

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20646**

**CHEMISTRY REVIEW(S)**

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS  
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-646

CHEM.REVIEW # 1

REVIEW DATE: 22-JUL-96

SUBMISSION TYPE:	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	03-NOV-95	07-NOV-95	17-NOV-95
Amendment	14-MAR-96	15-MAR-96	15-MAR-96
Amendment	27-MAR-96	28-MAR-96	28-MAR-96
Amendment	03-APR-96	04-MAR-96	05-APR-96
Amendment	06-APR-96	08-APR-96	08-APR-96
Amendment	12-APR-96	15-APR-96	15-APR-96
Amendment	18-MAY-96	17-MAY-96	17-MAY-96
Amendment	04-JUN-96	05-JUN-96	05-JUN-96
Amendment	18-JUL-96	19-JUL-96	19-JUL-96
Amendment	19-AUG-96	20-AUG-96	20-AUG-96
Amendment	23-AUG-96	27-AUG-96	27-AUG-96

NAME & ADDRESS OF APPLICANT:

Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-3500

DRUG PRODUCT NAME

Proprietary:  
Nonproprietary/USAN:  
Code Name/#:  
Chem.Type/Ther.Class:

GABITRIL®  
Tiagabine Hydrochloride  
Abbott-70569.HCl  
GABA uptake inhibitor

PHARMACOL.CATEGORY/INDICATION:

Adjunctive therapy for partial seizures w/w  
secondary generalization

DOSAGE FORM:

Tablets

STRENGTHS:

4 mg, 12 mg, 16 mg & 20 mg

ROUTE OF ADMINISTRATION:

Oral

DISPENSED:

XXXXX Rx \_\_\_\_\_ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

(R)-(-)-1-[4,4-bis(3-methyl-2-thienyl)-3-butenyl]-3-piperidinecarboxylic acid hydrochloride \*

C<sub>20</sub>H<sub>25</sub>N<sub>3</sub>O<sub>2</sub>S<sub>2</sub>.HCl; Molecular Weight: 412.0;

CAS #: 115103-54-3

SUPPORTING DOCUMENTS: INC

RELATED DOCUMENTS: None

REMARKS/COMMENTS: The organization/disorganization of the application provides quite a

CONCLUSIONS & RECOMMENDATIONS: Recommend the NDA 20-646

APPROVABLE subject to positive and acceptable response to observations and recommendations

cc: Orig. NDA 20-646

HFD-120

HFD-120/WJRzeszotarski

HFD-120/JWara

HFD-120/SWBlum

Init by: SWB

AMB 9/12/96

  
W. Janusz Rzeszotarski, Ph.D., Chemist

filename: N020646.000

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS  
Review of Chemistry, Manufacturing, and Controls

JUL 17 97

NDA #: 20-646

CHEM.REVIEW # 2

REVIEW DATE: 09-JUN-97

SUBMISSION TYPE:	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Amendment	31-MAR-97	01-APR-97	02-APR-97
Amendment	05-JUN-97	09-JUN-97	09-JUN-97

NAME & ADDRESS OF APPLICANT: Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-3500

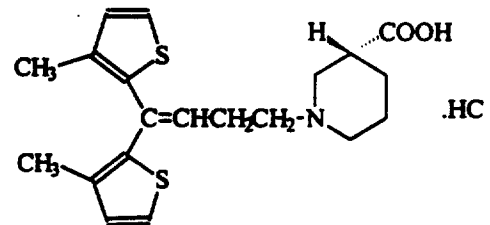
DRUG PRODUCT NAME  
Proprietary: GABITRIL®  
Nonproprietary/USAN: Tiagabine Hydrochloride  
Code Name/ #: Abbott-70569.HCl  
Chem.Type/Ther.Class: GABA uptake inhibitor

PHARMACOL.CATEGORY/INDICATION: Adjunctive therapy for partial seizures w/w/o secondary generalization  
DOSAGE FORM: Tablets  
STRENGTHS: 4 mg, 12 mg, 16 mg & 20 mg  
ROUTE OF ADMINISTRATION: Oral  
DISPENSED: XXXXX Rx \_\_\_\_\_ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,  
ECULAR WEIGHT:

(R)-(-)-1-[4,4-bis(3-methyl-2-thienyl)-3-butenyl]-3-piperidinecarboxylic acid hydrochloride

C<sub>20</sub>H<sub>25</sub>N<sub>2</sub>O<sub>2</sub>S<sub>2</sub>.HCl; Molecular Weight: 412.0; CAS #: 115103-54-3



SUPPORTING DOCUMENTS: IND  
RELATED DOCUMENTS: None

REMARKS/COMMENTS: A response to approvable letter of 31-OCT-95. The CMC deficiencies have been addressed satisfactory except for the disputed levels of degradants.

CONCLUSIONS & RECOMMENDATIONS: Recommend the NDA 20-646, as amended, APPROVABLE subject to conclusive negotiation of degradants levels.

cc:  
Orig. NDA 20-646  
HFD-120  
RFD-120/WJRzeszotarski  
HFD-120/JWare  
HFD-120/SWBlum  
Init by:SWB

  
W. Janusz Rzeszotarski, Ph.D., Chemist

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*AMB*  
7/17/97

DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS  
Review of Chemistry, Manufacturing, and Controls

SEP 23 1997

NDA #: 20-646

CHEM.REVIEW # 3

REVIEW DATE: 23-SEP-97

SUBMISSION TYPE:	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
GC	01-AUG-97	xx-xxx-97	xx-xxx-97
GC	21-AUG-97	xx-xxx-97	xx-xxx-97
GC	19-SEP-97	xx-xxx-97	xx-xxx-97

NAME & ADDRESS OF APPLICANT:

Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-3500

DRUG PRODUCT NAME

Proprietary:  
Nonproprietary/USAN:  
Code Name/#:  
Chem.Type/Ther.Class:

GABITRIL®  
Tiagabine Hydrochloride  
Abbott-70569.HCl  
GABA uptake inhibitor

PHARMACOL.CATEGORY/INDICATION:

Adjunctive therapy for partial seizures w/wo  
secondary generalization

DOSAGE FORM:

Tablets

STRENGTHS:

4 mg, 12 mg, 16 mg & 20 mg

ROUTE OF ADMINISTRATION:

Oral

DISPENSED:

XXXXX Rx \_\_\_\_\_ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,  
MOLECULAR WEIGHT:

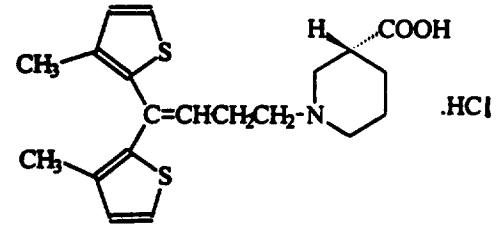
(1S)-(-)-1-[4,4-bis(3-methyl-2-thienyl)-3-butenyl]-3-piperidinecarboxylic acid  
hydrochloride

C<sub>20</sub>H<sub>25</sub>N<sub>2</sub>O<sub>2</sub>S<sub>2</sub>.HCl; Molecular Weight: 412.0; CAS #: 115103-54-3

SUPPORTING DOCUMENTS: IND

RELATED DOCUMENTS: None

REMARKS/COMMENTS: The responses to Requests for Information. The continuing issue of the level of degradants that should be qualified prior to submission of the application (an issue beyond the scope of chemistry review).



CONCLUSIONS & RECOMMENDATIONS: Recommend the NDA 20-646, as amended, APPROVED subject to careful monitoring of degradant in the commercial batches.

NDA 20-646

D-120

HFD-120/WJRzeszotarski

HFD-120/

HFD-120/MEGuzewska

R/D Init by:MEG inf 9.23.97

W. Jariusz Rzeszotarski, Ph.D., Chemist

filename: c:\wpfiles\N20646a.003

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20646**

**ENVIRONMENTAL ASSESSMENT AND/OR FONSI**

**ENVIRONMENTAL ASSESSMENT**  
**AND**  
**FINDING OF NO SIGNIFICANT IMPACT**  
**FOR**

**Tibex™**  
**(Tiagabine Hydrochloride)**  
**Tablets**

**NDA 20-646**

**ABBOTT LABORATORIES**

**FOOD AND DRUG ADMINISTRATION**  
**CENTER FOR DRUG EVALUATION AND RESEARCH**  
**DIVISION OF NEUROPHARMACOLOGICAL DRUG**  
**PRODUCTS**  
**(HFD-120)**

**FINDING OF NO SIGNIFICANT IMPACT**

**NDA 20-646**

**Tibex**

**(Tiagabine Hydrochloride)**

**Tablets**

The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impact of their actions. FDA is required under NEPA to consider the environmental impact of approving certain drug product applications as an integral part of its regulatory process.

The Food and Drug Administration, Center for Drug Evaluation and Research, has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

In support of their new drug application for Tibex Tablets, Abbott Laboratories prepared an environmental assessment (attached) in accordance with [21 CFR 25.31a(a)], which evaluates the potential environmental impact of the manufacture, use and disposal of the product. The maximum expected environmental concentration is at a level that normally relieves the applicant from completing format items 7, 8, 9, 10, 11, and 15 in accordance with the tier 0 approach specified in the "Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements."

Tiagabine Hydrochloride is a chemically synthesized drug administered as adjunctive therapy for partial seizures with and without secondary generalization. The drug substance will be manufactured by Abbott Laboratories Limited, Queensborough, Kent, United Kingdom. The Drug Product will be manufactured by Abbott

Laboratories, Abbott Park, Illinois and Abbott Pharmaceuticals, Inc., Cruce Davilla, Barceloneta, Puerto Rico. The finished drug product will be used in hospitals, clinics and by patients in their homes.

Tiagabine Hydrochloride may enter the environment from excretion by patients, from disposal of pharmaceutical waste or from emissions from manufacturing sites.

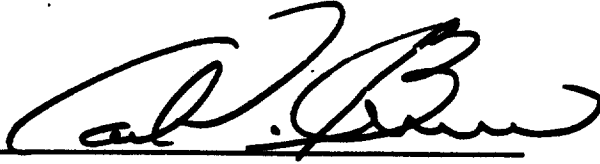
Disposal of the drug may result from out of specification lots, discarding of unused or expired product, and user disposal of empty or partly used product and packaging. Returned or out-of-specification drug substance and rejected or returned drug product will be disposed of at a licensed incineration or landfill facility. At U.S. hospitals and clinics, empty or partially empty packages will be disposed of according to hospital/clinic regulations. From home use, empty or partially empty containers will typically be disposed of by a community's solid waste management system that may include landfills, incineration and recycling, while minimal quantities of unused drug may be disposed of in the sewer system.

The Center for Drug Evaluation and Research has concluded that the product can be manufactured, used and disposed of without any expected adverse environmental effects. Precautions taken at the sites of manufacture of the bulk product and its final formulation are expected to minimize occupational exposures and environmental release. Adverse effects are not anticipated upon endangered or threatened species or upon property listed in or eligible for listing in the National Register of Historic Places.

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ON ORIGINAL**

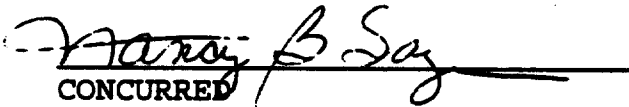
**APPEARS THIS WAY  
ON ORIGINAL**





PREPARED BY  
Carl J. Berninger, Ph.D.  
Environmental Scientist  
Environmental Assessment Team  
Center for Drug Evaluation and Research

9/19/96  
Date



CONCURRED  
Nancy B. Sager  
Team Leader  
Environmental Assessment Team  
Center for Drug Evaluation and Research

9/20/96  
Date

Attachments: Environmental Assessment (FOI copy)  
Material Safety Data Sheet (drug substance)

APPEARS THIS WAY  
ON ORIGINAL

CORRECTED COPY

APPEARS THIS WAY  
ON ORIGINAL

**NDA SUBSECTION 3.6**  
**ENVIRONMENTAL ASSESSMENT**

**Tiagabine Hydrochloride Tablets**

**Abbott Laboratories**  
**One Hundred Abbott Park Road**  
**Abbott Park, Illinois 60064**

The National Environmental Policy Act requires Environmental Assessments (EAs) to be public documents. NDA subsections 3.6.1 through 3.6.15 (i.e., Items 1 through 15 of this EA) and accompanying Appendix A (from Subsection 3.6.15) are suitable for public disclosure. These nonconfidential subsections, as applicable under CDER's guidance for industry for the submission of EAs, and Appendix A are complete with the exception of proprietary information. The proprietary information, which is contained in Appendix B could be beneficial to competitors and therefore, must remain confidential. The text of the public document (Subsections 3.6.1 through 3.6.15 and Appendix A) is based on the text of Appendix B. Appendix B is intended for review as the confidential version of EA Items 1 through 15. Appendix A contains Material Safety Data Sheet (MSDS) information.

APPEARS THIS WAY  
ON ORIGINAL

**REDACTIONS MADE  
BY APPLICANT**

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3.6.1        **DATE**  
October 15, 1995 (Amended February 22, 1996; July 30, 1996)

3.6.2        **NAME OF APPLICANT**  
Abbott Laboratories

3.6.3        **ADDRESS**  
100 Abbott Park Road  
Abbott Park, Illinois 60064

3.6.4        **DESCRIPTION OF THE PROPOSED ACTION**

3.6.4.1      **REQUESTED APPROVAL**

Approval of NDA 20-646 is sought for the manufacturing of tiagabine hydrochloride bulk drug substance and the manufacture, packaging, distribution and use of the product designated in the Environmental Assessment (EA) as tiagabine hydrochloride tablets containing one of the following concentrations of tiagabine hydrochloride: 4, 12, 16, and 20 mg. Abbott Laboratories is submitting an NDA pursuant to Section 505(b) of the Food, Drug, and Cosmetic Act for tiagabine hydrochloride tablets packaged in high density polyethylene bottles (two sizes) and in two types of blister/foil packages. An EA is herewith submitted in accordance with 21 CFR § 25.31a(a) and has been amended in accordance with the recent CDER guidance to industry. All Items (1 through 15) that are presented in this section are also discussed in the confidential Appendix B.

3.6.4.2      **NEED FOR ACTION**

Tiagabine hydrochloride is a potent and specific inhibitor of gamma-aminobutyric acid (GABA) uptake into glial and neuronal elements *in vitro*. GABA-mediated inhibitory systems have an important role in the regulation of seizure activity. Enhancement of GABA-mediated inhibition has an anticonvulsant effect. The indication and usage of tiagabine hydrochloride tablets proposed in this NDA is for the management of

07/25/96

seizure disorders and epilepsy, specifically as adjunctive therapy for partial seizures with or without secondary generalization.

#### **3.6.4.3      LOCATIONS OF MANUFACTURE**

Three locations are involved in the manufacture of this product (Figure 3.6.4-1).

Approval is sought to manufacture the bulk drug substance at the following location: Abbott Laboratories Limited, Queenborough, Kent ME11 5EL, United Kingdom.

Approval is also sought to manufacture, package, and distribute the tablets at two locations:

- (1) Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60064, and
- (2) Abbott Pharmaceuticals, Inc., KM 58.0 Carretera 2, Cruce Davila, Barceloneta, Puerto Rico 00617

All packaging operations are carried out at these two drug product manufacturing facilities. Information concerning all three manufacturing sites is provided in Section 3.6.6 (Introduction Of Substances Into The Environment).

#### **3.6.4.4      LOCATIONS OF USE AND DISPOSAL**

As medication prescribed to alleviate the symptoms of seizure disorders and epilepsy, the tablets in which tiagabine hydrochloride is present will be ingested by patients throughout the United States. Tiagabine hydrochloride and its metabolites will be excreted from the human body in urine and feces and will be discharged through a domestic sewer into the municipal sewer systems and then into wastewater treatment plants (WTP).

Tiagabine hydrochloride does not fall under the US Environmental Protection Agency's (EPA) Hazardous Waste Definition, and therefore can be disposed of in an approved landfill or incinerator. Rejected off specification lots of bulk drug substance or drug product (tiagabine hydrochloride tablets) from Abbott Park will be sent to one of a number of alternative contractors for incineration which are: Aptus, 11600 N. Aptus Road, Argonite, Utah 84029, Permit No. UTD981552177 and Hwy. 169 North, Coffeyville, Kansas 67337,

Permit No. KSD 981506025; and Long Beach Recycling & Rec., 70 Water Street, Long Beach, New York 11561, Permit No. 9360595556. This listing is not all inclusive and is dynamic in the fact that companies are added and subtracted for various reasons (e.g. service and cost, etc.). There are no expiration dates on the licenses for these solids incineration facilities. These materials could also be disposed of in a land-fill (Waste Management of Wisconsin, 19414 60th Street, Bristol, Wisconsin 53104). Landfilling at this location is permitted by the state of Wisconsin, Department of Natural Resources (Permit No. 3062, Expiration date: 9/30/95). Unused drug products (tiagabine hydrochloride tablets past their labeled expiration date) will be returned to Abbott Park where they will be accumulated, classified (as appropriate), and sent off-site for disposal as nonhazardous solid waste to the landfill or the incinerators listed above.

Rejected off specification lots of bulk substance or drug product from the Barceloneta facility will be sent to an approved medical waste incinerator, which is currently Chambers Medical Technologies of South Carolina Inc., 100 Nix Street, Hampton, South Carolina 28924 (Permit No.'s #1280-0021CD, 1280-0021CE, 1280-0021CF, and 1280-0021CG). There is no expiration date on the licenses for this incineration facility. Disposal service is contracted through Environmental Healthcare Incorporated, P.O. Box 2286; Delray Beach, Florida 33447.

### 3.6.4.5 ENVIRONMENTAL SETTING OF FACILITIES

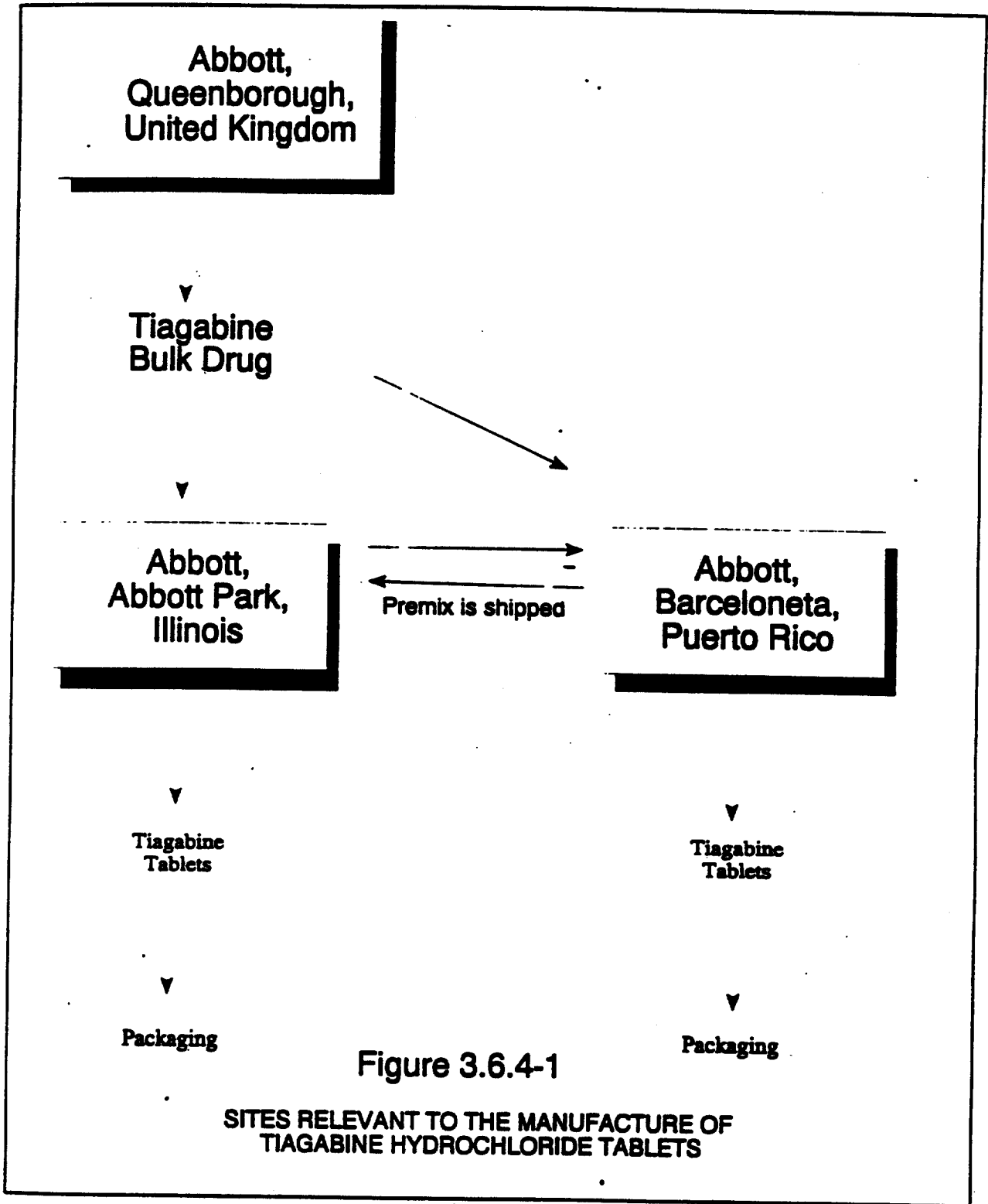
#### 3.6.4.5.1 Abbott Laboratories, Queenborough, United Kingdom

The bulk drug is manufactured at Abbott Laboratories Limited, Queenborough, United Kingdom. The production facilities of Abbott U.K. are situated on the north edge of Queenborough on the Isle of Sheppey, Kent. The Isle is on the south coast of the Thames Estuary approximately sixty miles east of London. The site elevation is approximately zero to three meters above mean sea level. The site includes 146 acres of land, 60 acres of which is currently utilized and topographically flat. To the west lies the Swale which borders the site. The tidal zone is a special site of scientific interest (SSSI) which is also owned by Abbott. To the north lies an automobile transporter compound

07/25/96

3





**Figure 3.6.4-1**

**SITES RELEVANT TO THE MANUFACTURE OF  
TIAGABINE HYDROCHLORIDE TABLETS**

storage area and docks development. The east side of the site is bordered by the Queenborough by-pass and property owned by Abbott dissected by the Whiteway Road. Queenborough lies to the south/southeast of the facility. The climate is mild and the predominant prevailing wind is from the southwest. The temperature range is approximately -5°C to 35°C. Both water supply and industrial wastewater treatment are undertaken by Southern Water plc. No ground waste is abstracted and the underlying geology is London Clay. The land use around is a mixture of industrial, agricultural and residential. The area falls under control of the Swale Borough Council and Kent County Council (Appendix B).

#### 3.6.4.5.2 Abbott Laboratories, Abbott Park, Illinois

The properties of Abbott Laboratories are located within Lake County, Illinois. The Abbott Park property is located approximately five miles to the west of Lake Michigan. There are no other significant geographic features, such as mountains, lakes (aside from Lake Michigan) or rivers in proximity to the manufacturing site. The area is topographically flat and slopes very gently to the east, toward Lake Michigan. Drainage is dominantly to the east-southeast again toward the lake. Information on the geologic and hydrologic stratigraphy of the Chicago region is provided in Appendix B. The climate of northeastern Illinois is characterized by warm summers (74 to 94°F) and cold winters (20 to 32°F). The average annual rainfall is 32 inches; wind directions are highly variable.

