

Product Information

Healthcare

Solution

DOW CORNING

Dow Corning® Dimethiconol Blend 20

FEATURES & BENEFITS

- Clear
- Non-volatile fluid as carrier
- Substantive
- Non-occlusive
- Film former
- Long-lasting
- Wash off resistance
- Smooth and lubricious feel

COMPOSITION

- High molecular weight hydroxy-terminated polydimethylsiloxane (dimethiconol) in a low viscosity and non-volatile silicone fluid
- INCI name: Dimethicone and Dimethiconol
- Cas number: 70131-67-8 and 63148-62-9

REGULATORY SUPPORT

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 for the ingredients
- Summary of Health Data

Excipient for pharmaceutical applications

APPLICATIONS

- Dow Corning® Dimethiconol Blend 20 is commonly used in pharmaceutical formulations thanks to its long lasting, film barrier and wash-off resistance properties.
- Such silicone gum blends are currently used in a range of dermatological and pharmaceutical applications such as protective and barrier creams, gels for scar treatment and formulations for skin and scalp treatments.

TYPICAL PROPERTIES

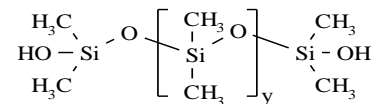
Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

Property	Unit	Result
Appearance		Crystal clear liquid
Viscosity at 25°C (77°F)	mPa.s	387
Refractive index at 25°C (77°F)		1.4011
Specific gravity at 25°C (77°F)		0.952
Silicone content	%	100
Dimethiconol content	%	6
Flash point	°C (°F)	200 (392°F)

DESCRIPTION

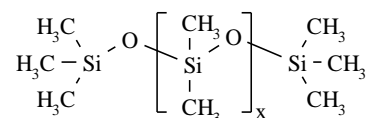
Dow Corning® Dimethiconol Blend 20 is a blend of an ultra high molecular weight hydroxy-terminated polydimethylsiloxane (dimethiconol) in a low viscosity and non-volatile silicone fluid (dimethicone, 20 cSt).

And



where y = approx. 8000

Figure 1: The chemical structure of the two blend components:



where x = approx. 26

SPECIFIC TESTING

- Infrared identification on each batch
- Dow Corning Dimethiconol Blend 20 has not been tested for Elemental Impurities but the ingredients used to make the blend have been tested according to <232> and ICH Q3D guideline for metal impurities.

HOW TO USE

Dow Corning Dimethiconol Blend 20 is an easy to use blend of dimethicone and dimethiconol. It is compatible with a range of topical excipients (refer to Table 1).

Dow Corning Dimethiconol Blend 20 can be added to various anhydrous or water based formulations.

Dow Corning Dimethiconol Blend 20 can be used alone or blended with other excipient to provide a fluid base for a variety of formulation and provide a smooth, long lasting film on skin.

The presence of *Dow Corning* Dimethiconol Blend 20 can increase the viscosity of water-in-oil emulsions.

When preparing an emulsion containing *Dow Corning* Dimethiconol Blend 20, it is recommended to add the oil(s) to the silicone blend under high shear speed; the emulsion can then potentially be processed through a homogenizer to improve its stability.

The blend is easily emulsified in water with standard emulsifiers and normal emulsification techniques.

REGULATORY INFORMATION

Dow Corning Dimethiconol Blend 20 is produced, 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 application. 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. This site is 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 (77°F) in original unopened containers *Dow Corning* Dimethiconol Blend 20 has and usable life of 24 months from the date of production.

PACKAGING INFORMATION

Dow Corning Dimethiconol Blend 20 is available in pails and in drums.

Samples for *Dow Corning* Dimethiconol Blend 20 are available in bottles.

LIMITATIONS

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.

SHIPPING LIMITATIONS

Shipping: None

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. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customers' 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> Dimethiconol Blend 20	50% <i>Dow Corning</i> Dimethiconol Blend 20	90% <i>Dow Corning</i> Dimethiconol Blend 20
Alcohols and polyols			
Ethanol	C	NC	NC
Isopropanol	C	NC	NC
Ethoxydiglycol	NC	NC	NC
Glycerin	NC	NC	NC
Octyldodecanol	NC	NC	C
Propylene glycol	NC	NC	NC
Squalane	NC	NC	C
Oils			
Almond oil	NC	NC	NC
Castor oil	NC	NC	NC
Soybean oil	NC	NC	NC
Sun flower	NC	NC	NC
Esters			
Caprylic/Capric Triglyceride	NC	NC	C
C12-C15 alkyl benzoate	NC	NC	C
Coco-caprylate/capratae	NC	NC	C
Diisopropyl Adipate	C	NC	C
Isopropyl Myristate	C	C	C
Isopropyl Palmitate	C	C	C
Hydrocarbons			
Mineral oil	C	C	C
Isododecane	C	C	C
Petrolatum	C	NC	NC
Silicones			
Hexamethyldisiloxane	C	C	C
Octamethyltrisiloxane	C	C	C
Dimethicone (20 cSt)	C	C	C
Dimethicone (100 cSt)	C	C	C
Dimethicone (350 cSt)	C	C	C
Dimethicone (1000 cSt)	C	C	C
Dimethicone (12,500 cSt)	C	C	C
Dimethicone and Dimethiconol	C	C	C
Hexamethyldisiloane and Dimethiconol	C	C	C
Cyclopentasiloxane	C	C	C

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

Table 1: Compatibility data (continued)			
Type of material	10% <i>Dow Corning</i> Dimethiconol Blend 20	50% <i>Dow Corning</i> Dimethiconol Blend 20	90% <i>Dow Corning</i> Dimethiconol Blend 20
Glyceryl Esters			
Apricot Kernel Oil PEG-6 Esters	NC	NC	NC
Alkoxylated Alcohol			
PEG-15 Stearyl Ether	NC	NC	NC
PEG 8	NC	NC	NC

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