



326 Exchange Drive
Arlington, Texas 76011
817-469-7777

Technical Data Sheet SPI-350 NF

Applications:

As an excipient (inactive ingredient), SPI-350NF can be used in topical pharmaceutical applications. The product functions to provide emolliency, ease of spreading, smooth feel, long lasting lubrication, and reduced tackiness.

SPI-350NF is currently used in a wide range of dermatological treatments and pharmaceutical applications. It is also used to help prevent and temporarily protects skin and lips against chafing, chapping, cracking and windburn.

SPI-350NF is tested according to and complies with all Natural Formulary (NF) requirements for Dimethicone and is within accordance to FDA guidelines.

Composition Information:

Chemical Name: Polydimethylsiloxane
INCI Name: Dimethicone
CAS Number: 63148-62-9

Features:

- ✦ Clear
- ✦ Spreadability
- ✦ Water Repellant
- ✦ Non-occlusive
- ✦ Emollient
- ✦ Smooth Feel
- ✦ Lubricity
- ✦ Skin Protectant

Test Data/Units	Specification	Typical Result
Refractive Index @ 25°C	1.4013 – 1.4053	~1.403
Specific Gravity @ 25°C	0.967-0.975	~.970
Viscosity	332 – 368 cSt	350
Volatile Content,	0.0 - 0.3%	Pass

Specific Testing:

SPI-350NF is tested for elemental impurities according to <232> and ICH Q3D guideline for metal impurities and infrared identification on each batch.

Limitations:

SPI-350NF Silicone Fluid is not intended for use in parenteral drug applications. This material is not to be used as a new drug or new device as defined by regulatory authorities until the user has obtained appropriate until the user has obtained



326 Exchange Drive
Arlington, Texas 76011
817-469-7777

appropriate approval from those regulatory authorities. This fluid is not approved by the FDA for tissue augmentation and Silicones Plus does not support this use.

Handling and Precautions:

Product safety information required for safe use is not included in this document. Before handling, read Safety Data Sheets and container labels for safe use, physical and health hazards information. Safety Data Sheet will be available upon request through the below listed contact information.

Shelf Life:

3 year from date of manufacture when stored in unopened original container at temperatures between 5°C and 35°C.

This data is offered in good faith as typical values and not as a Product Specification. No warranty, either expressed or implied, is hereby made. SILICONES PLUS INC. believes that the information contained in this publication is an accurate description of the typical characteristics and/or uses of this product but it is your responsibility to thoroughly test the product in your specific application to determine its performance, efficacy and safety. Suggestions of uses should not be taken as inducements to infringe any particular patent.

Company Details:

Silicones Plus, Inc.
326 Exchange Drive Arlington, Texas 76011
Email: samples@siliconesplus.com

P: 817-469-7777
F: 817-303-7070
www.siliconesplus.com