Species : Rabbit  
Result : Not irritant  
Method : Draize test (10 % in liquid paraffin):

## Sensitisation

### In case of skin contact

Parameter : Sensitisation  
Species : Guinea pig  
Result : Not sensitizing  
Method : DGF method

## CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

The ingredients in this mixture do not meet the criteria for classification as CMR category 1A or 1B according to CLP.

## SECTION 12: Ecological information

### 12.1 Toxicity

No information available.

### 12.2 Persistence and degradability

#### Biodegradation

Biodegradable.

### 12.3 Bioaccumulative potential

No information available.

### 12.4 Mobility in soil

No information available.

### 12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

### 12.6 Other adverse effects

No information available.

### 12.7 Additional ecotoxicological information

None

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

##### Waste code product

Waste code (91/689/EEC) : 20 01 26\*

##### Waste code packaging

Waste code (91/689/EEC) : 15 01 02

#### Waste treatment options

##### Appropriate disposal / Product

Dispose of waste according to applicable legislation.

##### Appropriate disposal / Package

Completely emptied packages can be recycled.

## SECTION 14: Transport information

### 14.1 UN number

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Calendula Oil CLR  
Revision date : 27.06.2016  
Print date : 15.03.2017

Version (Revision) : 3.3.0 (3.2.0)

No dangerous good in sense of these transport regulations.

#### 14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

#### 14.3 Transport hazard class(es)

##### Land transport (ADR/RID)

No dangerous good in sense of these transport regulations.

Class(es) : -

##### Sea transport (IMDG)

No dangerous good in sense of these transport regulations.

Class(es) : -

##### Air transport (ICAO-TI / IATA-DGR)

No dangerous good in sense of these transport regulations.

Class(es) : -

#### 14.4 Packing group

No dangerous good in sense of these transport regulations.

#### 14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

#### 14.6 Special precautions for user

None

### SECTION 15: Regulatory information

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

##### National regulations

##### Water hazard class (WGK)

Class : nwg (Non-hazardous to water) Classification according to VwVwS

##### Additional information

##### Substance/product listed in the following inventories

EINECS/ELINCS DSL/NDL IECSC

#### 15.2 Chemical safety assessment

No information available.

### SECTION 16: Other information

#### 16.1 Indication of changes

02. Label elements · 03. This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH · 03. This mixture contains the following substances of very high concern (SVHC) which are subject to authorisation according to Annex XIV of REACH

#### 16.2 Abbreviations and acronyms

None

#### 16.3 Key literature references and sources for data

None

#### 16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

No information available.

#### 16.5 Relevant H- and EUH-phrases (Number and full text)

None



# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Calendula Oil CLR  
Revision date : 27.06.2016  
Print date : 15.03.2017

Version (Revision) : 3.3.0 (3.2.0)

---

## 16.6 Training advice

None

## 16.7 Additional information

None

---

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

---