Most industries and residences near the Abbott Park facility are served by the City of North Chicago municipal water supply. The source of the municipal water supply is Lake Michigan. The Abbott Park facility currently uses both municipal water and ground-water from onsite wells. Wastewater is sewered to the treatment facility of the North Shore Sanitary District. Land use (zoning) near the Abbott Park facility is primarily residential and industrial. The portion of Lake County in which it is located is part of the Chicago metropolitan area.

#### 3.6.4.5.3 Abbott Laboratories, Barceloneta, Puerto Rico

The manufacturing site of Abbott Pharmaceuticals, Inc., Barceloneta, Puerto Rico, is situated in a mainly agricultural area. The flat land of this area has been devoted to pineapple growing and pasture for many decades. There are no significant geographic

features, such as mountains, lakes, or rivers in proximity to the manufacturing facilities. During the 1970's several industrial plants were established nearby, most of which are engaged in pharmaceutical manufacturing (Maps of the area are provided in Appendix B). To date the agricultural and industrial uses (zoning) of land coexist in the region, though most of the land remains agricultural.

The climate of Puerto Rico, including the Barceloneta Region, is influenced by Puerto Rico's location in the Caribbean. Located approximately 10 degrees north latitude, it is situated in the belt of prevailing northeasterly tradewinds. The predominance of tradewinds results in little variability of wind direction. Puerto Rico's tropical climate also produces only a small range of temperature variation. Typically, the average summer and winter temperatures differ by less than 10 degrees Fahrenheit (°F). The average annual temperature is approximately 78°F. Precipitation varies widely over the island due to local meteorological effects. On an annual basis, Barceloneta receives between 50 and 60 inches of rain. Water for operations at the Abbott facility is supplied by three shallow wells. An artisan well also exists at the facility, but is not currently used. Wastewater is treated onsite. Treated effluent is piped to a facility of the Puerto Rico Aqueduct and Sewer Authority (PRASA) where it is treated further before being released 1.5 miles off the coast.

### 3.6.5 IDENTIFICATION OF SUBSTANCES THAT ARE THE SUBJECT OF THE PROPOSED ACTION

The drug product, tiagabine hydrochloride, will be prepared and administered as tablets.

#### 3.6.5.1 NOMENCLATURE

##### 3.6.5.1.1 Chemical Abstract Service (CAS) and INN Name

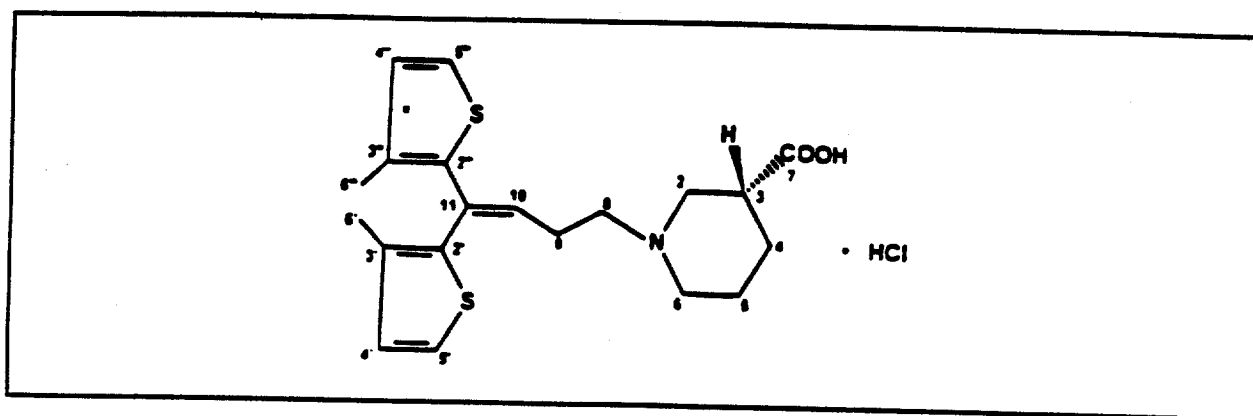
CAS: (R)-(-)-1-[4,4-bis(3-methyl-2-thienyl)-3-butenyl]-3-piperidinecarboxylic acid, hydrochloride.

INN: R-(-)-1-[(4.4)-(3-methyl-2-thienyl)-3-butenyl]-3-piperidinecarboxylic acid, hydrochloride.

07/25/96

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- 3.6.5.1.2 United States Adopted Name (USAN)  
Tiagabine Hydrochloride
- 3.6.5.1.3 CAS Registry Number  
115103-54-3
- 3.6.5.1.4 Abbott Laboratory Codes  
A-70569-1, A-70569.HCl, ABT-569
- 3.6.5.1.5 Empirical Formula and Molecular Weight  
Empirical Formula:  $C_{20}H_{23}NO_2S_2 \cdot HCl$   
Molecular Weight: 412.02



**Figure 3.6.5-1**  
**Structure of Tiagabine Hydrochloride**

3.6.5.2 **PHYSICAL DESCRIPTION**

In appearance, tiagabine hydrochloride is a white to off-white powder with essentially no detectable odor. Its chemical and physical properties are listed below. Tiagabine hydrochloride is most soluble in water (24 mg/mL) followed by organic solvents, among which it is most soluble in chloroform (12 mg/mL) and least soluble in n-heptane (<0.01 mg/mL). The log octanol and aqueous buffer partition coefficient for tiagabine hydrochloride at pH 7.0 is 1.6. The dissociation constants representing carboxylic acid functionality was found to be 3.3 ( $pK_{a1}$ ) and the tertiary amine functionality was found to be 9.4 ( $pK_{a2}$ ).

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## Chemical and Physical Properties of Tiagabine Hydrochloride

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Physical appearance:	White to off-white powder with lumps and essentially no odor
Melting point:	192-193°C
Solubility in water:	24 mg/mL
Log octanol-aqueous buffer partition coeff.(log P):	log P at pH 7.4 is 1.6
Dissociation Constants:	$pK_{a1} = 3.3$ ; $pK_{a2} = 9.4$
Ultraviolet-Visible Adsorption Spectrum:	$\lambda$ max at 256.4 nm with a shoulder at 280 nm

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### 3.6.5.3 IMPURITIES AND ADDITIVES

Related impurities in tiagabine hydrochloride were found to be substantially below 1%. The constituents that are present in the formulated tablets are listed in Table I. The chemical nature of the majority of these components indicates their potential biodegradability after they are transformed in the human body and released into the environment.

**Table I****Constituents in the Formulation for Tiagabine Hydrochloride Tablets Manufacture**

<b>Tiagabine HCl Tablet Pre-Mix:</b>	<b>35883</b>
Tiagabine Hydrochloride	49462
Colloidal Silicon Dioxide, NF	17400
Cellulose, Microcrystalline, NF (Avicel PH 102)	19617
Acid, Ascorbic, USP	11450
Cellulose, Microcrystalline, NF (Avicel PH 101)	19615
Lactose, Anhydrous, NF	77216
Starch, Pregelatinized, NF	68511
Water, Purified, USP (Distilled) <sup>1</sup>	75146
Crospovidone, NF	21982
Colloidal Silicon Dioxide, NF	17400
Wax, Hydrogenated Vegetable Oil (Sterotex)	75452
Acid, Stearic, NF	12540
Magnesium Stearate, NF	43660
Water, Purified, USP (Distilled) <sup>1</sup>	75146
Hydroxypropyl Methylcellulose, 2910 USP, 15 cps	45506
Hydroxypropyl Cellulose, NF, Visc. of 10% H <sub>2</sub> O Solution: 200-600 cps	68341
Titanium Dioxide, USP	72179
Water, Purified, USP (Distilled) <sup>1</sup>	75146
Hydroxypropyl Methylcellulose, 2910 USP, 15 cps	45506
Hydroxypropyl Cellulose, NF, Visc. of 10% H <sub>2</sub> O Solution: 200-600 cps	68341
Titanium Dioxide, USP	72179
<b>4 mg:</b>	
Dye, Yellow, D&C, No.10 Aluminum Lake, 14-17%	26392
<b>12 mg:</b>	
Dye, Yellow, D&C, No.10 Aluminum Lake, 14-17%	26392
Dye, Blue, D&C, No.1 Lake, 11-13%	25041
<b>16 mg:</b>	
Dye, Blue, D&C, No.2 Aluminum Lake, 11-14%	25050
<b>20 mg:</b>	
Dye, Red, FD&C, No.30 Aluminum Lake	26109

<sup>1</sup>Removed during drying process or tablet coating.

### 3.6.6 INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

#### 3.6.6.1 MANUFACTURE OF THE BULK DRUG, TIAGABINE HYDROCHLORIDE (Queenborough, United Kingdom)

The production of the bulk drug tiagabine hydrochloride at this facility conforms to the environmental protection regulations which are mandated by Her Majesty's Inspectorate of Pollution (Environmental Protection Act of 1990). No proprietary intermediates are manufactured outside this site. The facility complies with all relevant legal requirements under Health and Safety At Work ETC ACT 1974 to protect worker occupational health and safety. The compliance letter is provided in Appendix B. Certificate of compliance with applicable emission requirements set forth in permits, as well as applicable emission requirements set forth in local and UK national statutes provided by the facility manager of Abbott Laboratories Limited is in Appendix B.

#### 3.6.6.2 PREPARATION OF THE TIAGABINE HYDROCHLORIDE TABLETS (ABBOTT PARK, ILLINOIS)

##### 3.6.6.2.1 Substances Emitted During Manufacturing

###### *Atmospheric Emissions*

The instructions for the manufacture of tiagabine hydrochloride tablets is described in Appendix B. A schematic of the manufacturing steps for tiagabine hydrochloride tablets is provided in Appendix B. Water is the only volatile solvent that will be used to prepare the tablets. The water will evaporate before the tablets are packaged. Emissions due to tiagabine hydrochloride tablet manufacturing are expected to be negligible based on the low production volume of the drug at this manufacturing facility.

During the manufacture, it is expected that some of the constituents of tablet manufacturing will be exhausted as particulate emissions. This exhausted material is treated by passing it through a high efficiency dust collector where the majority of the waste is captured in drums for disposal as solid waste (Appendix B).

### *Aqueous Wastes*

Equipment will be handscraped to remove residual solids before being washed with water. The handscrapings are disposed of as solid waste. The washdown water, including room washdown, will be sewerred into process drains [with the exception of pan coaters (Accelacota) and the coating solution manufacturing rooms which discharge into a scrubber drain which empties into an equalization tank]. The tank discharges to the North Shore Sanitary District (NSSD) under controlled conditions (Appendix B). The washdown water will be metered into the general wastestream for discharge into the sewer system of the NSSD.

Manufacturing data (Appendix B) indicate losses of drug product from tableting to aqueous waste as follows:

- Fluid Bed Dryers - 0.05 to 0.1 percent
- Fluid Air Mill and Granulators - 0.1 to 0.2 percent
- V-blender - 0.1 to 0.2 percent
- Fette 2000 Compressor - 0.1 percent

The total estimate for loss of product to wastewater is 0.35 to 0.5 percent. Based on the marketing forecast in Appendix B, and assuming that manufacturing of the tablets could occur only at Abbott Park, the quantity of tiagabine hydrochloride that could be released as sewage during 2000 (the fifth year following approval) is provided as a worst case estimate of 5.39 to 7.7 kg.

### *Solid Wastes*

Solid wastes from manufacturing are expected to be as follows (Appendix B):

- Granulation - 0.15 percent as powder in the dust collector , 0.2 to 0.6 percent as remnants and fines and 0.5 to 1 percent while vacuuming the equipment and floors
- Pre-mix - 0.5 percent as powder in the dust collector
- Blending - 0.2 percent as powder in the dust collector
- Compressing—0.6 percent as powder and tablet culls
- Coating—0.1 percent at tablet culls



The above material, after collection and containment into drums, will be disposed of as solid waste as outlined in 3.6.4.4. Packaging rejects and protective clothing worn by employees will be collected in drums and rolloff boxes for landfilling. Packaging rejects are estimated to be 1% for bottles caps, 5% for blister foil packages and 2% for printed supplies (labels, enclosures, and tamper evident bands). Based on the projected number of work orders for tiagabine hydrochloride tablets, the quantity of packaging rejects is estimated to be 250 lbs/year. A Tyvek full body covering with attached booties is worn during the changing of dust collectors, as well as during blending and manufacture of pre-mix. An estimated 5 lbs of this protective clothing worn in association with tiagabine hydrochloride manufacture would be disposed of per year. These solid wastes will be transported to the landfill managed by Waste Management of Wisconsin (Permit No. 3062).

#### 3.6.6.2.2 Controls Exercised on Residuals and Emissions

Safety precautions for the chemicals introduced into tablet manufacture are provided in Material Safety Data Sheets (Appendix A). No volatile organic emissions will be generated during production of the tablets. Release of particulates from the encapsulating facility cannot exceed three tons per year and will be controlled by bag filters, HEPA filters, and Torit dust collectors (Appendix B). Aqueous wastes (Appendix B) are sewered into the general wastewater discharge. Solid wastes are disposed of at permitted waste facilities.

#### 3.6.6.2.3 Compliance of Proposed Action with Applicable Emission Requirements

Handling procedures specified in the Material Safety Data Sheets (Appendix A) will be followed throughout all operations. Particulate emissions from the encapsulating facility at Abbott Park is regulated under a permit issued by the Illinois Environmental Protection Agency (Appendix B). Wastewater from manufacturing must meet the General Pretreatment Standards in 40 CFR Part 403 and the Effluent Guidelines and standards for Pharmaceutical Manufacturing in 40 CFR Part 439. The prohibitions and limitations for discharge into the sewer system of the North Shore Sanitary District (NSSD) are listed in Appendix B. Solid wastes will be landfilled by Waste Management of Wisconsin under Permit No. 3062 from the State of Wisconsin, Department of Natural Resources.

Certification of compliance with applicable emission requirements from facility managers is provided in Appendix A.

3.6.6.2.4 Effect of the Proposed Action on Compliance with Current Emission Requirements

Emissions and releases from the manufacture of tiagabine hydrochloride tablets or packaging of tiagabine hydrochloride tablets will not exceed the limitations of current permits. Manufacturing of this product will be scheduled to fit within the existing framework of activities from which current emission requirements are applicable.

3.6.6.3 PREPARATION OF THE TIAGABINE HYDROCHLORIDE TABLETS (BARCELONETA, PUERTO RICO)

3.6.6.3.1 Substances Emitted During Manufacturing

*Atmospheric Emissions*

Tablet manufacturing at Barceloneta will be carried out with similar manufacturing instructions as will be used at Abbott Park (Appendix B). No volatile organic emissions will be generated. Atmospheric emissions are considered negligible based on the low production volume and treatment with high efficiency dust collectors.

*Aqueous Wastes*

Water from equipment washdown, room cleaning, and wet scrubbers is sent to an onsite wastewater treatment plant (Permit No. GDA-93-202-050). An estimate of the sewerage aqueous waste produced during the manufacture of tiagabine hydrochloride tablets at Barceloneta is located in Appendix B. Manufacturing estimates indicate losses of drug product during tablet manufacture to wastewater to be 5.9 to 10 Kg based on a 600 kg tablet lot.

### ***Solid Wastes***

An estimation of the solid wastes produced during the manufacture of tiagabine hydrochloride tablets at Barceloneta is provided below (Appendix B):

- **Granulation** - 19.8 kg discarded as excess
- **Pre-mix** - 1 kg discarded as excess
- **Blending & Lubricating** - 1 kg as lubricated granulation
- **Compressing** - 13.0 kg as culls and 3.7 kg as lubricated granulation
- **Coating & Finishing** - 0.20 kg of tablet culls

This disposition of these wastes will be through incineration at Chambers Medical Technologies of South Carolina, Inc., 100 Nix Street, Hampton, South Carolina 29924. Because tiagabine hydrochloride is exempt from U.S. Environmental Protection Agency (EPA)'s Toxic Substances Control Act (TSCA) and not regulated by Department of Transportation (DOT), it can be disposed of in an approved incinerator (Appendix A). Approximately 400 lbs. of solid waste is generated per batch of tiagabine hydrochloride tablets. This waste consists primarily of fiber cartons and drums, plastic bags and paper. The quantity of protective clothing disposed of will be approximately 31 lbs. per batch of tiagabine hydrochloride tablets. Packaging waste will be landfilled by Browning Ferris Industries (BFI). BFI is certified to operate in Puerto Rico at various qualified landfilling sites (P.R. Environmental Quality Board Permit No. SR930025, no expiration date).

#### **3.6.6.3.2 Controls Exercised on Residuals and Emissions**

Handling, storage and use of chemicals will be carried out as directed in the Material Safety Data Sheets (Appendix A). No volatile organic emissions will be generated. Solid wastes, including the collected dust and culls from manufacturing, tableting and packaging, will be segregated and stored in dedicated areas before final disposal. All solid wastes from the manufacture of tiagabine hydrochloride tablets will be incinerated at Chambers Medical Technologies of South Carolina, Inc. (Permit No.'s 1280-0021CD, 1280-0021CE, 1280-0021CF, 1280-0021CG). No expiration dates are applicable to these licenses. Packaging wastes will be landfilled by BFI as noted above.

Aqueous wastes will be treated in an onsite wastewater treatment system. The system includes an equalization and neutralization basin, two biological reactors and a secondary aerobic digester as part of the primary and secondary treatment scheme. The treatment system also includes sludge dewatering and tertiary treatment as final units of operation. Sludge is landfilled onsite. The effluent is discharged to the Barceloneta Regional Wastewater Treatment Plant, a publicly owned treatment works operated by the Puerto Rico Aqueduct and Sewer Authority (PRASA). The Barceloneta municipal sewer permit number is GDA-93-202-050. This permit expires in mid-1997. Requirements of the PRASA are listed in the facility agreement found in Appendix B. The wastewater effluent from WTP of PRASA is released into the coastal waters 1.5 miles of the coast.

#### 3.6.6.3.3 Compliance of Proposed Action with Applicable Emission Requirements

Operating personnel are required to read and follow the chemical handling procedures described in the Material Safety Data Sheets [Appendix A and the Waste Management Policy (Appendix B)]. The current permit for operating equipment to lessen air pollution is provided in Appendix B. Water that will be discharged from the onsite treatment system must comply with prohibitions and limitations listed in the facility agreement issued by PRASA (Appendix B). The incinerator that Chambers Medical Technologies operates in Hampton, South Carolina is permitted by the State Environmental Quality Board, Permit No.'s 1280-0021CD, 1280-0021CE, 1280-00021CF, and 1280-0021CG.

Certification of compliance with applicable emission requirements from the facility manager is provided in Appendix B.

#### 3.6.6.3.4 Effect of the Proposed Action on Compliance with Current Emission Requirements

Emissions and releases from the manufacturing, tableting, and packaging of tiagabine hydrochloride will not exceed the limitations of current permits. These permits are issued for the facility, and thus manufacturing of this product will be scheduled to fit within the activities that are permitted.

#### 3.6.6.4 OCCUPATIONAL SAFETY

Chemicals used in manufacture of the drug product are regulated by the Occupational Safety and Health Administration. Employees are trained in the proper operation of equipment in order to minimize potential safety, health and environmental risks. Extensive safety training is mandated, and Material Safety Data Sheets (Appendix A) are available to personnel for chemicals handled in the manufacturing area. Monitoring of employee exposure to hazardous materials is conducted and personnel participate in annual physical evaluations. Employee education on health is provided through lectures.

Existing work procedures (including the use of uniforms, respirators, gloves, safety shoes, and eye protection) and engineering controls designed for the equipment (e.g., exhausts to remove dust) are adequate to protect the employees.

The safe transport of all drug-related materials is ensured by following protocols which include formal qualification of vendors, training of personnel, and rigid specification of containers and materials. Access to drug substances and products is restricted to authorized personnel.

#### 3.6.6.5 AMOUNT OF SUBSTANCES ENTERING THE ENVIRONMENT

To conservatively (i.e., worst case) estimate the amount of tiagabine hydrochloride entering a typical wastewater treatment plant as a result of the proposed action, it is assumed that all of the drug produced in the year 2000, which is expected to be the peak production year, will be ingested and eliminated by the U.S. population. For example, for the year 2000, ~1.5 (1,540 kg) metric tons is now forecasted to be the amount of drug substance that will be processed into tiagabine hydrochloride tablets and the assumption includes that all 1.5 metric tons will be consumed and excreted by the patients.

Using the calculation stated in the CDER "Guidance For Industry For The Submission of an Environmental Assessment in Human Drug Applications and Supplements."

$$\text{EIC - Aquatic (ppm)} = A \times B \times C \times D$$

or

$$1540 \text{ kg} \times \frac{1}{1.115 \times 10^{11} \text{ } \mu\text{d}} \times \frac{1}{365 \text{ days}} \times \frac{10^6 \text{ mg}}{\text{kg}} = 0.0000378 \text{ ppm} = 0.0378 \text{ ppb}$$

Therefore, this drug meets the requirements of a Tier 0 Approach. No further analysis is needed.

3.6.7 **FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT**

No analyses needed, per Guidance.

3.6.8 **ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES**

No analyses needed, per Guidance.

3.6.9 **USE OF RESOURCES AND ENERGY**

No analyses needed, per Guidance.

3.6.10 **MITIGATION MEASURES**

No analyses needed, per Guidance.

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**PREPARERS**

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The preparers' resumes are provided in Appendix B.

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**CERTIFICATION**

**PREPARERS**

The undersigned certify that the information presented is true, accurate, and complete for preparation of the Environmental Assessment Report in accordance with 21 CFR 25.31(a).

Signature Ranga Velagaleti Date 7-29-96

Title Director, Environmental Fate and Assessment

Signature Ranga Velagaleti for Mrs Winberry Date 7-29-96

Title Program Manager, Environmental Fate and Assessment

**SPONSOR**

The undersigned certifies that the information presented herein and provided to Ranga Velagaleti by Abbott Laboratories (applicant) is true, accurate, and complete to the best of our knowledge.

Signature David Furman Date 8/15/96

Title



## 3.6.13

**REFERENCES**

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**APPENDICES**

**APPENDIX A.1 - CERTIFICATIONS OF COMPLIANCE FROM  
FACILITY MANAGERS**

**APPENDIX A.2 - MATERIAL SAFETY DATA SHEETS (same as  
Appendix A of March 27, 1996 submission)**

**APPENDIX B - CONFIDENTIAL**

**APPENDIX A**

**APPENDIX A.1 - CERTIFICATES OF COMPLIANCE  
FROM FACILITY MANAGERS**

**APPENDIX A.2 - MATERIAL SAFETY DATA SHEETS  
(same as Appendix A of March 27, 1996 submission)**

**APPENDIX A.1**

**CERTIFICATIONS OF COMPLIANCE  
FROM FACILITY MANAGERS**

**NON-CONFIDENTIAL**

**APPENDIX A.1.1**

**CERTIFICATE OF COMPLIANCE  
FROM FACILITY MANAGER**

**ABBOTT LABORATORIES, UNITED KINGDOM**



Abbott Laboratories Limited

Queenborough  
Kent  
ME11 5EL

TIAGABINE HYDROCHLORIDE - CERTIFICATE OF COMPLIANCE

ABBOTT LABORATORIES states that it is in material compliance with, or on an enforceable schedule to be in compliance with, applicable emission requirements set forth in permits, consent decrees, and administrative orders relating to the production of tiagabine hydrochloride at its facilities in Queenborough, UK, as well as applicable emission requirements set forth in local and UK national statutes.

