

BRISTOL-MYERS SQUIBB PHARMACEUTICAL CO APOTHECON -- CAFZIL FOR ORAL SUSPENSION
(125 MG/5 ML OR 250 GM/5 ML) -- 6505-01-356-4844

===== Product Identification =====

Product ID:CAFZIL FOR ORAL SUSPENSION (125 MG/5 ML OR 250 GM/5 ML)

MSDS Date:11/06/1992

FSC:6505

NIIN:01-356-4844

MSDS Number: BWTBX

=== Responsible Party ===

Company Name:BRISTOL-MYERS SQUIBB PHARMACEUTICAL CO APOTHECON

Address:600 COLL

EGE RD E

Box:4500

City:PRINCETON

State:NJ

ZIP:08543-4500

Country:US

Info Phone Num:609-243-6000

Emergency Phone Num:609-243-6000

CAGE:0MN35

=== Contractor Identification ===

Company Name:BRISTOL-MYERS SQUIBB PHARMACEUTICAL CO APOTHECON

Address:600 COLLEGE RD E

Box:4500

City:PRINCETON

State:NJ

ZIP:08543-4500

Country:US

Phone:609-243-6000

CAGE:0MN35

===== Composition/Information on Ingredients =====

Ingred Name:CEFPROZIL (ACTIVE INGREDIENT)

Fraction by Wt: 5-10%

Other REC Limit

s:NONE RECOMMENDED

Ingred Name:ASPARTAME (3-AMINO-N-(ALPHA-CARBOXYPHENYLETHYL) SUCCINIC
ACID, N-METHYL ESTER) (PER MSDS, AN INACTIVE INGREDIENT.)

CAS:22839-47-0

RTECS #:WM3407000

Other REC Limits:NONE RECOMMENDED

Ingred Name:CELLULOSE (PAPER FIBER) (PER MSDS, AN INACTIVE
INGREDIENT.)

CAS:9004-34-6

RTECS #:FJ5691460

Other REC Limits:NONE RECOMMENDED

OSHA PEL:15 MG/M3 TDUST

ACGIH TLV:10 MG/M3; 9495

Ingred Name:CITRIC ACID (PER MSDS, AN INACTIVE INGREDIENT.)

CAS:77-92-9

RTECS #:GE7

350000
Other REC Limits:NONE RECOMMENDED

Ingred Name:SILICONE DIOXIDE (PER MSDS, AN INACTIVE INGREDIENT.)
Other REC Limits:NONE RECOMMENDED
OSHA PEL:0.5 MG/M3
ACGIH TLV:0.5 MG/M3

Ingred Name:FD&C RED 3 (PER MSDS, AN INACTIVE INGREDIENT.)
CAS:16423-68-0
RTECS #:LM5950000
Other REC Limits:NONE RECOMMENDED

Ingred Name:FLAVORS (NATURAL & ARTIFICIAL) (PER MSDS, AN INACTIVE INGREDIENT.)
Other REC Limits:NONE RECOMMENDED

Ingred Name:GLYCINE (PER MSDS, AN INACTIVE INGREDIENT.)
CAS:56-40-6

RTECS #:MB7600000
Other REC Limits:NONE RECOMMENDED

Ingred Name:POLYSORBATE 80 (PER MSDS, AN INACTIVE INGREDIENT.)
Other REC Limits:NONE RECOMMENDED

Ingred Name:SODIUM BENZOATE (PER MSDS, AN INACTIVE INGREDIENT.)
CAS:532-32-1
RTECS #:DH6650000
Other REC Limits:NONE RECOMMENDED

Ingred Name:SODIUM CARBOXYMETHYLCELLULOSE (CELLULOSE GUM) (PER MSDS, AN INACTIVE INGREDIENT.)
CAS:9004-32-4
RTECS #:FJ5950000
Other REC Limits:NONE RECOMMENDED

Ingred Name:SODIUM CHLORIDE (PER MSDS, AN INACTIVE INGREDIENT.)
CAS:7647-14-5
RTECS #:VZ4725000
Other REC Limits:NONE RECOMMENDED

Ingred Name:SUCROSE (PER MSDS, AN INACTIVE INGREDIENT.)
CAS:57-50-1
RTECS #:WN6500000
Other REC Limits:NONE RECOMMENDED
OSHA PEL:15 MG/M3 TDUST
ACGIH TLV:10 MG/M3; 9495

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===== Hazards Identification =====

LD50 LC50 Mixture:LD50 (ORAL RAT) IS >5000 MG/KG
Routes of Entry: Inhalation:YES Skin:YES Ingestion:YES
Reports of Carcinogenicity:NTP:NO IARC:NO OSHA:NO
Health Hazard

ds Acute and Chronic: APPROXIMATELY 100% ADMINISTERED ORALLY IS ABSORBED IN G/I TRACT. IT IS ESSENCIALLY NON-TOXIC. IN SUB-ACUTE & CHRONIC STUDIES, EFFECTS WERE MINOR & REVERSABLE. SEE INFORMATION ABOUT THE THERAPEUTIC USE OF THIS PRODUCT ON THE PACKAGE INSERT.

