

Product Information Healthcare Solution

DOW CORNING

Dow Corning® Emulsifier 10

FEATURES & BENEFITS

- Make very stable W/O emulsions
- Formulation flexibility
- Emulsion with high water content
- Low emulsifier use level
- Hot and cold manufacturing process
- Co-emulsifier for O/W emulsion
- Multiple phase (W/O/W) emulsions
- Easy to spread
- Wide range of emulsion from: W/O, W/O/W and water-in-wax

COMPOSITION

- Alkyl methyl siloxane copolyol (main component)
- **INCI name:** Lauryl PEG/PPG – 18/18 Methicone
- Cas number: 212335-52-9, 112-41-4, 27458-93-1, 9003-11-6

COMPOSITION

Dow Corning can provide the following information:

- Letter of Authorization to Drug Master File maintained with the United States Food and Drug Administration (U.S. FDA)
- Technical File based on ICH CTD (International Conference on Harmonisation Common Technical Document) format
- Product Regulatory Information
- Elemental Impurities
- Summary of Health Data

Excipient for pharmaceutical applications

APPLICATIONS

- *Dow Corning*® Emulsifier 10 is a silicone emulsifier designed to prepare water in oil emulsions or water in silicone and organic oil emulsions.
- *Dow Corning* Emulsifier 10 provides very stable water-in-oil systems without the addition of waxes; up to 80% of water phase.
- This silicone emulsifier is currently used in range of dermatological treatments and pharmaceutical applications including creams, gels and sticks.

TYPICAL PROPERTIES

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

Property	Unit	Result
Appearance		Transparent, clear to light straw liquid
Viscosity at 25°C	mm ² /s	1100–3500
Refractive index at 25°C		1.452
Specific gravity at 25°C		0.9
Hydrophilic-lipophilic balance (HLB)		2.2

DESCRIPTION

- *Dow Corning* Emulsifier 10 is an alkylmethyl silicone polyglycol, 100% silicone polyether.
- It is very effective at producing water-in-oil emulsions with a low to medium polarity oil phase. It also can be used as a co-emulsifier in oil-in-water system.
- *Dow Corning* Emulsifier 10 enables the formulation of creams at room temperature, which can typically results in lower processing costs and faster processing times.
- *Dow Corning* Emulsifier 10 is a very efficient emulsifier and typically leads to water-in-oil formulations exhibiting excellent stability at high water concentration

(typically up to 80%) and low emulsifier levels (typically 2%).

SPECIFIC TESTING

- Infrared identification on each batch
- Tested for elemental impurities according to <232> and ICH Q3D guideline for metal impurities, every 2 years

HOW TO USE

Water-oil-emulsion

- The recommended use level of *Dow Corning* Emulsifier 10 is 2% for an oil phase ranging from 18% to 25% of low polarity oil (e.g. mineral oil) and from 25% to 28% for medium polarity oil (e.g. octyl palmitate). Generally, no heating

is required to produce these water-in-oil creams unless high melting point ingredients are incorporated.

- Stable emulsions can be prepared by **slowly** adding the water phase in the oil phase using a variety of common devices. The oil phase should be prepared first by mixing the *Dow Corning* Emulsifier 10 with the selected fluid (from low to medium polarity). High shear mixing at the end of the emulsification process will decrease particle size and build the viscosity.
- To ensure optimum stability of the final emulsion, the following procedure are recommended:
 - a) Regulate the speed of addition of water phase into the oil phase so there is continuous incorporation of the water in oil. Water should not be allowed to build up on the surface during the emulsification process.
 - b) **Stirrer and homogenizer:** the water phase is added very slowly to the oil phase with high speed agitation. The final emulsion is then processed through a homogenizer.
 - c) **Turbine type equipment:** Turbine is set to medium speed during the water addition. Turbine set to maximum speed to build the viscosity at the end.
 - d) Use sodium chloride (1%) in the water phase to formulation stability.
- The emulsion viscosity can be increased by the addition of water, within the limits defined above. Conversely, the viscosity of the formulation can be decreased by increasing the oil phase volume (up to 35%), but the emulsifier level needs to be increased accordingly.
- Cold and hot processes can be used to prepare emulsions.