Signed -

*A. P. Andrews*

A. P. ANDREWS

ASSISTANT TECHNICAL DIRECTOR

9th March, 1995

Telephone Sheerness (01795) 580099  
Fax (01795) 593335

Registered Number 329102 England  
Registered Office: Queenborough,  
Kent ME11 5EL



**NON-CONFIDENTIAL**

**APPENDIX A.1.2**

**CERTIFICATE OF COMPLIANCE  
FROM FACILITY MANAGER**

**ABBOTT PARK, ILLINOIS**




ABBOTT LABORATORIES  
PHARMACEUTICAL PRODUCTS DIVISION

ABBOTT PARK  
GENERAL ENVIRONMENTAL COMPLIANCE STATEMENT

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ABBOTT LABORATORIES states that it is in material compliance with, or on an enforceable schedule to be in compliance with, applicable emission requirements set forth in permits, consent decrees and administrative orders relating to the production of TIAGABINE at its facilities in Abbott Park, Illinois, as well as applicable emission requirements set forth in federal, state and local statutes and regulations, relating to the production of TIAGABINE.

 4-28-95  
STEVEN J. LICHTER, Director,  
Abbott Park Operations  
Pharmaceutical Products Division

**NON-CONFIDENTIAL**

**APPENDIX A.1.3**

**CERTIFICATE OF COMPLIANCE  
FROM FACILITY MANAGER**

**BARCELONETA, PUERTO RICO**

## GENERAL ENVIRONMENTAL COMPLIANCE STATEMENT

ABBOTT LABORATORIES states that it is in material compliance with, or on an enforceable schedule to be in compliance with, applicable emission requirements set forth in permits, consent decrees and administrative orders relating to the production of Tiagabine at its facilities in Barceloneta, Puerto Rico, as well as applicable emission requirements set forth in federal, state and local statutes and regulations relating to the production of Tiagabine.

*Luis A. Rivera*

Luis A. Rivera Figueroa  
Manager, Environmental  
Engineering Department

LARFAL  
C. 100  
S. 1000001

## **APPENDIX A.2**

### **MATERIAL SAFETY DATA SHEETS (same as March 27, 1996 submission)**

**MS/DS List**  
**Drug: Tiagabine Hydrochloride**

**Excipient**

**Acid, Ascorbic, USP, White, Powder**

**Acid, Ascorbic, USP, White, Powder**

**Acid, Ascorbic, USP, White, Powder**

**Acid, Stearic, NF, Fine Powder**

**Cellulose, Microcrystalline, NF (Avicel pH 101, 102)**

**Colloidal Silicon Dioxide, NF (CAB-O-SIL M-5)**

**Crospovidone, NF**

**Dye, Blue, FD&C No. 1, Lake, 11-13%**

**Dye, Blue, FD&C No. 2, Aluminum Lake (Fine Grind), 11-14%**

**Dye, Yellow, D&C No. 10, Aluminum Lake, 14-17%**

**Dye, Red D&C No. 30, Aluminum Lake**

**Hydroxypropyl Cellulose NF Vis. of 10% H<sub>2</sub>O Solution:**

**Hydroxypropyl Methylcellulose 2910 USP, 15 CPS**

**Lactose, Anhydrous, NF**

**Magnesium Stearate, NF, Impalpable Powder**

**Starch, Pregelatinized, NF**

**Titanium Dioxide, USP, Special Coating Grade**

**Wax, Hydrogenated Vegetable Oil (Sterotex K)**

**MATERIAL SAFETY DATA SHEET**

\*\*\*\*\*  
ABBOTT LABORATORIES  
CHEMICAL & AGRICULTURAL PRODUCTS DIVISION  
NORTH CHICAGO, ILLINOIS 60064  
EMERGENCY TELEPHONE 1-708-937-6100  
CHEMTREC 1-800-424-9300  
\*\*\*\*\*

ISSUE DATE: 10/31/94 TSCA STATUS: Exempt

APPROVAL: \_\_\_\_\_

LIST/CODE: /40403

PRODUCT NAME: Tiagabine Hydrochloride; A-65877; A-70260.1

CHEMICAL NAME: N-(1)-(4,4-Di(3-ethoxyphenyl)but-3-enyl)nicotinic Acid

DOT CLASSIFICATION: Not Regulated

**HAZARDOUS INGREDIENTS/IDENTITY INFORMATION**

NAME (CAS NO.)	OSHA PEL	ACGIH TLV	ABBOTT LIMIT
Tiagabine Hydrochloride*	SL	SL	**

\*-Hazardous per OSHA criteria

**PHYSICAL PROPERTIES**

Appearance: off white solid

Solubility: n/s

Boiling Point: n/s

pH: n/s

Vapor Density: n/s

Viscosity: n/s

Melting Point: 100-106 c

Vapor Pressure: n/s

Density: n/s

**FIRE AND EXPLOSION DATA**

Flash Point: n/s

Extinguishing Media: Use appropriate media for underlying cause of fire

Special Fire Fighting Procedures: wear protective clothing and self-contained breathing apparatus

Unusual Fire and Explosion Hazards: Ignition sensitivity: severe; Explosion severity: severe; Explosibility index: severe

**PRODUCT NAME:** Tiagabine Hydrochloride; A-65877; A-70569.1

### REACTIVITY

**Incompatibility:** n/s

**Hazardous Decomposition or By-products:** n/s

**Conditions to Avoid:** n/s

### HEALTH HAZARD DATA

**Routes of Entry:** Inhalation - Yes      Skin - No      Ingestion - No

**Oral Toxicity:** LD50 >2000 mg/kg in rats, >500 (1000 mg/kg in mice

**Dermal Toxicity:** LD50 > 1,000 mg/kg in rabbits. Slight redness was observed at the application site in one rabbit after a 24 hour exposure

**Inhalation Toxicity:** n/s

**Corrosiveness:** n/s

**Dermal Irritation:** not irritating to the skin of rabbits

**Ocular Irritation:** irritant. A moderate eye irritant in rabbits producing corneal opacity, iritis and conjunctival irritation with only partial recovery in 7 days

**Dermal Sensitization:** not a sensitizer in guinea pig maximization assay at a challenge concentration of 25% and 35% in petrolatum.

**Special Target Organ Effects:** n/s. Antiepileptic that inhibits the uptake of gamma-amine butyric acid (GABA) in the central nervous system (CNS). In repeat-dose studies in animals, tiagabine hydrochloride produced CNS changes (tremor, convulsions), salivation, lowered heart rate, changes in liver function parameters, morphologic changes in the liver attributable to enzyme induction at dosages of 3 mg/kg/day or more. In reproductive studies, maternal toxicity and fetal toxicity (decreased weight and increased resorptions) were noted at dosages of 33 mg/kg/day or more

**Carcinogenicity:** NTP - NL      IARC - NL      OSHA - NL      ACGIH - NL

**Signs and Symptoms of Exposure:** n/s. In clinical trials, tiagabine hydrochloride produced headache, numbness, dizziness, impaired concentration, alterations in mood, memory and perception, dry mouth, taste perversions, anhedonia (lack of energy), asthenia, and sweating. Animal data suggest alterations in liver function parameters

**Medical Conditions Aggravated by Exposure:** n/s. Data suggest pre-existing eye injury, CNS ailments or liver disease

**PRODUCT NAME: Tiagabine Hydrochloride; A-65877; A-70569.1**

**HEALTH HAZARD DATA (cont)**

**Emergency and First Aid Procedures:** Remove from source of exposure.  
If skin or eye contact occur, flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care as necessary.

**SPECIAL PROTECTION INFORMATION**

**Ventilation:** use local ventilation to control dust at its source(s)

**Respirator:** supplied air respirator if handling solid material.

**Gloves:** impervious

**Eye Protection:** full-face respirator

**Other Protection:** wear fullbody tyvek coverings with hood and shoe covers during dusty operations.

**SPECIAL HANDLING AND STORAGE**

**Special Precautions:** wash hands and face after handling this compound.

**Spill or Release Procedures:** sweep up product, place into appropriate container for disposal. Avoid dust. Ventilate and wash spill area

**Waste Disposal:** dispose of product in accordance with federal, state, and local regulations

**Other Handling:** n/s



PRODUCT NAME:Tiagabine Hydrochloride; A-65877; A-70569.1

**Legend**

- N/A = NOT APPLICABLE
- N/D = NOT DETERMINED
- NL = Not Listed
- L = Listed
- C = Ceiling
- S = Short Term
- (R) = A registered trademark of Abbott Laboratories
- (TM) = A registered trademark of Abbott Laboratories

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# MATERIAL SAFETY DATA SHEET

Page : 1

**HAST CORPORATION**  
1609 BIDDLE AVENUE  
WYANDOTTE, MI 48192  
(313) 246-6826

Original Date: 09/09/1993  
Revision Date: 02/02/1994

Emergency Telephone: (800) 424-9300 (CHEMTREC)  
(800) 832-HELP (HAST Hotline)  
BOTH NUMBERS ARE AVAILABLE DAYS, NIGHTS, WEEKENDS, & HOLIDAYS.

## SECTION 1 - PRODUCT INFORMATION

Product ID: NVN 651341  
ASCORBIC ACID USP, FCC POWDER  
Common Chemical Name:  
L-ASCORBIC ACID  
Synonyms:  
VITAMIN C POWDER  
Molecular Formula:  
C(6)H(8)O(6)  
Molecular Wt.: 176.1  
Chemical Family: Vitamin

## SECTION 2 - INGREDIENTS

Chemical Name:	CAS	Amount	PEL/TLV Data:
L-ASCORBIC ACID	50-81-7	> 99.8%	NOT ESTABLISHED

I - Denotes an IARC listed carcinogen  
N - Denotes an NTP listed carcinogen  
O - Denotes an OSHA carcinogen

H - Denotes an OSHA health hazard  
P - Denotes an OSHA physical hazard  
C - Denotes a CERCLA listed chemical

See section 18 for SARA-313 list.

## SECTION 3 - PHYSICAL PROPERTIES

Color:	White
Form/Appearance:	Powder
Odor:	Odorless
Bulk Density:	
Bulk Density:	0.7 - 0.8 G/CC
pH:	2.2 - 2.5 (5% AQUEOUS)

	Typical	Low-RANGE-High	Deg.	@ Pressure
Boiling Pt:	NOT AVAILABLE			
Freezing Pt:	- 190		C	1 ATMOSPHERES
Decomp. Temp:	> 190		C	1 ATMOSPHERES
Solubility in Water Description:			Soluble	

## SECTION 4 - FIRE AND EXPLOSION DATA

	Typical	Low-RANGE-High	Deg.	Method
Flash Point:	NOT AVAILABLE			
Autoignition:		370 - 375	C	NONE SPECIFIED

**SECTION 4 - FIRE AND EXPLOSION DATA (cont)**

---

**Extinguishing Media:**

Use water fog, foam or dry chemical extinguishing media.

**Fire Fighting Procedures:**

Firefighters should be equipped with self-contained breathing apparatus and turn out gear.

**Unusual Hazards:**

Adequate ventilation and cleanup must be maintained to minimize dust accumulation. May form explosive dust-air mixture.

**SECTION 5 - HEALTH EFFECTS**

---

Routes of entry for solids and liquids include eye and skin contact, ingestion and inhalation. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquified gases.

**Toxicology Test Data:**

Rat, Oral LD50 - > 10 G/KG

Practically Nontoxic

Human Occupational Exposure Experience -

Slight to moderate sensitizer

**Acute Overexposure Effects:**

Contact with the powder or its dusts may cause irritation of the eyes, skin and respiratory tract. Ingestion of large amounts may cause gastric disturbances.

Inhalation may result in respiratory irritation.

**Chronic Overexposure Effects:**

Chronic ingestion of large doses of vitamin C may cause gastrointestinal disturbances, including nausea and diarrhea, urinary effects involving urine acidification, oxalate and uric acid crystallization in the bladder and kidney and decreased reaction times and psychomotor coordination.

**First Aid Procedures - Skin:**

Wash affected areas with soap and water. Remove and launder contaminated clothing before reuse. If irritation develops, get medical attention.

**First Aid Procedures - Eyes:**

Immediately rinse eyes with running water for 15 minutes. If irritation develops, get medical attention.

**First Aid Procedures - Ingestion:**

If swallowed, dilute with water and immediately induce vomiting. Never give fluids or induce vomiting if the victim is unconscious or having convulsions. Get immediate medical attention.

**First Aid Procedures - Inhalation:**

Move to fresh air. Aid in breathing, if necessary, and get immediate medical attention.

**First Aid Procedures - Notes to Physicians:**

None known.

**First Aid Procedures - Aggravated Medical Conditions:**

No data is available which addresses medical conditions that are generally recognized as being aggravated by exposure to this product. Please refer to Section 5 (Effects of Overexposure) for effects

**SECTION 5 - HEALTH EFFECTS (cont)**

---

observed in animals.

**First Aid Procedures - Special Precautions:**  
None

**SECTION 6 - REACTIVITY DATA**

---

**Stability Data:**

Stable

**Incompatibility:**

No data available.

**Conditions/Hazards to Avoid:**

Heat, light, moisture and air.

**Hazardous Decomposition/Polymerization:**

Polymerization: Does not occur.

**Corrosive Properties:**

Corrosive to metal.

**Oxidizer Properties:**

Not an oxidizer

**SECTION 7 - PERSONAL PROTECTION**

---

**Clothing:**

Gloves, coveralls, apron, and boots as necessary to prevent contact.

**Eyes:**

Chemical Goggles

**Respiration:**

If dusts are generated, wear an approved dust respirator.

**Ventilation:**

Use local exhaust to control dusts.

**Explosion Proofing:**

None required.

**SECTION 8 - SPILL-LEAK/ENVIRONMENTAL**

---

**General:**

Spills should be contained, solidified and placed in suitable containers for disposal in a licensed facility. This material is not regulated by RCRA or CERCLA ("Superfund"). Wear appropriate respiratory protection and protective clothing and provide adequate ventilation during clean-up.

**Waste Disposal:**

Incinerate or bury in a licensed facility. Do not discharge into waterways or sewer systems without proper authority.

**Container Disposal:**

Dispose of in a licensed facility. Recommend crushing or other means to prevent unauthorized reuse.

**Environmental Toxicity Test Data:**

Inhibition of Activated Sludge - < OR = TO 1 G/L

No Inhibition

BOD/COD Calculation for eliminability - 70 PERCENT

Good Potential for Elimination

Golden Orfe, static 96 hr LC50 - 1000-2200 MG/L

Insignificant Hazard

Toxicity to Bacteria - EC/LC50=140 MG/L

ASCORBIC ACID USP, FCC POWDER  
NVN 651341

Page : 4

**SECTION 8 - SPILL-LEAK/ENVIRONMENTAL (cont)**

**TEST RATING NOT FOUND**

**SECTION 9 - STORAGE AND HANDLING**

**General:**

Store in a cool, dry place. Keep containers closed when not in use.  
Store in light impervious containers.

**SECTION 10 - REGULATORY INFORMATION**

**TSCA Inventory Status**

Listed on Inventory: YES  
Product Grades: USP: Y NP: FCC: Y

**SECTION 11 - TRANSPORTATION INFORMATION**

**DOT Proper Shipping Name:**

NONE

**DOT Technical Name:**

NONE

**DOT Primary Hazard Class:**

NONE

**DOT Secondary Hazard Class:**

NONE

**DOT Label Required:**

NONE

**DOT Placard Required:**

NONE

**DOT Poison Constituent:**

NONE

**HAZ Commodity Codes: 453 UN/NA Code: N/A E/R Guide:**

**Bill of Lading Description:**

FOOD, DRUGS OR MEDICINE, NOIBN

CLASS:	P. G.	SHIPPING NAME:
IATA: NONE	NA	NONE
IMO: NONE	NA	NONE
TDG: NONE	NA	NONE

WHILE BASF CORPORATION BELIEVES THE DATA SET FORTH HEREIN ARE ACCURATE AS THE DATE HEREOF, BASF CORPORATION MAKES NO WARRANTY WITH RESPECT THERETO AND EXPRESSINGLY DISCLAIMS ALL LIABILITY FOR RELIANCE THEREON. SUCH DATA ARE OFFERED SOLELY FOR CONSIDERATION, INVESTIGATION, AND VERIFICATION.

END OF DATA SHEET

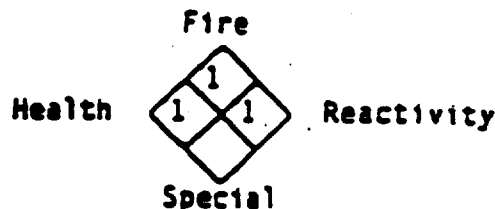
WITCO MATERIAL SAFETY DATA SHEET

HYSTRENE(R) 5016 NF FG

PAGE 1  
Product Code: HM HYST 5016 NF FG

CAS NO:57-11-4

NFPA HAZARD RATING  
4 - Extreme  
3 - High  
2 - Moderate  
1 - Slight  
0 - Insignificant



HMIS HAZARD INDEX		HMIS RATINGS	
Hazardous Materials Identification System	4 - Severe 3 - Serious 2 - Moderate 1 - Slight 0 - Minimal	Health	1
		Flammability	1
		Reactivity	1
		Personal protection	0

DIVISION AND LOCATION---SECTION I

Division: HMKO  
Location: MEMPHIS, TN  
P.O. BOX 125, 1231 POPE STREET, MEMPHIS, TN, 38108-2535  
Emergency Telephone Number: (901) 320-5800  
Transportation Emergency: CHEMTREC 1-(800) 424-9300 (U.S. and Canada)

CHEMICAL AND PHYSICAL PROPERTIES---SECTION II

Chemical Name: stearic acid  
Formula: mixture  
Hazardous Decomposition Products: carbon monoxide and carbon dioxide from burning.  
Incompatibility (Keep away from): strong oxidizers such as hydrogen peroxide, bromine, and chromic acid.  
Toxic and Hazardous Ingredients: none  
Form: solid (flake, powder or bead) odor: mild - typically fatty.  
Appearance: waxy Color: off-white to light tan.  
Specific Gravity (water=1): .875  
Boiling Point: greater than 315°C (600°F)  
Melting Point: approximately 53 to 56°C (127 to 133°F)  
Solubility in Water (by weight %): negligible  
Volatile (by weight %): negligible  
Evaporation Rate: negligible  
Vapor Pressure (mm Hg at 20°C): negligible  
Vapor Density (air=1): not applicable  
pH (as is): no data available  
Stability: Product is stable under normal conditions  
Viscosity SUS at 100°F: not applicable

(Continued on next page)

**WITCO MATERIAL SAFETY DATA SHEET**

HYSTRENE(R) 5016 NF FG

PAGE 2

Product Code: HUN HYST 5016 NF FG

.....  
**FIRE AND EXPLOSION DATA---SECTION III**  
.....

Special Fire Fighting Procedures:

Do not use heavy stream of water. Fatty material will float.

Unusual Fire and Explosion Hazards:

none. see Section VII

Flashpoint: (Method Used) Cleveland open cup approximately 190°C (374°F)

Flammable limits %: no data available

Extinguishing agents:

Drychemical or Waterspray or Waterfog or CO<sub>2</sub> or Foam or Sand/Earth  
Closed containers exposed to fire may be cooled with water.

.....  
**HEALTH HAZARD DATA---SECTION IV**  
.....

Permissible concentrations (air):

Particulates not otherwise regulated: Total dust TWA: 15mg/m<sup>3</sup> Respirable

Fraction: 5mg/m<sup>3</sup> (OSHA)

Particulates not otherwise classified: TWA: 10 mg/m<sup>3</sup> (ACGIH)

Chronic effects of overexposure:

no data available

Acute toxicological properties:

acute oral LD50 greater than 10 g/kg (rat)

Emergency First Aid Procedures:

Eyes: Immediately flush with large quantities of water for at least 15 minutes and call a physician.

Skin Contact: Wash with soap and water. For contact with hot molten material, cool burned skin area by immersing in cold water or apply cold water.

Inhalation: Remove victim to fresh air.

If Swallowed: Contact a physician immediately.

.....  
**SPECIAL PROTECTION INFORMATION---SECTION V**  
.....

Ventilation Type Required (Local, mechanical, special):

Local if necessary to control dust or fumes from hot material and to maintain the permissible exposure limit (PEL) or time-weighted average (TWA) value

Respiratory Protection (Specify type):

Use NIOSH/MSHA certified dust mask and/or respirator where appropriate.

Protective Gloves:

neoprene type

Eye Protection:

chemical safety goggles and, if handled hot, full face shield

Other Protective Equipment:

neoprene protective type apron.

(Continued on next page)

WITCO MATERIAL SAFETY DATA SHEET

HYSTRENE(R) 5016 NF FG

PAGE 3

Product Code: HUN HYST 5016 NF FG

.....  
HANDLING OF SPILLS OR LEAKS---SECTION VI  
.....

Procedures for Clean-Up:

Ordinary housekeeping procedures are adequate. Melted material can cause thermal burns. Material can be burned or landfilled. In case of spillage, sweep up and dispose of in accordance with federal, state and local regulations.

Waste Disposal:

Dispose of in accordance with all applicable federal, state and local regulations.

.....  
SPECIAL PRECAUTIONS---SECTION VII  
.....

Precautions to be taken in handling and storage:

Where dusty and/or misting conditions exist an explosive atmosphere could develop as with any organic material. Keep containers sealed until ready for use. Avoid excessive long term storage temperatures to prolong shelf life.

Maximum Storage Temperature: 66°C (150°F)

.....  
TRANSPORTATION DATA---SECTION VIII  
.....

D.O.T.: Not Regulated

Reportable Quantity: not applicable

Freight Classification:

Special Transportation Notes:

.....  
ENVIRONMENTAL/SAFETY REGULATIONS---SECTION IX  
.....

Section 313 (Title III Superfund Amendment and Reauthorization Act):

This product does not contain any chemical subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

.....  
COMMENTS  
.....

For Industrial Use Only.

(Continued on next page)



**WITCO MATERIAL SAFETY DATA SHEET**

**HYSTRENE(R) 5016 NF FG**

**PAGE 4**

**Product Code: HUM HYST 5016 NF FG**

**(COMMENTS continued)**

**Prepared by:** Bruce Moorman \_\_\_\_\_  
**Title:** Regulatory Compliance \_\_\_\_\_  
**Original Date:** 10/16/85 **Sent to:** \_\_\_\_\_  
**Revision Date:** 06/17/93 \_\_\_\_\_  
**Supersedes:** 01/10/90 \_\_\_\_\_  
**Date Sent:** \_\_\_\_\_

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage, or expense, direct or consequential, arising out of their use.

# Product Name: Avicel® PH Microcrystalline Cellulose

7

## MATERIAL SAFETY DATA SHEET

This document has been prepared to meet the requirements of the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200; the EEC Directive, 91/155/EEC and other regulatory requirements.

### 1. Company and Product Identification

**FMC CORPORATION**  
Pharmaceutical and Bioscience Division  
1735 Market Street  
Philadelphia, PA 19103 (U.S.A.)

**FMC CORPORATION NV**  
Avenue Louise 488-B9  
1050 Brussels, Belgium

**Chemical Name** : Microcrystalline Cellulose  
**Brand Name** : Avicel® PH 101, 102, 103, 105, 112, 200  
**Chemical Family** : Carbohydrate  
**Formula** : (C<sub>6</sub>H<sub>10</sub>O<sub>5</sub>)<sub>x</sub>  
**Synonyms** : Microcrystalline Cellulose, MCC

#### EMERGENCY TELEPHONE NUMBERS:

**U.S.A. & Canada**  
Medical (303) 595-9048  
Chemical (800) 424-9300  
Plant (302) 451-0100

**Europe**  
Medical 01 (303) 595-9048  
Transportation 01 (202) 483-7616  
Plant (Cork) 353 21 354 133

**General Information:** (215) 299-6000

**Brussels** 32 2 645 5511

### 2. Composition/Information on Ingredients

<u>Ingredient Name</u>	<u>CAS#</u>	<u>EEC Symbol and Risk Phrases</u>
Microcrystalline Cellulose	9004-34-6	Not classified as dangerous

### 3. Hazards Identification

#### Emergency Overview:

Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed.

