

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 21-084

CHEMISTRY REVIEW(S)

JAN 21 2000

U.S. FOOD and DRUG ADMINISTRATION

OFFICE OF NEW DRUG CHEMISTRY

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS

—Review of Chemistry, Manufacturing, and Controls—

NDA #: 21-084

CHEM.REVIEW #: 1

REVIEW DATE: January 10, 2000

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	18-AUG-99	19-AUG-99	20-AUG-99
BC	02-SEP-99	03-SEP-99	04-SEP-99
BC	09-DEC-99	09-DEC-99	09-DEC-99

NAME & ADDRESS OF APPLICANT:

Commander
U.S. Army Medical Research and Material Command
ATTN: MCMR-RCQ-RA
504 Scott Street
Ft. Detrick, MD 21702-5012

Contact:
Daikie Liu, Ph.D.
(301) 619-2051

DRUG PRODUCT NAME

Proprietary:
Nonproprietary/USAN:

Topical Skin Protectant
Fomblin Y25 TSP and Polymist F5A TSP
50% Perfluoroalkylpolyether (PFPE) plus 50%
Polytetrafluoroethylene (PTFE)

Code Names/#'s:
Chemical Type:
Therapeutic Class:

1
P

PATENT STATUS:

U.S. Patent No. 5,607,979

Issue date:

04 March 1997

Expiration date: 30 May 2015

Patent Owner:

The United States of America as represented by the Secretary
of the Army.

Type of Patent:

Drug product composition

Claims:

The formulation and composition of a cream made of certain
PTFE resins as protectants against CW agents.

PHARMACOLOGICAL INDICATION:

Barrier paste for protection against chemical
warfare agents.

NDA 21-084 Topical Skin Protectant
U.S. Army-Office of the Surgeon General

DOSAGE FORM:

paste

STRENGTHS:

neat

ROUTE OF ADMINISTRATION:

topical

DISPENSED:

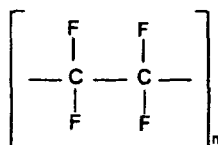
X R, ___ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLC. FORMULA & WT:

- A. Polytetrafluoroethylene (PTFE), known commercially as Teflon

CAS number: 9002-84-0

Structure:

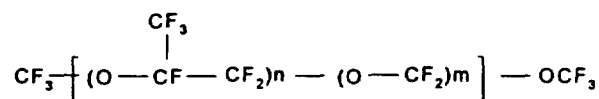


- B. Chemical nomenclature: Perfluoroalkylpolyether (PFPE) (oil)

CAS number:

69991-67-9

Structure:



SUPPORTING DOCUMENTS:

IND	_____	Topical Skin Protectant; U.S. Army
DMF	_____	Type II. _____ Fomblin Y25 TSP. Letter of authorization for FDA access dated 09-AUG-99. Date of last review: 23-SEP-99.
DMF	_____	Type II. _____ Polymist F5A TSP. Letter of authorization for FDA access dated 165-JUN-98. Date of last review: 15-OCT-99.
DMF	_____	Type III. _____ Letter of authorization for FDA access 16-JUN-98. Date of last review: DEC-99.
DMF	_____	Type I. _____ Letter of authorization for FDA access: 13-OCT-87. Date of last review: Not reviewed.

NDA 21-084 Topical Skin Protectant
U.S. Army-Office of the Surgeon General

RELATED DOCUMENTS: None

CONSULTS: Labeling and Nomenclature Committee; Microbiology

REMARKS/COMMENTS:

1. The recommendation is made to call Topical Skin Protectant a *paste* and not a *_____* see discussion in Section F, Labeling.
2. An information request letter was issued 24-SEP-99 regarding the drug substance Fomblin Y25 TSP, referenced in DMF *_____*
3. An information request letter was issued 05-NOV-99 regarding the drug substance Polymist F5A TSP, referenced in DMF *_____*
4. A CMC information request letter for NDA 21-084 was issued 10-NOV-99. A copy of this letter is presented in Appendix IV.

CONCLUSIONS & RECOMMENDATIONS:

The application is recommended as APPROVABLE under section 505 of the FFD&C Act, pending an overall EER recommendation.