Explanation of Carcinogenicity: MFR GAVE THE ABOVE LISTINGS ON THE MSDS BUT NO OTHER COMMENTS WERE RECORDED.

Effects of Overexposure: ORAL: THERAPEUTIC DOSES MAY PRODUCE NAUSEA, VOMITING, DIARRHEA. HYPERSENSITIVE REACTION SYMPTOMS MAY BE

URTICARIA, PRURITUS, RASH, WHEEZING, FEVER, CHILLS, EOSINOPHILIA, JOINT PAIN, EDEMA, ERYTHEMA. ANAPHYLAXIS MAY BE FATAL. INHALED: MAY CAUSE ALLERGIC SYMPTOMS. SKIN: POSSIBLE ALLERGIC SKIN REACTION. EYE: NO INFORMATION.

Medical Cond Aggravated by Exposure: HYPERSENSITIVITY TO ANY PENICILLIN OR CEPHALOSPORIN. THERAPEUTIC DOSES MAY AGGRAVATE G/I DISEASE, HEPATIC DISORDERS, HEMATOLOGIC DISORDERS, RENAL DISORDERS.

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===== First Aid Measures =====
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First Aid: IF IRRITATION PERSISTS OR IS SEVERE, GET MEDICAL ATTENTION.
EYE: FLUSH W/WATER TO 15 MIN. SKIN: WASH W/SOAP & WATER.
INHALED: REMOVE FROM EXPOSURE. AID OR RESTORE BREATHING AS NEEDED.
INGESTED: GET IMMEDIATE MEDICAL ATTENTION.

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===== Fire Fighting Measures =====
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Extinguishing Media: USE WATER

Fire Fighting Procedures: EVACUATE PERSONNEL TO SAFE AREA. WEAR SELF-CONTAINED BREATHING APPARATUS & FULL PROTECTIVE CLOTHING. FIGHT FIRE FROM MAXIMUM DISTANCE OR USE UNMANNED HOSE.

Unusual Fire/Explosion Hazard: LIKE MOST ORGANIC MATERIAL IN POWDER FORM, MATERIAL IS CAPABLE OF CREATING A DUST EXPLOSION. MOVE CONTAINERS FROM FIRE AREA IF W/O RISK. DIVERT & HOLD RUNOFF.

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===== Accidental Release Measures =====
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Spill Release Procedures: AVOID SKIN OR EYE CONTACT & INHALING PRODUCT. WEAR APPROPRIATE PERSONAL PROTECTIVE EQUIPMENT. WET PRODUCT TO MINIMIZE DUST GENERATION. WASH HANDS & FACE AFT

ER HANDLING THE
COMPOUND. FOR LARGE SPILL, WEAR A NIOSH APPROVED DUST MASK
RESPIRATOR.

Neutralizing Agent:MFR GAVE NO INFORMATION ON MSDS.

===== Handling and Storage =====

Handling and Storage Precautions:MFR GAVE NO INFORMATION ON MSDS.

Other Precautions:MFR GAVE NO INFORMATION ON MSDS.

===== Exposure Controls/Personal Protection =====

Respiratory Protection:A NIOSH APPROVED DUST/MIST RESPIRATOR.

Ventilation:MFR GAVE NO INFORMATION ON MSDS.

Protective Gloves:LATEX GLOVES

Eye Protection:SAFETY GOGGLES

Other Protective Equipment:FOWN, SHOE COVERS

Work Hygienic Practices:PROMPTLY REMOVE CONTAMINATED CLOTHING. LAUNDRER
BEFORE REUSE. WASH HANDS & FACE AFTER HANDLING THIS PRODUCT.

Supplemental Safety and Health

THERAPEUTIC AGENTS ARE INTENDED FOR USE UNDER DIRECTION OF A PHYSICIAN
AND/OR UNDER THE CONDITIONS OF USE DESCRIBED ON THE LABEL. ALL
PERSONNEL WHO HANDLE DRUG SUBSTANCES SHOULD AVOID CONTACT (INGESTION
, INHALATION, SKIN & EYE CONTACT) WITH THESE SUBSTANCES.

===== Physical/Chemical Properties =====

HCC:T6

NRC/State Lic Num:NONE

Solubility in Water:PART SOL, PART SUSND

Appearance and Odor:GRANULAR POWDER, BUBBLE GUM ODOR

===== Stability and Reactivity Data =====

Stability Indicator/Materials to Avoid:YES
NONE KNOWN.

Stability Condition to Avoid:MFR GAVE NO INFORMATION ON MSDS.

Hazardous Decomposition Products:THERMAL DECOMPOSITION OR BUR

NING MAY

PRODUCE NOXIOUS PRODUCTS INCLUDING CARBON DIOXIDE & CARBON MONOXIDE, NOX & SOX.

Conditions to Avoid Polymerization:WILL NOT OCCUR.

===== Disposal Considerations =====

Waste Disposal Methods:MFR GAVE NO INFORMATION ON MSDS.

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