#### Potential Health Effects:

Minimally irritating to the eyes and non-irritating to the skin. No adverse human effects known.

### 4. First Aid Measures

**Eyes** : Flush with water for at least 15 minutes. If irritation occurs and persists, obtain medical attention.  
**Skin** : Wash with plenty of soap and water. Get medical attention if irritation occurs and persists.  
**Inhalation** : Remove to fresh air. If breathing difficulty or discomfort occurs and persists, obtain medical attention.  
**Ingestion** : Drink plenty of water. Never give anything by mouth to an unconscious person. If any discomfort persists, obtain medical attention.

**Notes to Medical Doctor:** This compound has very low toxicity. Treatment is symptomatic and supportive only.

## Product Name: Avicel® PH Microcrystalline Cellulose

### 5. Fire Fighting Measures

- Extinguishing Media** : Water
- Unusual Fire and Explosion Hazard** : Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed. The propagation of flame through air-floated dusts takes place usually following a small explosion which shakes down accumulated dust. According to NFPA 68 (Explosion Venting Guide), the Hazard Class of Dust Deflagrations for microcrystalline cellulose is St-1, the lowest hazard class.
- Special Fire Fighting Procedures** : For fires involving this material, do not enter any enclosed or confined fire space without wearing full protective clothing and self-contained breathing apparatus (SCBA) approved for firefighting. This is necessary to protect against the hazards of heat, products of combustion and oxygen deficiency. Do not breathe smoke, gases or vapors generated.
- Hazardous Decomposition Products** : None known

### 6. Accidental Release Measures

Maintain good housekeeping practices to minimize accumulation of settled dust, especially on overhead surfaces. Sweep up the spilled material and dispose of in accordance with the waste disposal method outlined in Section 13, "Disposal Considerations".

### 7. Handling and Storage

Use local exhaust or general dilution ventilation to control exposure to dust. Always use safe lifting techniques when manually moving containers, especially when shipping containers weighing more than 50 pounds (22.7 kg). To protect quality, store in a tight container in a dry place.

### 8. Exposure Controls/Personal Protection

#### Recommended Personal Protective Equipment

- Respiratory** : Whenever dust in the worker's breathing zone cannot be controlled with ventilation, workers should wear respirators which are approved by NIOSH/MSHA (or equivalent agency) for protection against airborne dust.
- Eyes** : Whenever airborne dust concentrations are high, appropriate protective eyewear, such as monogoggles, should be worn to prevent eye contact.
- Gloves** : Not required.
- Special Clothing and Equipment** : Not required.

#### Exposure Limits

Exposure Limit: Cellulose

	Inhalable Dust	Respirable Dust	STEL
Belgium (TWA)	10 mg/m <sup>3</sup>	-	-
France (TWA)	-	10 mg/m <sup>3</sup>	-
Switzerland (TWA)	-	6 mg/m <sup>3</sup>	-
United Kingdom (TWA)	10 mg/m <sup>3</sup>	5 mg/m <sup>3</sup>	20 mg/m <sup>3</sup>
USA (ACGIH TWA)	10 mg/m <sup>3</sup>	-	-
USA (OSHA TWA)	15 mg/m <sup>3</sup>	5 mg/m <sup>3</sup>	-

**Product Name: Avicel® PH Microcrystalline Cellulose**

**9. Physical/Chemical Properties**

<b>Appearance</b>	: White, free flowing powder	<b>Solubility in Water</b> (% by Weight)	: Insoluble
<b>Odor</b>	: Odorless	<b>Evaporation Rate</b> (butyl acetate = 1)	: Not applicable
<b>Melting Point</b>	: Not applicable	<b>Flash Point</b>	: Not applicable
<b>Boiling Point</b>	: Not applicable	<b>Flammable Limits (Air)</b> <b>Upper</b>	: Not applicable
<b>Vapor Pressure</b>	: Not applicable	<b>Lower</b>	: Not applicable
<b>Vapor Density</b> (Air = 1)	: Not applicable	<b>Autoignition Temperature</b> <b>Minimum Ignition Temp</b>	: 420°C
<b>pH (as is)</b>	: Not applicable	<b>Exosmotic Properties</b>	: Si-1
<b>pH (in soln)</b>	: 5.0-7.0 as an 11% solids dispersion	<b>Oxidizing Properties</b>	: Not applicable
<b>Specific Gravity</b> (H <sub>2</sub> O = 1)	: Bulk density, 0.3 g/cc	<b>Partition Coefficient (K<sub>ow</sub>)</b>	: Not applicable
<b>% Volatiles by Volume</b>	: Approximately 5% water, by weight	<b>Fat Solubility</b>	: Not available

**10. Stability and Reactivity**

<b>Stability</b>	: Stable	<b>Hazardous Decomposition Products</b>	: None known
<b>Conditions/Materials to Avoid (Incompatibility):</b> None known			

**11. Toxicological Information**

<b>Eye Contact</b>	: Minimally irritating (rabbit). FMC Study Numbers IE2-621, IE2-626.
<b>Skin Contact</b>	: Non-irritating. Primary Irritation Index (rabbit) = 0/8.0. FMC Study Number IE2-625. Non-sensitizing (guinea pig). FMC Study Number I91-1184.
<b>Skin Absorption</b>	: Dermal LD50 > 2 g/kg (rabbit). FMC Study Numbers IE2-620, IE2-624.
<b>Inhalation</b>	: No mortality at maximum attainable concentration. 4 hour LC50 > 5.05 mg/l (rat). FMC Study Numbers IE2-622, IE2-627.
<b>Ingestion</b>	: Oral LD50 > 5 g/kg (rat). FMC Study Number IE2-623.

**Acute Effects From Overexposure:** No significant hazard in animal toxicity tests.

**Chronic Effects From Overexposure:** A 90 day animal study showed no adverse effects when administered in the diet (FMC Study Number I92-1464). This product was negative (non-mutagenic) in the Ames test (FMC Study Number I91-1189). No adverse human effects known. Microcrystalline cellulose is considered an inert dust which is not toxic to the lung when exposures are properly controlled.

**Carcinogenicity:** IARC: No      NTP: No      Other (OSHA, ACGIH): No

**12. Ecological Information**

**Environmental Fate:** Biodegradation in soil: Inherently biodegradable (FMC Study Number I92-1300).

**Environmental Effects:**

<b>Rainbow Trout:</b>	96 hr LC50 > 100%. Saturated solution. (NOEC = 100%). FMC Study Number I92-1297.
<b>Daphnia:</b>	48 hr LC50 > 100%. Saturated solution (NOEC = 100%). FMC Study Number I92-1298.
<b>Algae:</b>	96 hr EC50 > 100%. Saturated solution (NOEC = 12.5%). FMC Study Number I92-1299.

## Product Name: Avicel® PH Microcrystalline Cellulose

### 13. Disposal Considerations

No special disposal methods are suggested. It is the user's responsibility to comply with all applicable local, state, and federal laws, rules, regulations, and standards.

### 14. Transportation Information

U.S. DOT : Not regulated in Title 49 of the U.S. Code of Federal Regulations as a hazardous material.  
Shipping Name : National Motor Freight Classification Item 71390, Flour Cellulose, Edible.  
UN (IMO/MDG) : Not Applicable  
Marine Designation : None  
Canada (TDG) : Not Applicable

### 15. Regulatory Information

U.S. TSCA Inventory : Yes  
U.S. SARA Title III  
Section 311/312 : None  
Section 313 (40 CFR 372) : This product does not contain any toxic chemicals subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA) and 40 CFR part 372.  
California Proposition 65 : This product does not contain any chemicals currently on the California list of known carcinogens and reproductive toxins.  
Canada WHMIS : Not a controlled product under the Canadian Workplace Hazardous Materials Information System (WHMIS).  
EEC EINECS No. : Z32-674-9 Cellulose  
Z31-595-7 Hydrochloric acid  
Note: Under the EINECS reporting guidelines, the reactants are reportable; the post-reacted natural polymer is not reportable.  
EEC Symbols : Not classified as dangerous  
EEC Risk Phrases : Not classified as dangerous  
EEC Safety Advice Phrases : Not classified as dangerous  
Additional Regulatory Information : Avicel® PH Microcrystalline Cellulose meets the standards set forth in the United States Pharmacopoeia/National Formulary, European Pharmacopoeia, British Pharmacopoeia, The Pharmacopoeia of Japan and the Food Chemicals Codex. Microcrystalline cellulose is generally recognized as safe (GRAS) by qualified experts and is in accordance with the United States Food and Drug Administration. FMC maintains a Drug Master File at the U.S. Food and Drug Administration to support the safe use of Avicel PH in drug products. The Avicel PH products are manufactured in accordance with Current Good Manufacturing Practice and are in compliance with the Federal Food, Drug and Cosmetic Act, as Amended.

### 16. Other Information

NFPA Designation 704

		Degree of Hazard	Degree of Hazard Code
Red	Fire:	1	4 = Extreme
Blue	Health:	0	3 = High
Yellow	Reactivity:	0	2 = Moderate
White	Special Hazard:	None	1 = Slight 0 = Insignificant

Prepared by: FMC Corporation  
Sections Revised: New Format

**Mandatory Safety Data Sheet:**  
 May be used to comply with  
 OSHA's Hazard Communication Standard,  
 29 CFR 1910.1200. Standards must be  
 consulted for specific requirements.

**U.S. Department of Labor**  
**Occupational Safety and Health Administration**  
 (Non-Mandatory Form)  
 Form Approved  
 OMS No. 1216-0072



**Section I - Product Identification**  
 Product Name (as used on label and SDS): **NF Lactose, Anhydrous DT**  
 Other Name(s) (if any): **Code # 41199**

**Section I - Manufacturer/Supplier Information**  
 Manufacturer's Name: **Sheffield Products**  
 Address: **Norwich, New York 13815**  
 P.O. Box: **630**  
 Emergency Telephone Number: **Chemtrec: 1-800-424-9300**  
 Telephone Number (in US/Canada): **607-334-9951**  
 Date Prepared: **10/31/88**  
 Signature of Preparer (optional):

**Section II - Hazardous Ingredients/Identity Information**

Hazardous Components (Include Chemical Name, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limit Requirements	% Report
NONE				

**Section III - Physical/Chemical Characteristics**

Boiling Point	N.A.	Specific Gravity (4°C = 1)	Bulk Density	Approx. 8
Vapor Pressure (mm Hg)	Negligible	Initial Boiling Point		Decomposes
Vapor Density (AIR = 1)	Negligible	Evaporation Rate (Butyl Acetate = 1)		N.A.
Solubility in Water	20g/100 ml @ 75°C			
Appearance and Odor	White Powder, Nearly Odorless			

**Section IV - Fire and Explosion Hazard Data**

Flash Point (closed cup)	Unknown	Flammable Limits	Unknown	LEL	UL
Evaporating Media	Water, CO <sub>2</sub>				
Special Fire Fighting Procedures	None Required				
UN ID No. / Fire and Explosion Hazard	None				

**Section V -- Reactivity Data**

Reactivity	Violent		Contains or emits
	Stable	X	

Intermediately (Contains or emits)

Not Determination or Synthesis

Reactivity Polymerization	May Occur		Contains or emits
	Will Not Occur	X	

**Section VI -- Health Hazard Data**

Amount of Entry: common?      Skin?      Ingestion?

Health Hazard (Skin and Others): **Not a Health Hazard**

Carcinogenicity      HFP?      OAC Management?      OSHA Required?

**Not a Carcinogen**

Signs and Symptoms of Exposure

Special Concerns  
Generally approved by Exposure

Emergency and First Aid Procedures **None Required**

**S in VII -- Precautions for Safe Handling and Use**  
Steps to be Taken in Case Release or Spill

**Sweep or Vacuum**

Waste Disposal Method **Normal solid waste disposal**

Precautions to be Taken in Handling and Storage

**No special precautions**

Other Precautions

**Section VIII -- Control Measures**

Respiratory Protection (NIOSH) **Not required**

Ventilation	Local Exhaust		Source
	Methodical Control		Other

Protective Clothing **Not Required**      Eye Protection **Not Required**

Other Protective Clothing or Equipment **Not Required**

Other Precautions **Normal**

# CABOT


## Material Safety Data Sheet

Cabot Corporation  
CAB-O-SIL Division  
P.O. Box 148  
Lynn, MA 01902-0148  
(617) 253-3370  
1-800-525-4746  
Telex: 970-003-2546  
Fax: (617) 253-4320

### CAB-O-SIL® UNTREATED FUMED SILICA

DATE ISSUED January, 1985	DATE REVISED January, 1993	EMERGENCY TELEPHONE NUMBER 217-253-3370
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#### SECTION I - IDENTIFICATION OF MATERIAL

CHEMICAL NAME OR COMPOSITION Silicon Dioxide, Crystalline-Free	HAZARD RATING  FIRE HEALTH REACT.
TRADE NAME & SYNONYMS CAB-O-SIL® Fumed Silica, Colloidal Silica, Synthetic Silica	
CHEMICAL FAMILY Oxide	MOLECULAR FORMULA SiO <sub>2</sub>

#### SECTION II - SIGNIFICANT COMPONENTS AND CONTAMINANTS

CAS NO.	COMPONENT	PERCENT	PERMISSIBLE EXPOSURE LIMIT	ACGIH Total Dust
112945-52-5	Silica, amorphous, fumed, cryst.-free	99 plus	*None Listed	*None Listed

\*CAB-O-SIL fumed silica is a non-hazardous material and thus does not have an assigned PEL or TLV. The industry standard for total dust sampling purposes is 6 mg/m<sup>3</sup>.

NOTE: Refer to SECTION XI for TSCA information.

#### SECTION III - PHYSICAL DATA

PHYSICAL CHARACTERISTICS Fine White Powder, Odorless
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BOILING POINT NA	FREEZING POINT NA	SPECIFIC GRAVITY (WATER = 1.0) 2.2
VAPOR PRESSURE (mm OF MERCURY) NA	pH 4.0 (4% Aqueous Slurry)	
VAPOR DENSITY (AIR = 1) NA	SOLUBILITY IN WATER Insoluble	

#### SECTION IV - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (SPECIFY METHOD) NA	FLAMMABLE (EXPLOSIVE) LIMITS (PERCENTAGE BY VOLUME)	
	LOWER EXPLOSIVE LIMIT NA	UPPER EXPLOSIVE LIMIT NA

FIRE EXTINGUISHING MEDIA NA
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SPECIAL FIRE FIGHTING PROCEDURES NA
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UNUSUAL FIRE AND EXPLOSION HAZARDS See Section IX
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**SECTION V - HEALTH HAZARD DATA****TOXICITY**

CAB-O-SIL® is not considered a carcinogen by IARC, NTP or OSHA. Primary route of entry: Inhalation.  
 Non-toxic Oral LD 50 = Greater than 5000 mg/kg.

**EFFECTS OF OVEREXPOSURE****ACUTE**

None known other than possible temporary discomfort due to inhalation of dust concentration above permissible exposure limit.

**CHRONIC**

Human studies have found that workplace exposures to fumed silica do not cause chronic health effects. However, some researchers believe that chronic inflammation, lung fibrosis and lung tumors can be developed from exposure to levels of respirable dust above the industry standard of 6 mgm<sup>-3</sup>. This exposure results in dust overload phenomenon which is due to the lung clearance mechanism being overloaded. Amorphous fumed silica was not used in these research tests.

**EMERGENCY AND FIRST AID PROCEDURES**

Flush eyes with plenty of water. For inhalation discomfort, move victim to fresh air.

**SECTION VI - REACTIVITY DATA****GENERAL REACTIVITY**

Stable

**INCOMPATIBILITY (MATERIALS TO AVOID)**

None

**HAZARDOUS DECOMPOSITION PRODUCTS**

None

**HAZARDOUS POLYMERIZATION**

None

**CONDITIONS TO AVOID**

NA

**SECTION VII - SPILL PROCEDURES / DISPOSAL REQUIREMENTS****STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED**

Spilled CAB-O-SIL fumed silica is not a hazardous waste under U.S. Federal RCRA Regulations.

**WASTE DISPOSAL METHOD**

CAB-O-SIL fumed silica may be swept up or vacuumed for normal disposal.

**CONTAINER DISPOSAL**

Ordinary methods for non-hazardous waste.

**SECTION VIII - SPECIAL PROTECTION INFORMATION (SPECIFY IN DETAIL)****EYE PROTECTION**

Safety glasses recommended

**GLOVES**

Not necessary

**RESPIRATORY**

NIOSH approved dust respirator recommended for concentrations above 6 mgm<sup>-3</sup>.

**VENTILATION**

Adequate for dusty environments

**OTHER**

None

**SECTION IX - SPECIAL PRECAUTIONS**

Dry powdered materials can build static electrical charges when subjected to friction. Proper precautions, when using CAB-O-SIL fumed silica in the presence of flammable or explosive liquids, should be taken to prevent accidents. (See NFPA-77 Static Electricity)

**SECTION X - SHIPPING REGULATIONS (D.O.T. NOMENCLATURE)**

CAB-O-SIL fumed silica is not restricted/non-hazardous.

**SECTION XI - REGULATORY INFORMATION**

CAB-O-SIL fumed silica is not a hazardous substance under EPA CERCLA and SARA Title III. The following EPA CERCLA and SARA Title III notification requirements do not apply to this non-hazardous substance: 1) Release; 2) Emergency planning based on threshold quantities (TPC); 3) Release reporting on reportable quantities; 4) Submission of annual reports of release of toxic chemicals. CAB-O-SIL synthetic silica is listed in the United States of American Environmental Protection Agency (USEPA) Toxic Substance Control Act (TSCA) Chemical Substance Inventory under its former CAS #7631-86-8.

CAB-O-SIL fumed silica does not contain, and is not manufactured with Class I or Class II ozone depleting chemicals, as defined in the Clean Air Act of 1990

The data and conclusions contained herein are based on studies made in Cabot Corporation laboratories and are believed to be reliable as of 1/82. We do not guarantee if further results appear contradictory will be obtained by others. We disclaim any liability resulting from the use of the contents of this report.

# CABOT

Dear Customer:

Attached is the information you requested on CAB-O-SIL<sup>®</sup> fumed silica and/or its related products.

As you know, U.S. federal and state government authorities have instituted many regulatory laws which require that complete information on material safety and composition be published and made available upon request.

The Cab-O-Sil Division of Cabot Corporation has complete information covering the regulations listed below:

- OSHA 1910.1200 - Hazard Communication
- IARC, NTP, and OSHA Carcinogenicity Reports
- F.D.A. Testing and Approval Information
- Sara Title III Information
- California Proposition 65
- Pennsylvania's Worker and Community Right-To-Know Act
- New Jersey Worker and Community Right-To-Know Act N.J.A.C. 8:59
- TSCA Registration and Similar Foreign Registrations

## OSHA 1910.1200 - Hazard Communication, IARC, NTP, AND OSHA Carcinogenicity Reports

Information requested regarding OSHA 1910.1200 and the carcinogenicity of CAB-O-SIL fumed silica product(s) is included in that product's Material Safety Data Sheet (MSDS). Cabot's MSDS format meets or exceeds the requirements for material information disclosure under 1910.1200.

In addition, you will note under Section V of the MSDS, *Health Hazard Data*, the IARC, NTP, and OSHA do not classify CAB-O-SIL fumed silica and its related products as carcinogens.

## F.D.A. Testing and Approval Information

The United States Food and Drug Administration (FDA) has approved the use of hydrophilic fumed silica for many food applications (both as a direct food additive and as a substance allowed into direct contact with food). The FDA has also approved the use of fumed silica in cosmetic and pharmaceutical applications. To our knowledge, no agency or organization characterizes CAB-O-SIL fumed silica or any of its related products as reproductive toxins. Additionally, to our knowledge, no study provides any indication that these products might be considered a reproductive toxin.

Cabot Corporation  
Cab-O-Sil Division  
P.O. Box 188  
Tucson, IL 61953-0188  
317-255-3370  
Toll Free 1-800-322-5725

### **SARA Title III Information**

Information on CAB-O-SIL fumed silica or its related products in connection with SARA - Title III Community Right-to-Know may be found on the product's MSDS.

### **California Proposition 65, Pennsylvania and New Jersey's Worker and Community Right-To-Know Acts**

With regard to California's Toxic Enforcement Act - Proposition 65 and Pennsylvania's Worker and Community Right-To-Know Act, the Health and Safety Data Sheet and MSDS have been published to answer many of the required questions. While CAB-O-SIL fumed silica and related products are listed on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory, they have been proven to be non-toxic. The fumed silica and related products do not contain as additives or components any of the chemicals identified as toxic under either of the state acts. Some substances may occur in trace amounts as impurities. However, for purposes of the Pennsylvania law, they would not be present in reportable quantities. Moreover, for purposes of the California law, Cabot believes that exposure to its fumed silica poses no significant risk of cancer and no observable effect on reproduction.

The Cab-O-Sil Division of Cabot Corporation has properly labeled all Cab-O-Sil fumed silica and related product packages to insure that they are in compliance with the New Jersey Worker and Community Right-To-Know Act.

### **TSCA Registration**

CAB-O-SIL hydrophilic and treated fumed silicas are listed on the United States of America Environmental Protection Agency (USEPA) Toxic Substances Control Act (TSCA) Chemical Substance Inventory. CAB-O-SIL fumed silica and other related products are also listed on several similar foreign chemical inventories such as ECOIN - European Core Inventory for EINECS - European Inventory of Existing Commercial Chemical Substances (European Community), MITI - Ministry of International Trade and Industry - Department of the Japanese Government (Japan), ACOIN - Australian Inventory of Chemical Substances (Australia), and DSL/NDSL - Domestic Substances List/Non-Domestic Substances List (Canada).

It is our desire to comply with all federal and state regulations and as such, we trust this letter, together with the enclosed information, will be adequate to answer all of your questions. However, if I may be of further assistance, please contact me.

Sincerely,



Michael A. Yusko  
Health & Safety Manager

MAY/gaw

Enclosures

# CABOT

## Technical Data

Great Britain  
CAB-O-SIL Division  
P.O. Box 100  
Totton, S. 01120-0100  
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1-800-422-0742  
Telex: 914-022-0242  
Fax: 0171 253-2070

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CAB-O-SIL Division  
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Telex: 779451  
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Great Britain Ltd.  
CAB-O-SIL Division  
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Bury House Road  
Sully, S. Gloucestershire GPO 22P  
LONDON England  
Telephone: +44 1452-72000  
Fax: +44 1452-72712

## Health, Safety and Regulatory Status of CAB-O-SIL<sup>®</sup> Untreated Fumed Silica

### Manufacture

CAB-O-SIL<sup>®</sup> fumed silica is a synthetic, amorphous, colloidal silicon dioxide. It is produced by the vapor hydrolysis of chlorosilanes, such as silicon tetrachloride, in a hydrogen-oxygen flame.