/S/

William C. Timmer, Ph.D.
Review Chemist, HFD-540/830

/S/

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, HFD-540/830 *1/24/00*

cc:

Original DMF (2 copies)
HFD-540/DMF/Division File
HFD-540/DD/JWilkin
HFD-540/Chem/WCTimmer
HFD-540/ChemTL/WHDeCamp
HFD-540/PM/FHCross
HFD-540/MO-TL/SWalker
HFD-540/MO/MOkun
HFD-540/Pharm-TL/AJacobs
HFD-540/Pharm/LReid
HFD-540/Biopharm/EDBashaw
HFD-830/DD/CWChen
HFD-830/DDD/BBDunn
File Name: _____

/S/ 1/28/00

/S/ 2/4/00

FEB 7 2000

U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF NEW DRUG CHEMISTRY

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS
 ---Review of Chemistry, Manufacturing, and Controls---

NDA #: 21-084 CHEM.REVIEW #: 2 REVIEW DATE: February 7, 2000

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	18-AUG-99	19-AUG-99	Chem Review #1
BC	02-SEP-99	03-SEP-99	Chem Review #1
BZ	32-NOV-99	24-NOV-99	24-NOV-99
BC	09-DEC-99	09-DEC-99	Chem Review #1
BC	26-JAN-00	27-JAN-00	28-JAN-00

NAME & ADDRESS OF APPLICANT:

Commander
 U.S. Army Medical Research and Materiel Command
 ATTN: MCMR-RCQ-RA
 504 Scott Street
 Ft. Detrick, MD 21702-5012

Contact:
 Daikee Liu, Ph.D.
 (301) 619-2051

DRUG PRODUCT NAME

Proprietary:
Nonproprietary/USAN:

Topical Skin Protectant
 Fomblin Y25 TSP and Polymist F5A TSP
 50% Perfluoroalkylpolyether (PFPE) plus 50%
 Polytetrafluoroethylene (PTFE)

Code Names/#'s:
Chemical Type:
Therapeutic Class:

1
 P

PATENT STATUS:

U.S. Patent No. 5,607,979

Issue date:	04 March 1997
Expiration date:	30 May 2015
Patent Owner:	The United States of America as represented by the Secretary of the Army.
Type of Patent:	Drug product composition
Claims:	The formulation and composition of a cream made of certain PTFE resins as protectants against CW agents.

PHARMACOLOGICAL INDICATION:

Barrier paste for protection against chemical warfare agents.

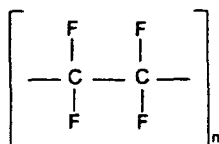
NDA 21-084 Topical Skin Protectant
U.S. Army-Office of the Surgeon General

FEB - 7 2000

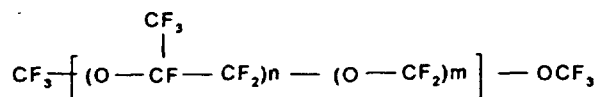
DOSAGE FORM: paste
STRENGTHS: neat
ROUTE OF ADMINISTRATION: topical
DISPENSED: X R, OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLC. FORMULA & WT:

- A. Polytetrafluoroethylene (PTFE), known commercially as Teflon
CAS number: 9002-84-0
Structure:



- B. Chemical nomenclature: Perfluoroalkylpolyether (PFPE) (oil)
CAS number: 69991-67-9
Structure:



SUPPORTING DOCUMENTS:

IND	—	Topical Skin Protectant; U.S. Army
DMF	—	Type II. ————— Fomblin Y25 TSP. Letter of authorization for FDA access dated 09-AUG-99. Date of last review: 23-SEP-99.
DMF	—	Type II. ————— Polymist F5A TSP. Letter of authorization for FDA access dated 16-JUN-98. Date of last review: 15-OCT-99.
DMF	—	Type III. ————— Letter of authorization for FDA access 16-JUN-98. Date of last review: Not reviewed.
DMF	—	Type I. ————— Letter of authorization for FDA access: 13-OCT-87. Date of last review: Not reviewed.

NDA 21-084 Topical Skin Protectant
U.S. Army-Office of the Surgeon General

RELATED DOCUMENTS: None

CONSULTS: Microbiology

REMARKS/COMMENTS:

CONCLUSIONS & RECOMMENDATIONS:

The application is recommended for APPROVAL under section 505 of the FFD&C Act.

/S/
William C. Timmer, Ph.D.
Review Chemist, HFD-540/830

/S/ 2/7/00
Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, HFD-540/830

/S/ 2/9/00
Bonnie B. Dunn, Ph.D.
Deputy Division Director, HFD-830
Division of New Drug Chemistry III
Office of New Drug Chemistry

APPEARS THIS WAY
ON ORIGINAL