Co-emulsifier for oil-in-water emulsions

- *Dow Corning* Emulsifier 10 is an efficient co-emulsifier for oil-in-water emulsions at concentrations between 0.5% and 0.9 %.

Clear shampoos and shower gels

- *Dow Corning* Emulsifier 10 can be easily incorporated into clear shampoos and shower gels.
- *Dow Corning* Emulsifier 10 is mixed with fatty acid alkanolamides heated to 60°C. A thickening agent is required to adjust the viscosity of the system

REGULATORY INFORMATION

Dow Corning Emulsifier 10 is produced at the *Dow Corning* Midland plant in Midland, Michigan and further tested and packaged at the *Dow Corning* Healthcare Industries Materials Site (HIMS) in Hemlock, Michigan. The HIMS facility is dedicated to the production of silicone materials for healthcare applications. The Healthcare Industries Materials Site is registered as drug establishment with the United States Food and Drug Administration. The site registration number is 1816403. The site quality system for pharmaceutical excipients utilizes principle of current Good Manufacturing Practices for Bulk Pharmaceutical Products. Both the *Dow Corning* Midland and Hemlock facilities are registered as part of *Dow Corning's* global quality system according to ISO 9001:2008.

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HANDLING

PRECAUTIONS

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE SAFETY DATA SHEET IS AVAILABLE ON THE DOW CORNING WEBSITE AT DOWCORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

USABLE LIFE AND STORAGE

When stored at or below 25°C in original unopened containers *Dow Corning* Emulsifier 10 has and usable life of 30 months from the date of production.

PACKAGING INFORMATION

Dow Corning Emulsifier 10 is available in pails.

Samples for *Dow Corning* Emulsifier 10 are available in bottles.

LIMITATIONS

Shipping: None.

This product is not tested for specific pharmaceutical use(s). Should you wish to use this product in a pharmaceutical application, please contact *Dow Corning* to discuss such potential use.

It remains the User's responsibility to ensure the safety, efficacy and legal and regulatory compliance in each relevant jurisdiction (including targeted geographic regions of manufacture and supply) of these materials for its intended uses.

Dow Corning makes no representation concerning the suitability of these products for any particular medical or pharmaceutical application. Under no circumstances should these materials be considered for implantation into the human body for periods that exceed 30 days in duration.

HEALTH AND ENVIRONMENTAL INFORMATION

To support customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION – PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate at the date the information is provided. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that our products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that our products will meet the sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, DOW CORNING SPECIFICALLY DISCLAIMS

ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 1: Compatibility Data

Type of material	10% <i>Dow Corning</i> [®] Emulsifier 10	50% <i>Dow Corning</i> [®] Emulsifier 10	90% <i>Dow Corning</i> [®] Emulsifier 10
Alcohols and polyols			
Ethanol	C	C	C
Isopropanol	C	C	C
Glycerin	NC	NC	NC
Octyldodecanol	C	C	C
Propylene Glycol	NC	NC	NC
Squalane	C	C	C
Oils			
Almond oil	C	C	C
Castor oil	NC	NC	NC
Esters			
Caprylic/Capric Triglyceride	C	C	C
C12-C15 Alkyl Benzoate	C	C	C
Coco-Caprylate/Caprates	C	C	C
Diisopropyl Adipate	C	NC	C
Isopropyl Myristate	C	C	C
Isopropyl Palmitate	C	C	C
Hydrocarbons			
Mineral oil	C	C	C
Petrolatum	C	NC	C
Silicones			
Hexamethyldisiloxane	C	C	C
Octamethyltrisiloxane	C	C	C
Dimethicone (20 cSt)	NC	C	C
Dimethicone and Dimethiconol	NC	NC	NC
Hexamethyldisiloxane and Dimethiconol	C	C	C
Cyclopentasiloxane	C	C	C
Glyceryl Esters			
Apricot Kernel Oil PEG-6 Esters	C	C	C
Alkoxyated Alcohol			
PEG-15 Stearyl Ether	C	NC	NC
PEG 8	NC	NC	NC

C = Compatible, NC=Non Compatible (forms 2 phases)