The combustion process creates silicon dioxide molecules which condense to form particles. The particles collide, attach and sinter together. The result of these processes is a three dimensional branched chain aggregate with a length of approximately 0.2 to 0.3 microns. Once the aggregates cool below the fusion point of silica (1710°C), further collisions result in mechanical entanglement of the branched chain aggregates, termed agglomeration. Further agglomeration takes place in the collection system to yield a fine white fluffy powder with an agglomerate size of less than 325 US Mesh (44 microns) and surface areas ranging from 90 to 380 m<sup>2</sup>/g. Calcining reduces the hydrogen chloride level to less than 100 ppm. The manufacturing system combined with the high quality of the feedstock insures the purity of the silica.

### Toxicology

CAB-O-SIL fumed silica is amorphous and does not possess the fibrogenic potential of many crystalline silicas. Experience over the past 30 years of manufacturing fumed silica shows not a single complaint case of lung fibrosis or loss of pulmonary functions due to fumed silica inhalation.

Tests with laboratory animals have given the following results:

### Acute Oral Toxicity

CAB-O-SIL was administered by oral gavage to 10 albino rats at dose levels of 5 grams per kilogram of body weight. All animals survived the 14 day duration of the study.

### Primary Dermal Irritation

CAB-O-SIL was evaluated for primary dermal irritation potential when applied under impervious bandages to clipped, intact, and abraded skin of albino rabbits. The Primary Irritation Index was calculated to be 0.44 on a scale of 0-8. The fumed silica was considered inert to mildly irritating.

### Primary Eye Irritation

CAB-O-SIL was evaluated for primary eye irritation potential when instilled in the eyes of rabbits. The mean Primary Eye Irritation Scores for unwashed eyes were 1.0 and 0.3 (in a scale of 0-110) after 24 and 48 hours, respectively, and 0.0 for the duration of the test. Scores for washed eyes were 0.0 throughout the 7 day test period. The fumed silica was considered inert to very mildly irritating.

### Acute Dust Inhalation (4 hr. Gravimetric)

A group of 10 test animals (rats) was exposed to an atmosphere with a gravimetric concentration of 2.08 mg/l (nominal concentration 59 mg/l) of CAB-O-SIL for a 4 hour period followed by a 14 day observation period. No animals perished during the exposure or in the 14 day period after exposure. At necropsy, no gross lesions were observed.

When tested under the stated conditions, the LC-50 for CAB-O-SIL<sup>®</sup> fumed silica is greater than the gravimetric concentration of 2.08 mg/l or nominal concentration of 59 mg/l.

#### Mutagenicity Testing

CAB-O-SIL fumed silica was evaluated in a battery of four standard tests for mutagenicity. The fumed silica was found to be negative in all four tests.

#### Purity

CAB-O-SIL is the purest commercially available amorphous silica. It is at least 99.8 percent by weight silicon dioxide on an ignited weight basis. Typical levels of trace metallic impurities are shown below:

Typical Analysis of CAB-O-SIL fumed silica for Trace Metallic Contaminants

Element ppm	Element ppm	Element ppm
Ag <0.1	Cr <0.1	P <0.1
Al <1	Cu <0.1	Pb <0.1
As <0.05	Fe <1	Sb <0.1
B <1	Hg <0.1	Se <0.1
Ba <0.1	Li <0.1	Sn <0.1
Be <0.1	Mg <1	Ti <1
Bi <0.1	Mn <0.1	V <0.1
Cs <1	Mo <0.1	Zn <0.1
Cd <0.1	Na <0.1	Zr <0.1
Co <0.1	Ni <1	

The "less than" sign (<) indicates that the element was not detected at the level given. These data do not represent a guarantee or specification but simply show typical values found when random production samples were tested by various analytical methods.

#### Regulatory Status

##### CAB-O-SIL Fumed Silica in Foods

The use of CAB-O-SIL has been approved by the United States Food and Drug Administration (F.D.A.) for many food applications as both a direct food additive at levels up to 2 percent by weight and as a substance allowed in the manufacture of materials that come into direct contact with food in various producing, manufacturing, packing, preparing, transporting, and holding operations.

Relevant sections can be found in Title 21 Code of Federal Regulations, Part 172 "Food Additives Permitted for Direct Addition to Food for Human Consumption." Additional information on the use of CAB-O-SIL fumed silica in foods is available in the publication, *CAB-O-SIL<sup>®</sup> Fumed Silica as a Conditioning Agent for the Food Processing Industry*.

#### Food Chemicals Codex

CAB-O-SIL meets all of the requirements for "Silicon Dioxide" (Synthetic Amorphous Silica). Lot analysis available upon request.

#### CAB-O-SIL Fumed Silica in Pharmaceuticals

CAB-O-SIL has been authorized by United States Food and Drug Administration (F.D.A.) for use in pharmaceutical products for internal and topical applications. Information on the use of CAB-O-SIL fumed silica in pharmaceuticals may be found in the publication, *CAB-O-SIL<sup>®</sup> Fumed Silica in Cosmetics and Pharmaceuticals*.

#### USP-National Formulary

CAB-O-SIL meets all of the requirements for "Colloidal Silicon Dioxide" as described in the United States USP-National Formulary, the European Pharmacopoeia, the DAB 9 and other national pharmacopoeias.

#### Chemical Substance Inventory Listings

CAB-O-SIL is listed in the Chemical Substance Inventories as follows:

TSCA AND AICS (U.S. and Australia)	EINECS (Europe)	MITI (Japan)
7631-86-9 <sup>(1)</sup>	2315454	1-548 (1-810) <sup>(2)</sup>

(1) The Chemical Abstract Service (C.A.S.), a division of the American Chemical Society, has issued CAB-O-SIL the registration number, 112945-52-5 (silica, amorphous, fumed, crystalline-free). CAB-O-SIL is included in the Toxic Substance Control Act (TSCA) inventory as CAS registry number, 7631-86-9, which identifies silica (SiO<sub>2</sub>) regardless of its physical form.

(2) Issued MITI numbers refer to the Official Gazette Announcement while the numbers in parentheses ( ) refer to the Reference Number of Classification by Structure.

## OSHA Hazard Communication Standard

CAB-O-SIL fumed silica is not considered a hazardous chemical under the U.S. Occupational Safety and Health Administration's Hazard Communication Standard (29 CFR Sec. 1910.1200). All CAB-O-SIL fumed silica manufactured and sold in the United States is labeled in accordance with the requirements of the Hazard Communication Standard. Material Safety Data Sheets are available upon request.

## Industry Recognized Exposure Concentration

CAB-O-SIL is a non-hazardous material and thus does not have an assigned PEL or TLV. The industry standard for total dust sampling purposes is  $6 \text{ mg/m}^3$ .

## Handling and Storage

### Handling

Since CAB-O-SIL is a dry powder material, we recommend the following for maximum comfort and safety:

- Avoid continued excessive inhalation. Fumed silica dust levels should not exceed an 8 hour time weighted average total dust exposure of  $6 \text{ mg/m}^3$ . The German (1990) MAK value has been fixed at  $4 \text{ mg/m}^3$  total dust.
- Provide adequate ventilation of the work area. Where ventilation is not available, a NIOSH approved dust respirator is recommended for concentrations above  $6 \text{ mg/m}^3$ .
- Wear eye protection.
- Exposure to fumed silica dust may dry the skin, hence protective skin oils, creams and gloves are useful.

- Clean-up of CAB-O-SIL untreated fumed silica spills can be handled using a vacuum or wet absorbent materials. Wet CAB-O-SIL on a walking surface may be slippery.
- Dry powders, such as CAB-O-SIL, can build static electrical charges when subjected to friction by pouring, conveying or mixing. Proper safety precautions, including electrical grounding, inert atmosphere, etc., should be taken when handling near flammable or explosive liquids. For further information see NFPA #77, *Static Electricity*.

### Storage

Due to CAB-O-SIL fumed silica's high purity and stability, it will not chemically degrade. However, it should be noted that as the surface area of the untreated grades of fumed silica increases, the tendency to adsorb moisture increases during storage. Due to this fact, it is recommended that the product be stored in a clean, dry area away from chemical vapors at ambient temperatures. It is recommended that the product be used within the first two years of its date of manufacture.

The moisture content of CAB-O-SIL is less than 1.0 wt % at the time of packaging. This will increase, depending upon the percent relative humidity, time and temperature.

Surface moisture can interfere in some applications, but the original moisture levels can be recovered by drying the fumed silica in an oven set to  $105^\circ\text{C}$  or higher. If an application is critically sensitive to moisture, a local CAB-O-SIL fumed silica representative should be contacted to discuss packaging and handling options.

Compliance with the various government regulations is incumbent upon the user.

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The data and conclusions contained herein are based on studies made in Cabot Corporation laboratories and are believed to be reliable as of 3/92. We do not guarantee that similar results and/or conclusions will be obtained by others. We disclaim any liability resulting from the use of the contents of this report.

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TD-106

3/92

ACID, ASCORBIC USP WHITE POWDER

ACID, ASCORBIC, SURFACE COATED



HOFFMANN-LA ROCHE INC.  
CORP. ENVIRONMENTAL & SAFETY AFFAIRS  
NUTLEY, NEW JERSEY 07110  
(201) 226-3333

MATERIAL SAFETY DATA

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ORIGINATED	07/07/81
APPROVED	-
REVISED	02/17/86

CHEMICAL NAME  
3-Oxo-L-gulofuranolactone(enal); L-3-Keto-threobexuronic acid  
Lactone (keto)  
ABBOTT PRODUCT CODE #11450 & #11455

CODE NO. 60406, 60456, 60470, 60476, 60481, 60482, 60491  
CAS NO. 50-81-7  
REG. NO. 1-3091

Formula:  $C_6H_8O_6$   
Formulation/s: Redoxon; SEROCIA Tablets; SEROCIA PN; SEROCIA Plus Tabs;  
LAROSEC; VI-PENTA F Chewables; VI-PENTA Infant Drops; VI-PENTA F Infant Drops  
Synonyms: vitamin C; L(+)-ascorbic acid  
Chemical Family: Unsaturated hydroxylated gamma-lactone  
Molecular Weight: 176

HAZARD WARNING:  
Clinical Indication: Vitamin C source  
Biological Activity or Toxicological Class: High-dose irritation of mucous membranes/Avoid prolonged dust inhalation  
Environmental Hazard/Caution: Dust explosion hazard/See Section IV  
Emergency Hazard Symbol:

I. PHYSICAL PROPERTIES Sources: CD

Appearance and Odor: White to slightly off-white granular powder or crystals; nearly odorless with a pleasantly tart taste  
Specific Gravity ( $H_2O = 1$ ): 1.65  
Soluble in: Alcohol (slight)  
Melting Point: 192°C  
Solubility in Water, % by wt. at 20°C: 30%  
Bulk Density: 0.55-1.2 g/ml  
Specific Rotation: -20.5° to -21.5° at 25°C

II. CHEMICAL PROPERTIES Sources: CD

Stability: Stable  
Conditions to Avoid: moisture, light especially if in aqueous solution (promotes oxidation)  
Materials to Avoid: alkalis, iron, copper, water, air oxidizing agents (metal ions catalyze; oxidation) do not formulate with sodium salicylate, sodium nitrate  
Hazardous Polymerization: Will not occur

**MATERIAL SAFETY DATA****III. HAZARDOUS INGREDIENTS Sources: CISA**

Not Applicable (If code 0 identifies a formulated product, the non-active moiety is inert and non-toxic).

**IV. FIRE AND EXPLOSION HAZARD Sources: CISA**

Dry, free-flowing powder may present a dust explosion hazard.

Maximum explosion pressure: 88 psi  
Maximum rate of pressure rise: 4800 psi/sec  
Minimum cloud ignition energy: 0.06 joules  
Minimum explosion concentration: 0.07 oz/cu. ft.  
Ignition temperature cloud: 460°C

Extinguishing Media: Water spray, dry chemical, carbon dioxide or foam, as appropriate for surrounding fire and materials.

Fire Fighting Procedures: Evacuate personnel to an area of upwind direction and remove unneeded materials; keep fire-exposed containers cool with water spray, and provide fire fighters with self-contained breathing equipment.

**V. HEALTH HAZARDS Sources: CISA**

Threshold Limit Value:

TWA: None established

STEL: None established

Toxicity:

Industrial Exposure: No adverse clinical findings have been reported at dose levels of 9000 mg/day or less, orally in man. At a level of 50-80 g/day for a week to 10 days, there was some gastroenteritis and anal irritation; amounts of 1g/day may cause diarrhea; 4-12 g/day can cause formation of urate and cystine stones in the urinary bladder.

Primary Route/s of Exposure: Ingestion, inhalation

Experimental: LD<sub>50</sub> (mouse, iv) 518 mg/kg  
LD<sub>50</sub> (mouse, oral) >8 g/kg

Emergency and First Aid:

Eye contact: Irrigate surfaces with water thoroughly

Skin contact: Flush areas with water thoroughly

Ingestion: Drink large quantities of water to combat the dehydrating effect  
(CISA)

**VI. SAFETY MEASURES AND EQUIPMENT Sources: CISA**

Ventilation: Mechanical acceptable

Respiratory: NIOSH-approved dust respirator

Eyes: Safety goggles

Gloves: Rubber

Other Directives:

Precautionary Label: L(+)-Ascorbic acid

Vitamin C

CAS # 50-81-7

High doses affect mucous membranes and kidney





**MATERIAL SAFETY DATA**

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**Storage and Handling Conditions:** Store within tightly-sealed containers in a dark, moisture-free place at temperatures of 8-15° C. After opening container, avoid exposing it to heat and humidity.

**VII. SPILL CONTROL, WASTE TREATMENT AND DISPOSAL Sources: CISA**

**Spill Control:** Scoop up all spills and transfer to labeled containers.

**Waste Treatment and Disposal:** Recycle. Release small quantities to process drain with plenty of water.

**VIII. REGULATIONS Sources: CISA**

**DOT:** Not regulated

**EPA:** Not regulated

**OSHA:**

**Hazard Class:** Flammable solid and health hazard (targets mucous membranes; potential neurotoxin)

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The information contained herein is, to the best of Hoffmann-La Roche's knowledge, complete and accurate. Roche, however, uses many sources and references for gathering this information. Thus, Roche cannot guarantee completeness or accuracy and disclaims all liability for its handling or use.

**Material Safety Data Sheet**  
 May be used to comply with  
 OSHA's Hazard Communication Standard,  
 29 CFR 1910.1200. Standard must be  
 consulted for specific requirements.

**U.S. Department of Labor**  
 Occupational Safety and Health Administration  
 (Non-Mandatory Form)  
 Form Approved  
 OMS No. 1218-0072

IDENTIFY the hazard on label and tag  
**I-Inorganic Acid**

NOTE: Blank spaces are not provided. If any item is not completely applicable to product, the space must be marked as such.

**Section I**

Manufacturer's Name <b>Takada Chemical Industries, Ltd.</b>	Emergency Telephone Number <b>Takada U.S.A., INC. - (914) 365-2000</b>
Address (Street, City, State, and ZIP Code) <b>2-3-6, Doshomachi, Chuo-ku, Osaka</b>	Telephone Number for Information <b>Takada U.S.A., Inc. - (914) 365-2000</b>
Country <b>Japan</b>	Date Prepared <b>August, 1991</b>
Zip Code: <b>541</b>	Signature of Preparer (optional)

**Section II - Hazardous Ingredients/Identity Information**

Hazardous Components (Specify Chemical Identity, CASRN Number)	OSHA PEL	ACGIH TLY	Other Limit Recommendations
<b>Not applicable</b>			

**Section III - Physical/Chemical Characteristics**

Boiling Point <b>Not applicable</b>	Specific Gravity (H <sub>2</sub> O = 1) (20°/20°): <b>1.65</b>
Vapor Pressure (mm Hg) <b>Not applicable</b>	Melting Point (°C): <b>about 190°</b>
Vapor Density (air = 1) <b>Not applicable</b>	Evaporation Rate (Butyl Acetate = 1) <b>Not applicable</b>
Solubility in Water <b>Freely soluble</b>	

Appearance and Color  
**White or very faintly yellow crystals or crystalline powder. Odor:**

**Section IV - Fire and Explosion Hazard Data**

Flash Point (closed cup) <b>Not applicable</b>	Flammable Limit <b>Not known</b>	LEL	UEL
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Emergencing Hazards  
**Carbon dioxide, Water spray**

**Special Fire Fighting Procedures:**

**Approved respirator should be worn**

**Unusual Fire and Explosion Hazards**

**None**

**Section V - Reactivity Data**

Reactivity	Unstable		Conditions to Avoid
	Stable	X	

Incompatibility (Materials to Avoid)

Heavy metals, Alkali, Oxidants

Hazardous Decomposition or Byproducts

Not known

Hazardous Polymerization	May Occur		Conditions to Avoid
	Will Not Occur	X	Not applicable

**Section VI - Health Hazard Data**

Routes of Entry	Ingestion?	Not applicable	Inhalation?
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Health Hazards (Acute and Chronic) No information

Carcinogenicity	NTP?	Not applicable	MSD (Mutagenic)?	OEPA Requirement?
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Signs and Symptoms of Exposure Not known

Medical Conditions Generally Accepted by Exposure Not known

Emergency and First Aid Procedures

Irritating to eye: Should be washed away with water

**Section VII - Precautions for Safe Handling and Use**

Steps to Be Taken in Case Material is Released or Spilled

- \*Mechanical removing
  - \*Washing away with water
  - \*Incineration
  - \*Burying under the ground
  - \*Drainage after dilution and/or activated sludge process, while controlling H.O.D. and C.O.D.
- Store in tight, light-resistant containers.
- Avoid exposure to sunlight and contact with metallic ions
- Other Precautions None

**Section VIII - Control Measures**

Respiratory Protection (OSHA 1988)

Approved respiratory should be worn if needed

Ventilation	Local Exhaust	None	General	None
	Respiratory (General)	Air conditioning and ventilation		Other

Protective Gloves Use gloves Eye Protection Better to wear safety glasses

Other Protective Clothing or Equipment Better to wear mask

Work Hygiene Practices None



**GAF CHEMICALS CORPORATION**  
 A DIVISION OF GAF CORPORATION

Tel: 201 426 2200  
 201 426 2200  
 201 426 2200  
 Wayne, NJ 07494

Emergency  
 Medical Information: 1 800 228 2425  
 Transportation  
 Emergency: CHEMTREC 1 800 424 9300

**MATERIAL SAFETY DATA SHEET**

**SECTION 1 - IDENTIFICATION**

NAME: POLYFLUORINE A-10 (POLYMERIZATION OF...)

DOMESTIC TRADE NAME: POLYFLUORINE A-10  
 EXPORT TRADE NAME: POLYFLUORINE A-10

CAS NUMBER: 26177-07-1  
 CAS NUMBER: 26177-07-1  
 SYNONYM: POLY(VINYLFLUORIDE)

MOLECULAR FORMULA:  $C_2F_2n$

**SECTION 2 - PHYSICAL & CHEMICAL CHARACTERISTICS**

NAME

**SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS**

BOILING POINT: NO DATA FOUND  
 VAPOR PRESSURE: NOT VOLATILE  
 VAPOR DENSITY: NOT VOLATILE  
 WATER SOLUBILITY: INSOLUBLE  
 MELTING POINT: NO DATA FOUND  
 APPEARANCE: FREE FLOWING, OFF WHITE POWDER  
 SPECIFIC GRAVITY: NO DATA FOUND  
 PERCENTAGE VOLATILE: 5.0% WATER-BASE  
 EVAPORATION RATE: NOT VOLATILE  
 pH OF SOLUTION: 5.0 - 7.0 (10% SOLUTION)  
 ODS: NO DATA FOUND

**SECTION 4 - PHYSICAL HAZARD DATA**

FLASH POINT: NO FLASH POINT  
 AUTOIGNITION TEMP: NO DATA FOUND  
 FLAMMABLE LIMITS: NO DATA FOUND  
 FIRE FIGHTING MEDIA:  
 USE MEDIA PROPER TO PRIMARY CAUSE OF FIRE.  
 SPECIAL FIRE FIGHTING PROCEDURES:  
 NONE KNOWN  
 PNEUMONIC HAZARD:  
 NONE KNOWN  
 NFPA HAZARD CODES - HEALTH/FLAMMABILITY/REACTIVITY  
 NO DATA FOUND  
 MSDS HAZARD CODES - HEALTH/FLAMMABILITY/REACTIVITY 0 0 0

**SECTION 5 - REACTIVITY DATA**

STABILITY: STABLE  
 HAZARDOUS POLYMERIZATION: WILL NOT OCCUR  
 CONDITIONS TO AVOID:  
 NONE KNOWN  
 INCOMPATIBLE MATERIALS:  
 STRONG OXIDIZING OR REDUCING AGENTS  
 HAZARDOUS DECOMPOSITION PRODUCTS:  
 NONE KNOWN

**SECTION 6 - HEALTH HAZARD DATA**

ACUTE TOXICITY -  
 ORAL TOXICITY  
 RAT LD50 - 10.000 MG/KG  
 DERMAL TOXICITY  
 NOT ASSIGNED TOXICALLY  
 INHALATION TOXICITY  
 HUMAN (LUNGS) PC AND RABBIT. EXPOSURE TO AEROSOLS AND CLOUDS OF SMALL PARTICLES DID PRODUCE NO EVIDENCE OF HARMFUL EFFECTS.



# GAF CHEMICALS CORPORATION

A DIVISION OF GAF CORPORATION

TELEPHONE  
201 682 2200  
1301 AND ROAD  
WAYNE, NJ 07090

Emergency  
TOLL FREE NUMBER: 1 800 228 2623  
TOLL FREE NUMBER  
Emergency: CHEMTREC 1 800 424 9300

MSDS NO. 0401 REV. 8 DATE 07/85 POLYFLUORINE 25-10 (CONTINUED ON

## SECTION 11.2 HEALTH HAZARD DATA SHEET

SKIN IRRITATION  
HUMAN REPEAT IRRITATION TEST: NOT A PRIMARY IRRITANT.

EYE IRRITATION  
RABBIT: NO IRRITATION OBSERVED.

SENSITIZATION  
HUMAN REPEAT IRRITATION TEST: NOT A SENSITIZER.

ODT IRRITATIVE: NO

PRIMARY ROUTES OF ENTRY: CONTACT

- SIGNS & SYMPTOMS OF EXPOSURE -

SYMPTOMS OF IRRITATION  
NO EFFECTS OF EXPOSURE EXPECTED.

SYMPTOMS OF IRRITATION  
IF INHALED NO EFFECTS OF EXPOSURE EXPECTED.

SYMPTOMS OF SKIN CONTACT  
NO EFFECTS OF EXPOSURE EXPECTED DUE TO ADOPTION OF CONTACT. MAY FREQUENTLY CAUSE IRRITATION OR SENSITIVITY IN SOME INDIVIDUALS UPON FREQUENT CONTACT.

SYMPTOMS OF EYE CONTACT  
NO EFFECTS OF EXPOSURE EXPECTED WITH THE EXCEPTION OF FREQUENT IRRITATION.

- EMERGENCY FIRST AID PRECAUTIONS -

FIRST AID FOR IRRITATION:  
GENERAL PRECAUTIONARY MEASURES SUGGEST WASHING VENTURES IMMEDIATELY BY SPRING TWO GLASSES OF WATER AND STICKING FINGER DOWN THROAT NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. CALL A PHYSICIAN.

FIRST AID FOR IRRITATION:  
NONE REQUIRED.

FIRST AID FOR SKIN CONTACT  
FOR ALL FOREIGN MATERIALS WASH AFTER EXPOSURE

FIRST AID FOR EYE CONTACT  
FOR ALL FOREIGN MATERIALS IMMEDIATELY FLUSH EYES WITH PLENTY OF WATER.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE  
NO DATA FOUND.

EXPOSURE LIMITS:  
MUSKANELE DUST: 10 mg/m<sup>3</sup>-TOTAL, 3 mg/m<sup>3</sup>-RESPIRABLE  
POLYMER DUST: 10 mg/m<sup>3</sup>-TOTAL, 3 mg/m<sup>3</sup>-RESPIRABLE

- OTHER TOXICITY -

OTHER ACUTE TOXICITY: NO DATA FOUND

SUB CHRONIC ORAL TOXICITY  
ACUTE AND SUB CHRONIC NO ADVERSE EFFECT LEVEL EXCEEDS 10% OF TOTAL DMT: NO EVIDENCE OF CARCINOGENIC ACTIVITY.

SUB CHRONIC IRRITATION TOXICITY: NO DATA FOUND

SUB CHRONIC IRRITATION TOXICITY: NO DATA FOUND

ACUTE TOXICITY: NO DATA FOUND

MUTAGENICITY  
CHROMOSOME ABERRATION AND SOS MUTAGEN TESTS SHOW THAT THE NO ADVERSE EFFECT LEVEL EXCEEDS 10% OF THE DMT WITH NO EVIDENCE OF CARCINOGENIC ACTIVITY

MUTAGENICITY  
PPF WAS TESTED IN THE AMES ASSAY, DOMINANT MUTAGEN TEST ON BACILLUS SUBTILIS (LIVERMORE ASSAY), SOS MUTAGEN ASSAY AND THE SALMONELLA MUTAGEN ASSAY. IN EACH CASE PPF WAS FOUND NOT TO BE MUTAGENIC.

REPRODUCTIVE TOXICITY  
FERTILITY STUDIES WITH PPF CONCENTRATIONS UP TO 10% OF THE DMT SHOW NO EVIDENCE OF REPRODUCTIVE TOXICITY OR TERATOGENICITY.



**GAF CHEMICALS CORPORATION**

A DIVISION OF GAF CORPORATION

TOLL FREE  
24 HOURS SERVICE  
1 800 438 6666  
WINDY, NJ 07093

Emergency  
Medical Information: 1 800 235 5433  
Transportation  
Emergency: CHEMTREC 1 800 424 9300

MSDS NO. 0401 REV. 3 DATE 07/89 FILTRATIONS 2L-10 (REMOVED) 079

**SECTION 01 - HEALTH HAZARD DATA SHEET**

miscellaneous toxicity: no data found

**SECTION 02 - OCCUPATIONAL CONTROL PROCEDURES**

**VENTILATION**

GENERAL PRECAUTIONARY MEASURES SUGGEST USE WITH APPROPRIATE VENTILATION.

**RESPIRATORY PROTECTION:**

DUST MASK WHERE ELUCTION CANNOT BE AVOIDED.

**EYE PROTECTION:**

SAFETY GLASSES.

**SKIN PROTECTION:**

NONE REQUIRED.

**FEDERAL HYGIENE:**

OBSERVE GENERAL PRECAUTIONS OF FEDERAL HYGIENE.

**PROTECTIVE MEASURES DURING REPAIR/MAINTENANCE OF EQUIPMENT:**

WASH EQUIPMENT THOROUGHLY WITH STEAM OR COLD WATER UNTIL CLEAR. CHECK FOR FLAMMABLES WITH AN "EXPLORER TEST" AND ALSO CHECK THE GROUND LEVEL WITH AN OILYER TEST. IN ALL CASES FOLLOW GOOD INDUSTRIAL SAFETY PRACTICES BEFORE ENTERING EQUIPMENT.

**SECTION 03 - PRECAUTIONS FOR SAFE HANDLING, STORAGE, AND USE**

**PRECAUTIONARY MEASURES**

AVOID BREATHING DUST.

**SPILL/LEAK CLEAN-UP PROCEDURES**

SCOP UP AVOID DUSTING. DISPOSE OF WITH SOLID WASTE ACCORDING TO FEDERAL, STATE AND LOCAL REGULATIONS. FLUSH SPILL AREA WITH WATER.

**DISPOSAL METHOD:**

DISPOSE OF WITH SOLID WASTE ACCORDING TO FEDERAL, STATE AND LOCAL REGULATIONS.

OPA HAZARDOUS SUBSTANCE REPORTABLE QUANTITY: NOT LISTED

RCRA CLASS: NOT REGULATED

**SECTION 04 - TRANSPORTATION DATA**

**- EMERGENCY DATA -**

DOT SHIPPING NAME: NOT REGULATED

DOT HAZARD CLASS: NOT REGULATED

HAZARDOUS INCIDENTS: NONE

UN NUMBER: NONE

**- EXPERT DATA -**

EXPERT SHIPPING NAME: NOT REGULATED

EXPERT HAZARD CLASS: NOT REGULATED

HAZARDOUS INCIDENTS: NONE

UN NUMBER: NONE

This information is provided for documentation purposes only.  
This product is not considered hazardous.

Warner-Jenkinson Company, Inc.  
2525 Baldwin Street  
St. Louis, MO 63108  
800/325-8110, ext. 7475

\*\*\*MATERIAL SAFETY DATA SHEET\*\*\*

DATE PREPARED: 1/86

REVISION DATE: Original

CHEMIST INITIALS:

SECTION I - PRODUCT IDENTIFICATION

PRODUCT CODE & DESCRIPTION: No. 9801 FD&C Blue #1 Lake

TECHNICAL NAME: Not applicable.

SYNONYMS: Color Additive

CLASSIFICATION CODE: Not hazardous.

PRODUCT CAS NOS. (NEW JERSEY COMPLIANCE): 15732-67-3 FD&C Blue #1 Lake

SECTION II - HAZARDOUS INGREDIENT (S)

None of the ingredients of this material meet the definition of "Hazardous Chemical", 29-CFR 1910.1200.

SECTION III - PHYSICAL DATA

MELTING POINT (°C): Not applicable.

SOLUBILITY IN WATER: Insoluble.

FLASH POINT (METHOD): Not applicable.

% VOLATILE BY VOLUME: Not applicable.

pH (as is): Not applicable.

APPEARANCE AND ODOR: A water insoluble pigment.

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

EXTINGUISHING MEDIA: Water, chemical foam, or dry chemical extinguisher.

SPECIAL FIRE FIGHTING PROCEDURES: None.

UNUSUAL FIRE AND EXPLOSION HAZARD: None.

SECTION V - REACTIVITY DATA

STABILITY: Under normal storage and handling conditions, this is a stable material when kept in a closed container.

MATERIALS/CONDITIONS TO AVOID: None.

HAZARDOUS DECOMPOSITION PRODUCTS: None.

**HAZARDOUS POLYMERIZATION:** Will not occur.

---

### SECTION VI - HEALTH HAZARD DATA

---

**INGESTION:** None.  
**OTHER EFFECTS:** None.

**EYE CONTACT:** None.  
**SKIN CONTACT:** None.

**INHALATION:** None.

---

### SECTION VII - EMERGENCY FIRST AID PROCEDURES

---

**SKIN:** No adverse effects. Wash skin with mild soap and water to remove nuisance color. Some dyes may temporarily stain skin.

**INGESTION:** If large quantities are ingested, consult your physician.

**INHALATION:** This product is not classified as an irritant, however, dry powder dust may cause irritation in some individuals.

**EYES:** This product is not classified as an irritant. If exposed, wash the eyes with large amounts of water, occasionally lifting the lower and upper lids; continue for 15 minutes. If irritation develops, seek medical attention.

---

### SECTION VIII - PERSONAL PROTECTION

---

**EYES:** Eye protection is suggested for compliance with Good Manufacturing Practices. (GMP)

**VENTILATION:** This product can generate dust. Ventilation or dust collection would be helpful, but not necessary.

**RESPIRATORY:** No respiratory protection required, but dust masks are suggested.

**OTHER PROTECTIVE EQUIPMENT:** None required. To minimize clean-up, wear gloves when handling material.

**WORK/HYGIENE PRACTICES:** Some dyes may temporarily stain skin. Use good personal hygiene practices; limit exposure to product whenever possible to minimize clean-up.

---

### SECTION IX - SPILL OR LEAK PROCEDURES

---

**STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:** If dry shovel, vacuum, or sweep color up for disposal. If wet, surfaces exposed to a spill may become slippery or sticky. Spills should be thoroughly flushed with soapy water until all apparent color is removed.

**WASTE DISPOSAL METHOD:** Sanitary landfill in accordance with Local, State and Federal regulations.

---

### SECTION X - STORAGE AND HANDLING

---

Store in a tightly sealed container. See specification for other product characteristics.

MATERIAL SAFETY DATA SHEET PREPARED BY WARNER-JENKINSON COMPANY, INC., DIVISION OF UNIVERSAL FOODS CORPORATION.

For additional information on this product, call (800) 824-7022, ext. 7443 during normal business hours.

CSL: L/LB



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**MATERIAL SAFETY DATA SHEET**

**NOTICE:** The information and recommendations contained herein are based upon data believed to be correct as of the date of issue. No guarantee or warranty of any kind, expressed or implied is made with respect to the information contained herein.

**HAZARD RATINGS**  
-----

HEALTH = 0  
FLAMMABILITY = 0  
REACTIVITY = 0

-----  
0 = Minimal    1 = Slight    2 = Moderate    3 = Serious    4 = Severe  
-----

**SECTION I - PRODUCT IDENTIFICATION**

**MANUFACTURER'S NAME:** COLORCON, A DIVISION OF BERWIND  
PHARMACEUTICAL SERVICES  
**ADDRESS:** MOYER BLVD., WEST POINT, PA 19486  
**EMERGENCY TELEPHONE NUMBER:** CHEMTREC: 800/424-9300  
**PRODUCT CLASS:** FD&C Pigment  
**TRADE NAME:** FD&C BLUE NO. 2  
Aluminum Lake  
**MANUFACTURER'S ID CODE:** 5625  
-----

ISSUE DATE: 4/1/92

FORM: FD-01

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**SECTION II - INGREDIENT DATA**

**HAZARDOUS COMPONENT:** CAS: EXPOSURE LIMITS: (ACGIH) (OSHA)  
The materials contained in this product are classified as non-hazardous  
in accordance with the definition set forth in 29 CFR 1910.1200.

**PENNSYLVANIA RIGHT-TO-KNOW:**  
FD&C Pigments N/A

Not Hazardous

**WELLS:**  
N/A

---

**SECTION III - PHYSICAL DATA**

**BOILING RANGE:** Not Applicable

**EVAPORATION RATE (VS. BUTYL ACETATE):**  
Not Applicable

**LIQUID DENSITY:** N/A

**ODOR THRESHOLD:** Odorless

**APPEARANCE AND ODOR:**  
Odorless FD&C BLUE NO. 2 powder.

**VAPOR DENSITY (VS. AIR):** N/A

**PERCENT VOLATILE (W/W):** N/A

**FREEZING POINT:** N/A

**AUTO IGNITION TEMPERATURE:**  
Not Applicable

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**SECTION IV - FIRE/EXPLOSION DATA**

**FLASH POINT:** Not flammable

**FLAMMABLE LIMITS - LEL:** N/A

**- UEL:** N/A

**RATE OF BURNING:** N/A

**SENSITIVITY TO STATIC DISCHARGE:** See explosion hazards

**EXTINGUISHING MEDIA:**

Water fog or spray, CO<sub>2</sub>, dry chemical

**SPECIAL FIRE FIGHTING PROCEDURES:**

Fire fighters should wear self-contained breathing apparatus operated in positive pressure mode and full turn-out gear.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:**

Excessive concentrations of air-borne dust may lead to an explosion hazard.

---

**SECTION V - HEALTH HAZARDS**

**EFFECTS OF OVEREXPOSURE:**

May cause transient eye, nose and throat irritation.

**ROUTES OF ENTRY:** Inhalation

**FIRST AID PROCEDURES:**

**Eye Contact:** Flush with water for at least 15 minutes.

**Skin Contact:** Wash with mild soap and water.

**Inhalation:** Remove victim to fresh air. If breathing is difficult, administer oxygen.

As in all cases of overexposure, if irritation persists, seek medical attention.

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**SECTION VI - TOXICITY DATA**

**CHRONIC EFFECTS:** No specific data available

**TARGET ORGANS:** No specific data available

**CARCINOGENITY:** NTP: No IARC: No OSHA: No

---

**SECTION VII - REACTIVITY**

**PRODUCT STABILITY:** Stable

**CONDITIONS TO AVOID:**  
The excessive generation of dust.

**HAZARDOUS POLYMERIZATION:** Will not occur.

**MATERIALS TO AVOID:**  
Strong oxidizing materials.

**DECOMPOSITION PRODUCTS:**  
Carbon monoxide, carbon dioxide.

---

**SECTION VIII - SPILL PROCEDURES**

**LARGE SPILLS:**  
Moisten slightly with water to avoid producing dust. Sweep or shovel material into proper waste container. Do not sweep dry material, as this will produce dust concentrations in the air.

**SMALL SPILLS:**  
Vacuum material or moisten slightly with water and place into proper waste container.

**WASTE DISPOSAL:**  
This product is not hazardous waste under RCRA regulations. Consult State and Local regulations for proper waste disposal method.

---

**SECTION IX - PROTECTION DATA**

**VENTILATION:**

General air circulation, use local exhaust to collect excessive dust at point of generation. Dust collection systems should be provided with explosion venting. Discharge from ventilation systems should comply with all applicable air pollution regulations.

**RESPIRATORY PROTECTION:**

A NIOSH approved dust respirator if required.

**PROTECTIVE CLOTHING:**

Gloves and overalls to protect from dust.

**EYE PROTECTION:**

Safety glasses and goggles. Contact lens should not be worn when handling this product. Contacts may intensify any exposures.

**OTHER PROTECTIVE EQUIPMENT:**

None

---

**SECTION X - SPECIAL PRECAUTIONS**

**HANDLING AND STORAGE:**

Store in a cool, dry area. Keep containers closed when not in use. Avoid handling procedures which suspend or accumulate dust. Avoid breathing dust.

**OTHER PRECAUTIONS:**

Handle with due care and avoid excessive personal contact. Thoroughly clean all equipment, piping and vessels before beginning maintenance or repairs.

---

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**SECTION XI - REGULATORY**

**CLASSIFICATIONS:**  
Not regulated.

**SARA TITLE III (Community Right-to-know):**

**SECTION 311/312:**  
Not regulated.

**SECTION 313:**  
This product does not contain any chemicals listed in section 313 above de minimis levels.

**TOXIC SUBSTANCE CONTROL ACT:**  
All materials contained in this product are listed on the TSCA inventory.

**STATE RIGHT-TO-KNOW:**  
N/A

MATERIAL SAFETY DATA SHEET

NOTICE: The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind is expressed or implied is made with respect to the information contained herein.

HAZARD RATINGS

HEALTH = 0
FLAMMABILITY = 0
REACTIVITY = 0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

SECTION I

MANUFACTURER'S NAME: Colorcon - A Division of Berwind Pharmaceutical Services, Inc.
ADDRESS: Moyer Blvd., West Point, Pa. 19434
EMERGENCY TELEPHONE NUMBER: 215-699-7733
PRODUCT CLASS: D&C Pigment
TRADE NAME: D&C YELLOW NO. 10
MANUFACTURER'S ID CODE: Lake 6010

SECTION II
HAZARDOUS INGREDIENTS

The materials listed in this Data Sheet are classified as non-hazardous in accordance with the definition set forth in 29CFR 1910.1200. Ingredients contained in this product are not subject to SARA TITLE III requirements.

SECTION III
PHYSICAL DATA

BOILING RANGE: N/A ; VAPOR DENSITY (VS AIR): N/A
EVAPORATION RATE (VS BUTYL ACETATE): N/A ; PERCENT VOLATILE (M/W) = N/A
LIQUID DENSITY (VS WATER): N/A
APPEARANCE AND ODOR: Odorless D&C YELLOW NO. 10 powder.

**SECTION IV  
FIRE AND EXPLOSION DATA**

FLASH POINT: N/A	:	FLAMMABLE LIMITS: Lel: N/A
	:	Uel:
EXTINGUISHING MEDIA:	:	SPECIAL FIRE FIGHTING PROCEDURES:
CO2	:	None.
Dry Chemical	:	
Water Fog	:	
-----		
UNUSUAL FIRE AND EXPLOSION HAZARDS:	:	None.
-----		

**SECTION V  
HEALTH HAZARD DATA**

EFFECTS OF OVEREXPOSURE: None.

PRIMARY ROUTE(S) OF ENTRY: Inhalation

EMERGENCY AND FIRST AID PROCEDURES:

In case of accidental eye contact, flush eyes with water. If irritation exists, obtain medical attention.

-----

**SECTION VI  
REACTIVITY DATA**

PRODUCT STABILITY: Stable

CONDITIONS TO AVOID: None known.

-----



**SECTION VII  
SPILL OR LEAK PROCEDURES**

**PROCEDURE WHEN MATERIAL SPILLED OR RELEASED:** Moisten slightly with water to reduce dust. Sweep up and discard into proper waste container.

**WASTE DISPOSAL METHOD:** Dispose of in accordance with Federal, State and Local regulations.

---

**SECTION VIII  
SPECIAL PROTECTION INFORMATION**

**VENTILATION:** Sufficient to prevent inhalation of dust.

**RESPIRATORY PROTECTION:** An approved dust respirator should be worn.

**PROTECTIVE CLOTHING:** Gloves and coveralls recommended to protect from dust.

**EYE PROTECTION:** Safety goggles.

**OTHER PROTECTIVE EQUIPMENT:**

---

**SECTION IX  
SPECIAL PRECAUTIONS**

**HANDLING AND STORING:** Store in cool, dry area. Keep containers closed.

**OTHER PRECAUTIONS:** In accord with good industrial practices, handle with due care and avoid personal contact. Wash exposed skin areas with soap and water.

---

**MATERIAL SAFETY DATA SHEET**

Product/Material                    D&C Red #30 Al. Lake - 6530.  
Manufacturer/Distributor           Warner-Jenkinson Cosmetic Colors  
Address                                155 Helen Street  
    South Plainfield, NJ 07080  
Emergency Telephone No.            (908) 757-4500

**SECTION I - PRODUCT IDENTIFICATION**

Composition                            D&C Red #30  
    Aluminum Hydrate

**SECTION II - HAZARDOUS INGREDIENTS**

None.

**SECTION III - PHYSICAL DATA**

Boiling Point (F)	Not applicable
Vapor Pressure (mmHg)	Not applicable
Vapor Density	Not applicable
Solubility in Water	Not soluble
Specific Gravity	
Percent Volatile by Weight	0
Evaporation Rate	0
Appearance and Odor	Red odorless powder

#### SECTION IV - FIRE AND EXPLOSION HAZARD DATA

Flash Point	Non-flammable
Flammable limits	LEL-Not applicable UEL-Not applicable
Extinguishing Media	Water
Special Fire Fighting Procedures	None
Unusual Fire and Explosion Hazards	None

#### SECTION V - HEALTH HAZARD DATA

Threshold limit values	5 mg/m3 respirable dust 10 mg/m3 Total dust(ACGIH)
Effects of overexposure	Overexposure may cause irritation of eyes and respiratory tract.
Emergency First Aid Procedures	Eyes and skin-flush with water. Wash skin with soap & water.
Carcinogen	No

#### SECTION VI - REACTIVITY DATA

	Product is stable.
Incompatibility	Strong oxidizing agents.
Hazardous Decomposition Products	None
	Hazardous polymerization will not occur.

#### SECTION VII-SPILL OR LEAK PROCEDURES

Steps to take in case material is released or spilled	Accidental releases can be cleaned up by sweeping, vacuuming or flushing with water.
Waste Disposal	Dispose of material in compliance with Local, State and Federal Regulations. Discarded iron oxide is not classified as hazardous waste.

**SECTION VIII-SPECIAL PROTECTION INFORMATION**

Ventilation	Local exhaust recommended.
Eye Protection	Wrap around goggles.
Gloves	Vinyl for personal hygiene.
Respiratory Protection	For dusty conditions, wear a NIOSH approved dust mask.

**SECTION IX-SPECIAL PRECAUTIONS**

Good industrial hygiene practice requires that employee exposure be maintained below the recommended level. This is preferably achieved through the provision of adequate ventilation where necessary. Where dust cannot be controlled, personal respiratory protection should be used.

ISSUED: 10/92

**MATERIAL SAFETY DATA SHEET**

PAGE: 01 of 07

**AQUALON**  
A Division of Hercules Incorporated  
1313 North Market Street  
P. O. Box 8740  
Wilmington, Delaware 19899-8740  
Phone 6: (302) 594-5000 (24 hrs)

**KLUCEL® Hydroxypropyl cellulose**  
(All grades and viscosities  
except KLUCEL® 3088)

MSDS No.: 623 1000 0000-05

Supersedes MSDS #: 623 1000 0000-04

Date: 05/28/93

---

**I. PRODUCT IDENTIFICATION**

---

**WARNING: STATIC CHARGES GENERATED BY EMPTYING PACKAGE IN OR NEAR FLAMMABLE VAPORS MAY CAUSE FLASH FIRE.  
MAY FORM FLAMMABLE DUST-AIR MIXTURES.  
MAY CAUSE EYE IRRITATION.  
SURFACES SUBJECT TO SPILLS OR DUSTING WITH THIS PRODUCT CAN BECOME SLIPPERY WHEN WET.**

**KLUCEL® Hydroxypropyl cellulose**  
(All grades and viscosities  
except KLUCEL® 3088)

CASRN: 9004-64-2

**HMIS RATINGS: (1)**

Health hazard:	1	Slight
Flammability hazard:	1	Slight
Reactivity hazard:	0	Minimal

**CHEMICAL & COMMON NAMES: Hydroxypropyl cellulose (HPC)**

**APPEARANCE AND ODOR: White to off-white, granular solid; slight odor**

\* Trademark of Aqualon

---

(1) Explanation of acronyms:

**HMIS: Hazardous Materials Identification System rating for product as supplied.**

**CASRN: Chemical Abstracts Service Registry Number**

**AIEA WZEL: American Industrial Hygienists Association - Workplace  
Environmental Exposure Level.**

**OSHA: Occupational Safety and Health Administration.**

**TLV: Registered trademark of American Conference of Governmental Industrial  
Hygienists for Threshold Limit Values.**

**TWA: Time Weighted Average**

**STEL: Short term exposure limit (See 29 CFR 1910.1048, March 1, 1989, revision)**

**C: Ceiling exposure concentration (See 29 CFR 1910.1000, March 1, 1989, rev.)**

**SKIN: May be absorbed through skin (See 29 CFR 1910.1048, March 1, 1989, rev.)**

**N/A: Not applicable**

---

**II. HAZARDOUS INGREDIENTS & EXPOSURE LIMITS**

---

This material is not expected to cause physiologic impairment at low concentration. Until a specific TLV(1) is adopted by the ACGIH (American Conference of Governmental Industrial Hygienists), or an OSHA (Occupational Safety & Health Administration) standard is issued, Aqualon Group suggests that this material be treated as a **NUISANCE DUST OR PARTICULATE** in accordance with the recommendations of ACGIH.

---

**III. TYPICAL PHYSICAL & CHEMICAL CHARACTERISTICS**

---

**CAUTION: SURFACES SUBJECT TO SPILLS OR DUSTING WITH THIS PRODUCT CAN BECOME SLIPPERY WHEN WET.**

**BOILING POINT:** N/A

**SOLUBILITY IN WATER:** Easily wetted with water forming gels; Insoluble above 45 C (113 F)

**VAPOR PRESSURE AT 20 C:** Negligible

**VAPOR DENSITY:** N/A

**SPECIFIC GRAVITY:** Heavier than water

**VOLATILE (WT. %):** 5

**pH IN WATER SOLUTION:** 5.0 to 8.5

**SOFTENING POINT:** 100-150 C (212-302 F)

**EVAPORATION RATE:** N/A

---

**IV. FIRE, EXPLOSION, & REACTIVITY HAZARD DATA**

---

**WARNING: STATIC CHARGES GENERATED BY EMPTYING PACKAGE IN OR NEAR FLAMMABLE VAPORS MAY CAUSE FLASH FIRE.  
MAY FORM FLAMMABLE DUST-AIR MIXTURES.**

**FLASH POINT:** Not determined

**FLAMMABLE LIMITS:** Not determined

**AUTOIGNITION TEMPERATURE:** 400 C (752 F) Dust

**EXTINGUISHING MEDIA:** Water spray, dry chemical, foam, carbon dioxide, or halon

**SPECIAL FIREFIGHTING PROCEDURES:** None

**UNUSUAL FIRE & EXPLOSION HAZARDS:** May form flammable dust-air mixtures.

**STABILITY CONSIDERATIONS:** Stable

Continued...

---

**IV. FIRE, EXPLOSION, & REACTIVITY HAZARD DATA**

---

...Continued

**INCOMPATIBILITY WITH:** None

**HAZARDOUS DECOMPOSITION PRODUCTS:** None

**HAZARDOUS PRODUCTS OF COMBUSTION:** Carbon monoxide, carbon dioxide and smoke

**HAZARDOUS POLYMERIZATION:** Will not occur.

---

**V. HEALTH HAZARD DATA**

---

**WARNING! MAY CAUSE EYE IRRITATION.**

**SIGNS & SYMPTOMS OF OVEREXPOSURE IN THE WORKPLACE:**

**EYES:** May cause mild eye irritation.

**SKIN:** None known.

**INHALATION:** Inhaling dust may cause respiratory irritation.

**INGESTION:** None known.

**EMERGENCY & FIRST AID PROCEDURES:**

**EYES:** In case of contact, immediately flush with plenty of low-pressure water for at least 15 minutes. Remove any contact lenses to ensure thorough flushing. Call a physician.

**INHALATION:** Remove to fresh air. Treat any irritation symptomatically. Call a physician.

---

**MEDICAL CONDITIONS GENERALLY RECOGNIZED AS BEING AGGRAVATED BY EXPOSURE:**  
None known.

**PRIMARY ROUTE OF ENTRY:**

Following standard industrial hygiene and recommended procedures, entry of the compound into the body is not expected.

**CANCER INFORMATION:**

Not listed as a carcinogen by NTP (National Toxicology Program); not regulated as a carcinogen by OSHA (Occupational Safety & Health Administration); not evaluated by IARC (International Agency for Research on Cancer).

**REPORTED HUMAN EFFECTS:**

None known.

**REPORTED ANIMAL EFFECTS:**

Minimal to mild eye (conjunctival) irritation after exposure to dust.

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**VI. SPILL PROCEDURES & WASTE DISPOSAL**

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**SPILL PROCEDURES:**

Sweep up spilled material for use or disposal.

**WASTE DISPOSAL METHOD:**

Incineration of combustible waste is the preferred disposal method. Landfilling in a licensed facility equipped with leachate collection in accordance with local, State, and Federal regulations is a satisfactory alternative.

This product is biodegradable. Wastewater containing this product can be considered for treatment in an acclimated biological treatment system of adequate capacity.

Refer to Section VIII for specific Federal Environmental and Regulatory Data regarding use or disposal of this product.

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**VII. APPLICABLE CONTROL MEASURES**

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**APPROPRIATE HYGIENIC PRACTICES:**

Avoid contact with eyes, skin, and clothing.

Avoid breathing dust.

Wash thoroughly after handling, and before eating, drinking or smoking.

**PERSONAL PROTECTIVE EQUIPMENT:**

Safety glasses

Impervious gloves

Appropriate respiratory protection is required when exposure to an airborne contaminant is likely to exceed acceptable limits. Respirators should be selected and used in accordance with OSHA, Subpart I (29 CFR 1910.134) and manufacturer's recommendations.

**WORK PRACTICES:**

Eyewash fountains should be easily accessible.

Keep floors clean. Spills can be slippery.

**HANDLING AND STORAGE PRECAUTIONS:**

**WARNING: STATIC CHARGES GENERATED BY EMPTYING PACKAGE IN OR NEAR FLAMMABLE VAPORS MAY CAUSE FLASH FIRE. MAY FORM FLAMMABLE DUST-AIR MIXTURES.** Avoid ignition sources such as sparks and flame. Ground all equipment. In addition, when emptying bags where flammable vapors may be present, blanket vessel with inert gas, ground operator, and pour material slowly into conductive, grounded chute.

To protect product quality, store in sealed containers in a dry place away from heat and sunlight.

Continued...



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**VII. APPLICABLE CONTROL MEASURES**

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...Continued

**ENGINEERING CONTROLS:**

Adequate ventilation should be provided to keep dust concentrations below acceptable exposure limits. Discharge from the ventilation system should comply with applicable air pollution control regulations.

**PROTECTIVE MEASURES DURING REPAIR AND MAINTENANCE:**

Eliminate ignition sources.

Completely isolate and thoroughly clean all equipment, piping or vessels before beginning maintenance or repairs.

Keep area clean. Product will burn.

---

**VIII. ENVIRONMENTAL & REGULATORY DATA**

The following environmental and regulatory data are provided to assist users of this product in defining their regulatory environmental compliance obligations.

**A. PRODUCT COMPOSITION**

PRODUCT (P) or COMPONENT NO.	TRADE NAME or CHEMICAL COMPONENT	CASRN	WT. PERCENT
P	KLUCEL® Hydroxypropyl cellulose	9004-64-2	94-100

**B. SARA TITLE III (See footnotes)**

COMPONENT NO.	SEC. 304 EHS RQ (lbs)	SEC. 302 EHS TPO (lbs)	SEC. 311/312 HAZARD CATEGORY	SEC. 313 TOXIC CHEMICAL (YES, NO)
P	N/A	N/A	HEX, EC-3	NO

**C. CERCLA (40 CFR 302.4 HAZARDOUS SUBSTANCE & REPORTABLE QUANTITIES)**

This product does NOT contain any hazardous substances listed in 40 CFR 302.4.

**D. RCRA INFORMATION**

This product is not listed in federal hazardous waste regulation 40 CFR 261.33, paragraph (e) or (f) - i.e., chemical products that are considered hazardous if they become wastes. It does not exhibit any of the hazardous characteristics listed in 40 CFR 261, Subpart C. State or local hazardous waste regulations may apply if they are different from the federal regulation.

**E. TSCA STATUS**

The components of this product are included on the EPA TSCA Chemical Substance Inventory.

Continued...

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**VIII. ENVIRONMENTAL & REGULATORY DATA**

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...Continued

**FOOTNOTES:**

**SEC. 302 - Threshold Planning Quantity, Extremely Hazardous Substance (EHS) (40 CFR 355 Emergency Planning and Notification regulations)**

**N/A:** This chemical is not an EHS. Therefore, there is no Threshold Planning Quantity (TPQ).

**SEC. 304 - Reportable Quantity for Releases of an EHS (40 CFR 355, Appendix A)**

**N/A:** This chemical is not an EHS. Therefore, there is no Reportable Quantity (RQ).

**SEC. 311/312 - 40 CFR 370 Hazardous Chemical Reporting Requirements "Hazard Categories"**

- HC-1** Immediate (acute) health hazard
- HC-2** Delayed (chronic) health hazard
- HC-3** Fire hazard
- HC-4** Sudden release of pressure hazard
- HC-5** Reactive hazard
- NHE** Not a health hazard
- NPH** Not a physical hazard

**SEC. 313 - 40 CFR 372 Toxic Chemical Release Reporting Requirements**

**NO:** This component is NOT subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372 Toxic Chemical Reporting requirements.

**YES:** This component is subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372 Toxic Chemical Reporting requirements. Percent composition (or estimated range) is listed above.

**N/A:** This product is a mixture. As such, it is not listed as a Toxic Chemical under 40 CFR 372, Section 313 reporting requirements. Reportable constituents are listed individually where they exceed threshold concentration limits.

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AQUALON HAS COMPILED THE INFORMATION AND RECOMMENDATIONS CONTAINED IN THIS MATERIAL SAFETY DATA SHEET FROM SOURCES BELIEVED TO BE RELIABLE AND TO REPRESENT THE MOST REASONABLE CURRENT OPINION ON THE SUBJECT WHEN THE MSDS WAS PREPARED. NO WARRANTY, GUARANTY OR REPRESENTATION IS MADE AS TO THE CORRECTNESS OR SUFFICIENCY OF THE INFORMATION. THE USER OF THIS PRODUCT MUST DECIDE WHAT SAFETY MEASURES ARE NECESSARY TO SAFELY USE THIS PRODUCT, EITHER ALONE OR IN COMBINATION WITH OTHER PRODUCTS, AND DETERMINE ITS ENVIRONMENTAL REGULATORY COMPLIANCE OBLIGATIONS UNDER ANY APPLICABLE FEDERAL OR STATE LAWS.

**HYDROXYPROPYL METHYLCELLULOSE 3919, 150, 6 LPS**

CE - 003

Page 1 of 6

**Section 1 - Identification of the substance and of the company**

Substance : Hydroxypropyl Methylcellulose (As indicated on label)

Trade Name(s)

• **Pharmacoat**

Grade	803
	803w
	845
	806
	806w
	815
	904

*Codes*  
310199  
45506  
*CSmetch*  
12-22-94

Manufacturer's Name and Address

- Shin-Etsu Chemical Co., Ltd.
- 6-1, Ohtsuka 2 Chome, Chiyoda-Ku, Tokyo 100, Japan.

Emergency Telephone Number

- 03-3246-8281 (Tokyo Japan)

Telephone Number for information

- 03-3246-8281 (Tokyo Japan)

Date prepared : Sep 1, 1994

**Section 2 - Composition / information on ingredients**

- Component : Hydroxypropyl Methylcellulose
- CAS Number : 9004-65-3
- TSCA Number : 9004-65-3

**Section 3 - Hazards Identification**

< Potential health effects >

Inhalation :

Short term effects : Breathing dust may irritate the respiratory tract, cause coughing and discomfort.

Long term effects : No information is available.

Skin contact :

Short term effects : May cause slight skin irritation, but no significant adverse effects are known.

Long term effects : No information is available.

Eye contact :

Short term effects : May cause abrasive irritation.

Long term effects : No information is available.

Ingestion :

Short term effects : No information of any adverse effects is available.

Long term effects : No information is available.

---

• Others •

- May form flammable or explosive dust-air mixtures. (Minimum explosive dust condition :  $30\text{g}/\text{m}^3$ )
- May liberate the following gases under fire conditions. Most of them have an irritating odour.

Carbon monoxide, Carbon dioxide, Methanol, Formaldehyde, Acetaldehyde, Methylformate, Methylacetate, Acetone, Acrolein

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### Section 4 - First aid measures

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Inhalation :

- Remove from exposure area to fresh air immediately. Give artificial respiration if not breathing. Keep the victim warm and at rest. Get immediate medical attention.

Skin contact :

- Wash off in flowing water using a mild soap.

Eye contact :

- Gently rinse eyes immediately with clean water for at least 15 minutes occasionally lifting upper and lower lids. Get immediate medical attention.

Ingestion :

- No effect is expected.

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### Section 5 - Fire-fighting measures

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Fire and explosive properties :

- Slight fire hazard when exposed to heat or flame.
- Dust-air mixtures may ignite or explode.

Suitable extinguishing media :

- Water spray, dry chemical powder, carbon dioxide or foam as appropriate for surrounding fire and materials.

Basic fire-fighting guidance :

- Move container from fire area if it can be done without risk. Use extinguishing agents suitable for type of surrounding fire.

Special exposure hazards from combustion products :

- During a fire, toxic fumes and irritating odour may be generated by thermal decomposition or combustion.

Special protective equipment for fire-fighters :

- Self-contained breathing equipment
- protective clothing

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### Section 6 - Accidental release measures

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• In case of small spills •

- Sweep up, place in suitable container for waste disposal.
  - If spillage is a viscous solution, flush it with plenty of water.
-

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**< In case of large spills >**

- Wear proper protective equipment, and keep unnecessary people away.
- Avoid raising dust and eliminate all sources of ignition and ventilate the area.
- Vacuum or sweep up, in suitable container for waste disposal.
- Do not wash away into sewers or watercourses.

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**Section 7 - Handling and storage**

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**Handling :**

- Avoid breathing dust or mist with adequate dust control. Use approved respirator in a place of dust generation.
- Avoid contact with eyes, skin or clothing.
- Avoid open flame, heat, sparks. Avoid contact to acid, peroxides, and other oxidizing materials.

**Storage :**

- Store in a sealed container. Store in a cool and dry location. Keep away from heat or sunlight. Keep away from possible source of ignition.
- When storing, follow all regulations in regard to this substance in your country or region.

**Other precautions :**

- Avoid grinding, welding, drilling and smelting near this substance.
- Avoid reuse of the empty container to other purpose.

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**Section 8 - Exposure controls / personal protection**

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**< Engineering controls >**

**Exposure limits :**

- Not established

**Ventilation :**

- Use with local exhaust ventilation. Ventilation equipment should be explosion-proof.
- Make available emergency shower and eye wash in the work area.

**< Personal protective equipment (PPE) >**

**Respiratory protection :**

Consider the type of application, environmental concentrations and materials being used concurrently when determining respirator selection and use. The specific respirator selected must be approved by the institutions concerned in your country.

- Any dust and mist respirator
- Any air-purifying respirator
- Any powered air-purifying respirator
- Any self-contained breathing apparatus.

**Hand protection :**

- Gloves (Rubber type is recommended)

**Eye protection :**

- Safety goggles (splash-proof or dust-resistant type).

**Skin protection :**

- No precautions other than clean body-covering clothing should be needed.
-

< Exposure guidelines >

OSHA PEL : Not established

NIH TLV : Not established

**Section 9 - Physical and chemical properties**

Appearance and physical state : White to off-white, fibrous or granular powder.  
odour : Practically odourless

pH	:	Not applicable
Boiling point / boiling range	:	Not applicable
Melting point / melting range	:	Not applicable
Flash point	:	Not applicable
Flammability(solid , gas)	:	Not applicable
Explosive properties	:	No explosion hazard. But fine dust may create explosive mixtures with air.
Oxidizing properties	:	None
Vapour pressure	:	Not applicable
Vapour density	:	Not applicable
Relative density	:	Not applicable
Water solubility	:	Soluble in cold water and produce a viscous solution or gel. Insoluble in hot water.
Solvent solubility	:	Soluble in glacial acetic acid, aniline, pyridine, dimethylformamide, equal volumes of alcohol and chloroform. Insoluble in anhydrous alcohol, chloroform and ether.

**Section 10 - Stability and reactivity**

Chemical stability :

- Stable under normal temperatures and pressures.

Conditions to avoid :

- This material may burn but does not ignite readily.
- Avoid contact with strong oxidizers, excessive heat, sparks, or open flame.

Materials to avoid :

- Acids, peroxides and other oxidizing agents

Hazardous decomposition products :

- Thermal decomposition products may include toxic oxides of carbon.

Hazardous polymerization :

- It has not been reported to occur under normal temperatures and pressures.

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## Section 11 - Toxicological information

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**Carcinogenicity** : This substance is not considered to be a carcinogen by ITP or OSHA in U.S.A or IARC, and other information is none.

**Mutagenicity** : No information is available.

**Effects on the reproductive system** : No information is available.

### < Health effects >

#### Inhalation :

Acute exposure - Dusts may cause irritation of the nose and chest discomfort.

Chronic exposure - No information is available. May cause damage of respiratory system.

#### Skin contact :

Acute exposure - No information is available.

Chronic exposure - No information is available.

#### Eye contact :

Acute exposure - May cause abrasive irritation

Chronic exposure - No information is available.

#### Ingestion :

Acute exposure - Very low acute oral toxicity. (LD50 > 1g/Kg. rat-oral. aq.soln)

Large quantities may cause intestinal obstruction or stomach constriction.

Chronic exposure - Very low chronic oral toxicity

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## Section 12 - Ecological information

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### Biodegradability :

This material is a cellulose ether product. Cellulose ether products have generally slow biodegradation rate. The biochemical oxygen demand (BOD5) for tested cellulose ethers is 0 parts/parts.

### Ecotoxicity :

Cellulose ether products are generally of low toxicity to fish.

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## Section 13 - Disposal information

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### < Recommended procedures >

#### Contents :

• Burying on approved landfill.

• Incinerating under carefully controlled conditions.

#### Container :

• Incinerating

#### NOTE :

When disposing using the above procedures, check all regulations in regard to this substance's disposal in your country or region, and follow them.

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**Section 14 - Transport information**

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Follow all regulations in your country.

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**Section 15 - Regulatory information**

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Shin-Etsu Chemical Co. Ltd. is not able to check up the regulatory information in regard to this substance in your country or region. therefore, we request the investigation of this matter be taken as your responsibility.

• UN Number : None

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**Section 16 - Other information**

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This materials safety data sheet is offered solely for your information, consideration and investigation. The data described in this MSDS consist of data on literature, our acquisitional data and analogical inference by data of similar chemical substances or products. Shin-Etsu Chemical Co., Ltd. provides no warranties, either express or implied, and assumes no responsibility for the accuracy or completeness of the data contained herein. Final determination of suitability of any material is the sole responsibility of the user.

---

**Material Safety Data Sheet**  
 May be used in comply with  
 OSHA's Hazard Communication Standard,  
 29 CFR 1910.1200. Standard must be  
 used for specific requirements.

**U.S. Department of Labor**  
 Occupational Safety and Health Administration  
 (Non-Mandatory Form)  
 Form Approved  
 OSHA No. 1218-0072



IDENTIFY the liquid on label and tag  
**MF Lactose, Anhydrous DT**

NOTE: This section on the form must be completed if the information is available. For spaces that are marked as optional.

**Section I**

Manufacturer's Name **WELT INTERNATIONAL**  
**Sheffield Products Division**  
 Address (Number, Street, City, State, and ZIP Code)  
**P.O. Box 630**  
**Norwich, New York 13815**

Emergency Telephone Number  
**CHEMTEC: 1-800-424-9300**  
 Telephone Number by location  
**607-334-9951**  
 Date Prepared  
**10/31/88**  
 Signature of Preparer

**Section II - Hazardous Ingredients/Identify Information**

Hazardous Components (Specify Chemical Name; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% Material
<b>NONE</b>				

**Section III - Physical/Chemical Characteristics**

Boiling Point	<b>N.A.</b>	Specific Gravity (4/4)	<b>Bulk Density</b>	<b>Approx. 8</b>
Vapor Pressure (mm Hg)	<b>Negligible</b>	Melting Point		<b>Decomposes</b>
Vapor Density (AIR = 1)	<b>Negligible</b>	Evaporation Rate (Pure Atmos = 1)		<b>N.A.</b>
Solubility in Water	<b>20g/100 ml @ 75°C</b>			
Appearance and Color	<b>White Powder, Nearly Odorless</b>			

**Section IV - Fire and Explosion Hazard Data**

Flash Point (Method Used)	<b>Unknown</b>	Flammable Limits	<b>Unknown</b>	LEL	<b>UK</b>	UEL	<b>UK</b>
Escalating Gases	<b>Water, CO<sub>2</sub></b>						
Special Fire Fighting Procedures	<b>None Required</b>						
Unusual Fire and Explosion Hazards	<b>None</b>						

**Section V -- Reactivity Data**

Reactivity	Unstable		Conflicts to Avoid
	Stable	X	

**b. Allotropy (Monomers to Avoid)**

**Maximum Concentration of Gases**

Maximum Polymerization	May Occur		Conflicts to Avoid
	Will Not Occur	X	

**Section VI -- Health Hazard Data**

Amount of Entry: Inhalation? \_\_\_\_\_ Skin? \_\_\_\_\_ Ingestion? \_\_\_\_\_

Health Hazard (Acute and Chronic) **Not a Health Hazard**

Classification: **MTP?** \_\_\_\_\_ **MRC Monograph?** \_\_\_\_\_ **OEPA Required?** \_\_\_\_\_

**Not a Carcinogen**

Signs and Symptoms of Exposure

Special Conditions Generally Approved by EPA

Emergency and First Aid Procedures **None Required**

**Section VII -- Precautions for Safe Handling and Use**

Steps to be Taken in Case Material is Released or Spilled

**Sweep or Vacuum**

Waste Disposal Method **Normal solid waste disposal**

Precautions to be Taken in Handling and Storage

**No special precautions**

Other Precautions

**Section VIII -- Control Measures**

Respiratory Protection (Specify Type) **Not required**

Ventilation	Local Exhaust		General
	Engineering Controls		Other

Protective Gloves **Not Required** Eye Protection **Not Required**

Other Protective Clothing or Equipment **Not Required**

Atypical Problems **Normal**

MAGNESIUM STEARATE

Material Safety Data Sheet

Effective Date: 11/21/85  
Supersedes : 02/13/85

Mallinckrodt, Inc.  
P.O. Box 9439  
St. Louis, Mo. 63147

Emergency Telephone Number  
314-982-3000

Product Identification:

Synonyms: Stearic acid, magnesium salt; seadecanoic acid, magnesium salt

Chemical Formula:  $Mg(C_{18}H_{35}O_2)_2$

Formula CAS No.: 557-04-0

Molecular Weight: 591.2 (pure)

Hazardous Ingredients: Magnesium Stearate.

The exact product composition depends on  
purity of the tallow used.

PRECAUTIONARY MEASURES

CAUTION MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR.

Store in a tightly closed container.

Avoid dust cloud in presence of an ignition source.

Wash thoroughly after handling.

As part of good industrial and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical substance and ensure prompt removal from skin, eye and clothing.

EMERGENCY/FIRST AID

SEE SECTION 5.

DOT Hazard Class: Not Regulated

Physical Data

SECTION 1

Appearance: Fine white to yellow-white powder.  
Odor: Slight odor of fatty acid.  
Solubility: Insoluble in water, ether; soluble in hot alcohol.  
Boiling Point: No information found.  
Melting Point: 150-170°C (302-338°F)  
Specific Gravity: 1.03  
Vapor Density (Air=1): Not applicable.  
Vapor Pressure (mm Hg): Not applicable.  
Evaporation Rate: Not applicable.

**Fire and Explosion Information**

**SECTION 2**

**FIRE:**

Minimum dust cloud ignition temperature:  
690°C (1274°F)

**Explosion:**

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Maximum explosion pressure: 68 lb./sq. in. at 0.1 seconds per cubic foot.

**Fire Extinguishing Media:**

Water spray, dry chemical, alcohol foam, or carbon dioxide. Water or foam may cause frothing.

**Special Information:**

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode. Pressure from the extinguishing media may cause severe dusting. Melted lumpy acid can give "grease" type fire.

**Reactivity Data**

**SECTION 1**

**Stability:**

Stable under ordinary conditions of use and storage.

**Hazardous Decomposition Products:**

Burning may produce carbon monoxide and magnesium oxide.

**Hazardous Polymerization:**

Will not occur.

**Incompatibilities:**

Acids which break up the salts.

**Leak/Spill Disposal Information**

**SECTION 4**

Remove all sources of ignition. Ventilate area of leak or spill. Clean-up personnel must require protection from inhalation of dust. Spills: Clean up spills in a manner that does not disperse dust into the air. Use non-sparking tools. Pick up spill for recovery or disposal and place in a closed container. Disposal: Whatever cannot be saved for recovery may be burned in an approved incinerator or disposed in an approved waste facility.

Ensure compliance with local, state and federal regulations.

Health Hazard Information

SECTION 1

A. Exposure/Health Effects

Inhalation:	Symptoms from excessive inhalation of dust may include coughing and difficult breathing.
Ingestion:	Low level of toxicity by ingestion.
Skin contact:	No information found. Not expected to be a hazard.
Eye contact:	May cause mechanical irritation.
Chronic Exposure:	Grossly excessive and chronic inhalation of the dust may cause a progressive chemical pneumonitis.
Aggravation of Pre-existing Conditions:	Persons with pre-existing skin disorders, impaired respiratory function, or a history of pulmonary disease should not be exposed to dusts.

B. FIRST AID

Inhalation:	Remove to fresh air. Get medical attention for any breathing difficulty.
Ingestion:	Give several glasses of water to drink to dilute. If large amounts were swallowed, get medical advice.
Skin contact:	Wash exposed area with soap and water. Get medical advice if irritation develops.
Eye contact:	Wash thoroughly with running water. Get medical advice if irritation develops.

C. TOXICITY DATA (RTECS, 1982)

No LD50/LC50 information found relating to normal routes of occupational exposure.

Occupational Control Measures

SECTION 6

**Airborne Exposure Limits:**

-ACGIH Threshold Limit Value (TLV):  
10 mg/m<sup>3</sup> of total dust.

**Ventilation System:**

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, "Industrial Ventilation, Manual of Recommended Practices", most recent edition, for details.

**Personal Respirators:**  
(NIOSH Approved)

If the TLV is exceeded, a dust/mist respirator may be worn up to ten times the TLV. Consult respirator supplier for details.

**Skin Protection:**

Gloves and lab coat, apron or coveralls.

**Eye Protection:**

Use chemical safety goggles. Contact lenses should not be worn when working with this material. Maintain eye wash fountain and quick-drench facilities in work area.

Storage and Special Information

SECTION 7

Avoid dust dispersal.

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Separate from incompatibilities.

\*\*\*\*\*  
The information contained herein is provided in good faith and is believed to be correct as of the date hereof. However, Mallinckrodt, Inc. makes no representation as to the comprehensiveness or accuracy of the information. It is expected that individuals receiving the information will exercise their independent judgment in determining its appropriateness for a particular purpose. Accordingly, Mallinckrodt, Inc. will not be responsible for damages of any kind resulting from the use of or reliance upon such information. NO REPRESENTATIONS, OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR TO THE PRODUCT TO WHICH THE INFORMATION REFERS.  
\*\*\*\*\*

Addendum to Material Safety Data Sheet

**REGULATORY STATUS**

**Hazard Categories for SARA Section 311/312 Reporting**

Products or Components of Product:	Acute	Chronic	Fire	Pressure	Reactive
	.....	.....	.... X	.....	.....
MAGNESIUM STEARATE (557-04-0)	No	No	No	No	No No

Products or Components of Product:	CERCLA Sec. 103 RQ lbs	RCRA Sec. 261.33	SARA EHS Sec. 302 RQ	SARA EHS Sec. 302 TPQ	SARA 313 Chemicals Name Chemical List Category
	.....	.....	....	.....	.....
MAGNESIUM STEARATE (557-04-0)	No	No	No	No	No No

SARA Section 302 EHS RQ: Reportable Quantity of Extremely Hazardous Substance, listed at 40 CFR 355.

SARA Section 302 EHS TPQ: Threshold Planning Quantity of Extremely Hazardous Substance. An asterisk (\*) following a Threshold Planning Quantity signifies that if the material is a solid and has a particle size equal to or larger than 100 micrometers, the Threshold Planning Quantity = 10,000 LBS.

SARA Section 313 Chemicals: Toxic Substances subject to annual release reporting requirements listed at 40 CFR 372.65.

CERCLA Sec. 103: Comprehensive Environmental Response, Compensation and Liability Act (Superfund). Releases to air, land or water of these hazardous substances which exceed the Reportabl. Quantity (RQ) must be reported to the National Response Center, (800-424-8802); Listed at 40 CFR 302.4

RCRA: Resource Conservation and Reclamation Act. Commercial chemical product wastes designated as acute hazards and toxic under 40 CFR 261.33





ISSUE DATE: 1/17/92

FORM: EX-01

Code # 68511  
PAGE 1 OF 6  
14710

MATERIAL SAFETY DATA SHEET

**NOTICE:** The information and recommendations contained herein are based upon data believed to be correct as of the date of issue. No guarantee or warranty of any kind, expressed or implied is made with respect to the information contained herein.

HAZARD RATINGS

HEALTH = 0  
FLAMMABILITY = 0  
REACTIVITY = 0

-----  
0 = Minimal    1 = Slight    2 = Moderate    3 = Serious    4 = Severe  
-----

SECTION I - PRODUCT IDENTIFICATION

MANUFACTURER'S NAME:            COLORCON, A DIVISION OF BERWIND  
   PHARMACEUTICAL SERVICES  
ADDRESS:                            MOYER BLVD., WEST POINT, PA 19486  
  
EMERGENCY TELEPHONE NUMBER:    CHEMTREC: 800/424-9300  
  
PRODUCT CLASS:                    Pharmaceutical Excipient  
  
TRADE NAME:                        STARCH 1500  
  
MANUFACTURER'S ID CODE:         2001  
-----

ISSUE DATE: 1/17/92

FORM: EX-01

PAGE 2 OF 6

SECTION II - INGREDIENT DATA

HAZARDOUS COMPONENT: Starch CAS: 9005-25-8 EXPOSURE LIMITS: (ACGIH) 10 MG/M3 (OSHA) 15 MG/M3\*  
\*(PEL is for nuisance dusts)

PENNSYLVANIA RIGHT-TO-KNOW: Starch 9005-25-8 10 MG/M3 15 MG/M3\*

WHMIS:

None - This product is not a controlled substance under the Canadian workplace hazardous materials information system.

SECTION III - PHYSICAL DATA

BOILING RANGE: N/A

EVAPORATION RATE (VS. BUTYL ACETATE) N/A

LIQUID DENSITY: N/A

ODOR THRESHOLD: N/A

VAPOR DENSITY (VS. AIR): N/A

PERCENT VOLATILE (W/W): 0

FREEZING POINT: N/A

AUTO IGNITION TEMPERATURE: N/A

APPEARANCE AND ODOR:

Dry, odorless, white powder.

ISSUE DATE: 1/17/92

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**SECTION IV - FIRE/EXPLOSION DATA**

FLASH POINT: N/A

FLAMMABLE LIMITS - LEL: N/A

- VEL: N/A

RATE OF BURNING: N/A

SENSITIVITY TO STATIC  
DISCHARGE: Yes

**EXTINGUISHING MEDIA:**

Use appropriate extinguishing media for surrounding fire.

**SPECIAL FIRE FIGHTING PROCEDURES:**

Fire fighters should wear self-contained breathing apparatus operated in positive pressure mode.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:**

Product dust may form an explosive mixture with air. Avoid conditions which produce dust.

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**SECTION V - HEALTH HAZARDS**

**EFFECTS OF OVEREXPOSURE:**

May produce transitional irritaion to eyes, nose and throat.

**ROUTES OF ENTRY:** Inhalation

**FIRST AID PROCEDURES:**

Eye Contact: Flush eyes with water for at least 15 minutes.

Skin Contact: Wash with soap and water.

Inhalation: Remove victim to fresh air.

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**SECTION VI - TOXICITY DATA**

**CHRONIC EFFECTS:** None identified.

**TARGET ORGANS:** Eyes, skin

**CARCINOGENITY:** NTP: No IARC: No OSHA: No

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**SECTION VII - REACTIVITY**

**PRODUCT STABILITY:** Stable

**CONDITIONS TO AVOID:**

Caution should be taken to avoid the production of dust, since finely divided particles in a suspended state may form explosive mixtures with proper air proportions and source of ignition.

**HAZARDOUS POLYMERIZATION:** Will not occur.

**MATERIALS TO AVOID:**

Strong oxidizing agents

**DECOMPOSITION PRODUCTS:**

Carbon monoxide, carbon dioxide

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**SECTION VIII - SPILL PROCEDURES**

**LARGE SPILLS:**

Moisten slightly with water to avoid producing dust. Sweep or shovel moistened material into proper waste container. Do not sweep dry material, as this will produce dust concentrations in the air.

**SMALL SPILLS:**

Vacuum material or moisten slightly with water and place into proper waste container.

**WASTE DISPOSAL:**

This product is not a hazardous waste under RCRA regulations. Consult State and Local regulations for proper waste disposal method.

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**SECTION IX - PROTECTION DATA**

**VENTILATION:**

Use general or local exhaust to meet TLV requirements.

**RESPIRATORY PROTECTION:**

An approved dust respirator if airborne concentrations exceed TLV.

**PROTECTIVE CLOTHING:**

Not required

**EYE PROTECTION:**

Safety goggles

**OTHER PROTECTIVE EQUIPMENT:**

Proper gloves

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**SECTION X - SPECIAL PRECAUTIONS**

**HANDLING AND STORAGE:**

Avoid handling procedures which produce dust. Keep containers tightly closed.

**OTHER PRECAUTIONS:**

None

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SECTION XI - REGULATORY

CLASSIFICATIONS:

N/A

SARA TITLE III (Community Right-to-know):

SECTION 311/312:

This product is categorized as an immediate and delayed health hazard.

SECTION 313:

This product does not contain any chemicals listed in section 313 above de minimis levels.

TOXIC SUBSTANCE CONTROL ACT:

All materials contained in this product are listed on the TSCA inventory.

STATE RIGHT-TO-KNOW:

N/A



# WHITTAKER, CLARK & DANIELS, INC.

GENERAL, GRADE, GENERAL

## MATERIAL SAFETY DATA SHEET

PRODUCT/MATERIAL: TITANIUM DIOXIDE  
 MANUFACTURER/DISTRIBUTOR: WHITTAKER, CLARK & DANIELS, INC.  
 1800 CHURCH STREET  
 SOUTH PLAINFIELD, N.J. 07080  
 TELEPHONE NUMBER: (908)881-6100

### SECTION I - PRODUCT IDENTIFICATION

TRADE NAME	TITANIUM DIOXIDE
CHEMICAL NAME	TiO <sub>2</sub>
CHEMICAL FORMULA	TiO <sub>2</sub>
CAS NUMBER	1344-49-7
MSDS RATING	HEALTH 0 FLAMMABILITY 0 REACTIVITY 0

### SECTION II - COMPOSITION

TITANIUM DIOXIDE	MSDS PEL: 15 mg/m <sup>3</sup> (Total) 5 mg/m <sup>3</sup> (Respirable)
	ACGIH TLV: 10 mg/m <sup>3</sup> (Total-TM) 5 mg/m <sup>3</sup> (Respirable)

### SECTION III - HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW:** NO IMMEDIATE FIRE OR SPILL HAZARD. LOW HEALTH RISK BY INHALATION. WHITE, ODORLESS POWDER.

**POTENTIAL HEALTH EFFECTS:** EYES - MAY CAUSE MECHANICAL IRRITATION.  
 SKIN - NONE  
 INHALATION - LOW HEALTH RISK BY INHALATION. TREAT AS A IRRITANT DUST.  
 ORAL LD<sub>50</sub> - GREATER THAN 7,000 mg/kg (RATS)

**EFFECTS OF OVEREXPOSURE:** ACUTE - EXPOSURE MAY IRRITATE THE THROAT AND AIR PASSAGES, SOMETIMES CAUSING COUGH AND PHLEGM.  
 CHRONIC - REPEATED HEAVY EXPOSURES MAY CAUSE BRONCHITIS, WITH COUGH AND PHLEGM. IF EXPOSURE CONTINUES, EMPHYSEMA MAY DEVELOP. LUNG SCARRING MAY ALSO RESULT.

**CARCINOGENICITY:** NOT LISTED WITH NTP, IARC OR OSHA AS A KNOWN OR SUSPECTED CARCINOGEN.

### SECTION IV - FIRST AID MEASURES

**EYES:** FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. CONSULT A PHYSICIAN IF IRRITATION PERSISTS.

**SKIN:** WASH WITH SOAP AND WATER FOR AT LEAST 15 MINUTES. CONSULT A PHYSICIAN IF IRRITATION PERSISTS.

**INHALATION:** REMOVE TO FRESH AIR. IF BREATHING IS LABORED OR STOPPED, GIVE ARTIFICIAL RESPIRATION. GET IMMEDIATE MEDICAL ATTENTION.

**INGESTION:** IF SWALLOWED, DILUTE WITH LARGE AMOUNTS OF WATER. DO NOT INDUCE VOMITING. CONSULT A PHYSICIAN IMMEDIATELY.

### SECTION V - FIRE FIGHTING MEASURES

**FLAMMABLE PROPERTIES:** NON-FLAMMABLE





# WHITTAKER, CLARK & DANIELS, INC.

MINERAL, COLOR, ORGANALS

FLASH POINT - NONE

FLAMMABLE LIMITS - NOT APPLICABLE

AUTO-IGNITION TEMPERATURE - NOT APPLICABLE

HAZARDOUS DECOMPOSITION PRODUCTS: NONE

EXTINGUISHING MEDIA: USE EXTINGUISHING AGENT APPLICABLE TO UNDERLYING FIRE.

FIRE FIGHTING INSTRUCTIONS: FIRE FIGHTERS SHOULD WEAR GEAR APPROVED, POSITIVE PRESSURE, SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING WHEN APPROPRIATE. TOXIC FUMES MAY BE PRODUCED IN FIRE.

## SECTION VI - ACCIDENTAL RELEASE MEASURES

SMALL/LARGE SPILL: CLEAN UP USING DRY PROCEDURES: AVOID BUSTERS.

## SECTION VII - HANDLING AND STORAGE

HANDLING: GOOD INDUSTRIAL HYGIENE PRACTICE REQUIRES THAT EMPLOYEE EXPOSURE BE MAINTAINED BELOW TLV. THIS IS PREFERABLY ACHIEVED THROUGH THE PROVISION OF ADEQUATE VENTILATION WHERE NECESSARY. WHERE DUST CANNOT BE CONTROLLED IN THIS WAY, PERSONAL RESPIRATORY PROTECTION SHOULD BE EMPLOYED.

STORAGE: STORE IN A DRY AREA AT AMBIENT TEMPERATURE.

## SECTION VIII - EXPOSURE CONTROLS

ENGINEERING CONTROLS: USE WITH ADEQUATE VENTILATION TO MEET EXPOSURE LIMITS LISTED IN SECTION II.

RESPIRATORY PROTECTION: GEAR APPROVED DUST RESPIRATOR IF OVEREXPOSURE POTENTIAL EXISTS.

SKIN PROTECTION: NONE

EYE PROTECTION: SAFETY GLASSES RECOMMENDED.

## SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: WHITE POWDER

BOILING POINT: 452° F

VAPOR PRESSURE: NOT APPLICABLE

VAPOR DENSITY: NOT APPLICABLE

SOLUBILITY IN WATER: INSOLUBLE; SOLUBLE IN CONCENTRATED SULFURIC ACID.

SPECIFIC GRAVITY: 3.7 - 4.2

PH: NOT DETERMINED

ODOR: NONE

ODOR THRESHOLD: NOT APPLICABLE

## SECTION X - STABILITY AND REACTIVITY

CONDITIONS TO AVOID: NONE

INCOMPATIBILITY: NONE

HAZARDOUS DECOMPOSITION PRODUCTS: NONE

HAZARDOUS POLYMERIZATION: NONE

## SECTION XI - TOXICOLOGICAL INFORMATION

LD<sub>50</sub> ORAL (RAT): GREATER THAN 7,500 mg/kg.

## SECTION XII - ECOLOGICAL INFORMATION

NO HARMFUL EFFECTS OTHER THAN THOSE ASSOCIATED WITH SUSPENDED INERT SOLIDS IN WATER.



## WHITTAKER, CLARK & DANIELS, INC.

GENERAL SAFETY DATA SHEET

### SECTION XIII - DISPOSAL CONSIDERATIONS

COLLECT IN CONTAINERS, BAGS, OR COVERED DUMPSTER BINS. IF BURNING OR RECYCLING IS NOT POSSIBLE, MATERIAL MAY BE DISPOSED OF AT A CHEMICALLY STABLE LANDFILL.

RCA HAZARDOUS WASTE NUMBER: NOT FEDERALLY REGULATED.

### SECTION XIV - TRANSPORTATION INFORMATION

U.S. DOT: NOT REGULATED - ENTER THE PROPER FREIGHT CLASSIFICATION ON THE SHIPPING PAPERWORK, "HAZARD CLASS", AND "PRODUCT NAME" FOR SHIPPING PURPOSES.

CANADIAN TOXIC HAZARD CLASS & PCB: NOT REGULATED.

### SECTION XV - REGULATORY INFORMATION

TSCA STATE: COMPONENTS OF THIS PRODUCT ARE LISTED ON THE TSCA INVENTORY.

CERCLA REPORTABLE QUANTITY: NONE

SARA TITLE III

SECTION 311/312 HAZARDOUS CATEGORIES: NONE

SECTION 313 TOXIC CHEMICALS: NONE

INTERNATIONAL REGULATIONS:

CANADIAN DEL - COMPONENTS ARE LISTED.

CANADIAN MOSES - THIS MATERIAL IS A CONTROLLED SUBSTANCE UNDER MOSES.

EUROPEAN COMMUNITY - LISTED ON MSDS, THE EUROPEAN CHEMICAL INVENTORY.

### SECTION XVI - OTHER INFORMATION

THE INFORMATION HEREIN IS GIVEN IN GOOD FAITH AS AUTHENTICATIVE AND VALID; HOWEVER, NO WARRANTY, EXPRESSED OR IMPLIED, CAN BE MADE.

ISSUED: 2/78

REVISIONS: 11/74

# ABITEC Corporation

P.O. Box 589  
COLUMBUS, Ohio 43216-0589  
614-289-3131

## MATERIAL SAFETY DATA SHEET

### SECTION 1: PRODUCT IDENTIFICATION & EMERGENCY INFORMATION

Trade Name:	Sterotex K
Issue Date:	3 September 1992
Chemical Name:	Hydrogenated Soybean and Castor Oils
Chemical Family:	Triglyceride
CAS No.:	8016-70-4 <sup>a</sup> & 8001-78-3 <sup>b</sup>
Composition:	Glycerin Esters of C14 - C22 Fatty Acids and Castor Oils
Formula:	Refined, bleached, partially hydrogenated, filtered and deodorized soybean and castor oils.

### EMERGENCY TELEPHONE NUMBERS:

ABITEC Corporation (Ohio)	800-848-1340
ABITEC Corporation (Wisconsin)	608-752-9007

### SEC. 2: HAZARDOUS INGREDIENT & OCCUPATIONAL EXPOSURE LIMITS

Ingredient	CAS No.	%	Exposure Limits
None			

### SECTION 3: HEALTH HAZARD DATA

Threshold Limit Value	Unknown
Effects of Overexposure	None known to ABITEC Corporation
Skin	Wash with soap and water.
Eyes	Flush with low pressure water.
Ingestion	Food grade product.
Inhalation	Vegetable oil mists are classified as <i>nuisance particulates</i> by the American Conference of Governmental Industrial Hygienists (no health effects reported).

#### SECTION 4: FIRST AID

<i>On Skin</i>	Wash with soap and warm water.
<i>In Eyes</i>	Flush with low pressure water.
<i>Ingested</i>	If gastrointestinal discomfort is encountered, contact a physician.
<i>Inhaled</i>	Move victim to fresh air.

#### SECTION 5: PROTECTION INFORMATION

<i>Respiratory</i>	In the presence of vegetable oil mists or dusts, the use of a NIOSH/OSHA approved mask and/or respirator is recommended.
<i>Ventilation</i>	Local, if necessary, to control dust or fumes from hot material.
<i>Eyes</i>	Goggles for hot oil.
<i>Hands</i>	Neoprene type gloves for hot oil.
<i>Other Protective Equipment</i>	Rubber boots and apron for hot oil.

#### SECTION 6: SPECIAL PRECAUTIONS AND COMMENTS

##### *Precautions to be taken in handling and storing*

At times, oil soaked materials may spontaneously combust. Do not allow absorptive materials to accumulate in closed conditions when exposed to air. Follow good housekeeping methods.

##### *Comments*

Vegetable oil mists are classified as *nuisance particulates* by the American Conference of Governmental Industrial Hygienists. No health effects reported.

### SECTION 7: PHYSICAL DATA

<b>Boiling Point</b>	>500°F	<b>Vapor Pressure</b>	< 1 mm Hg
<b>Vapor Density</b>	Not Determined (Air = 1)	<b>Evaporation Rate</b>	Nil (N-Butyl Acetate)
<b>Specific Gravity</b>	approx. 0.9 @ 100°F (Water = 1)	<b>Melting Point</b>	Not Determined
<b>Solubility</b>	Insoluble	<b>Viscosity</b>	Not Determined
<b>Percent Volatiles</b>	Nil		
<b>Appearance &amp; Odor</b>	White powder at room temperature, light yellow oil above melting point.		

### SECTION 8: REACTIVITY DATA

<b>Stability</b>	Stable	<b>Incompatibility/ Materials to avoid</b>	Strong oxidizing agents.
<b>Conditions to avoid</b>	High temperatures near flash point.		
<b>Hazardous Polymerization</b>	Not likely to occur	<b>Hazardous Decomposition</b>	None

### SECTION 9: FIRE & EXPLOSION DATA

<b>Flash Point</b>	>500°F COC-AOCS	<b>Flammable Limits</b>	No data available.
<b>LEL</b>	N/A	<b>UEL</b>	N/A
<b>Extinguishing Media</b>	Foams, carbon dioxide, inert powder.		
<b>Special Fire Fighting Procedure</b>	Treat as fat or oil fire. Do not use heavy stream of water. Fatty material will float and splatter surrounding area.		
<b>Unusual Fire &amp; Explosion Hazard</b>	Avoid use of water in extinguishing fire. Fine oil mists may be hazardous. At times, oil soaked rags may spontaneously ignite when exposed to air. High temperatures near flash point.		

### **SECTION 10: SPILL OR LEAK PROCEDURES**

Stop spill at source, dike area of spill to prevent spreading. Pump liquid to salvage tank. Absorb liquid on solid absorbent material and shovel into containers. Prevent run-off to sewers, streams or other bodies of water. Wash floors with detergent and rinse with hot water to prevent slipping.

### **SECTION 11: WASTE DISPOSAL METHOD**

Incineration is the recommended disposal method for all chemical wastes. Material collected on absorbent material may be land-filled in accordance with all applicable local, state and federal regulations.

### **SECTION 12: OTHER INFORMATION**

This product (or components, if a mixture) has not been found to be a carcinogen or potential carcinogen by IARC; is not listed in the NTP Third Annual Report; nor is it regulated by OSHA as a carcinogen.

The information presented herein has been compiled from sources considered by the company in good faith to be dependable and is accurate and reliable to the best of our knowledge and belief. However, the company cannot make any warranty or representation respecting the accuracy or completeness of the data and assumes no responsibility for any liability or damages relating thereto or for advising you regarding the protection of your employees, customers, or others. Users should make their own tests to determine the applicability of such information or suitability of any products for specific use.