



9 BAYEN

76#04

MATERIAL SAFETY DATA SHEET

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BAYER CORPORATION
CONSUMER CARE DIVISION
36 Columbia Road
Morristown, NJ 07962-1910

TRANSPORTATION EMERGENCY
CALL CHEMTREC: 800-424-9100
DISTRICT OF COLUMBIA: 202-483-7615

NON-TRANSPORTATION
BAYER EMERGENCY PHONE...: (800) 331-4536
BAYER INFORMATION PHONE...: (800) 331-4536

1. CHEMICAL PRODUCT IDENTIFICATION:

PRODUCT NAME.....: Midol (R) Maximum PMS Gelcaps
PRODUCT CODE.....: 372B, 374B
CHEMICAL FAMILY.....: Analgesic

2. COMPOSITION/INFORMATION ON INGREDIENTS:

INGREDIENT NAME /CAS NUMBER EXPOSURE LIMITS CONCENTRATION (%)

***** HAZARDOUS INGREDIENTS *****

This pharmaceutical product, available without a prescription, is for human use. These materials are not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. This Material Safety Data Sheet is not intended for industrial exposures.

***** OTHER INGREDIENTS *****

Acetaminophen
103-90-2 OSHA : Not Established Greater than 25 %
ACGIH: Not Established
* See Section 2 for potential health effects.

Pamabrom
606-04-2 OSHA : Not Established 1 - 5 %
ACGIH: Not Established
* See Section 3 for potential health effects.

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Approval date: 07/31/97

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1-554206
C-12843017253

1-257648
C-12843016347

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2. COMPOSITION/INFORMATION ON INGREDIENTS (Continued)

INGREDIENT NAME /CAS NUMBER	EXPOSURE LIMITS	CONCENTRATION (%)
Pyrilamine Maleate 59-33-6	OSHA : Not Established ACGIH: Not Established	1 - 5 %

* See Section 3 for potential health effects.

3. HAZARDS IDENTIFICATION:

 * EMERGENCY OVERVIEW *
 *
 * Color: Two-tone pink; Form: Solid; Caplet; Odor: Odorless; *
 * Product poses little or no hazard if spilled and no unusual *
 * hazard if involved in a fire; See Potential Health Effects *
 * if the recommended dosage is exceeded. *

POTENTIAL HEALTH EFFECTS:

ROUTE(S) OF ENTRY.....: Appropriate route of entry: oral

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE:

NOTE: This is a pharmaceutical material available without a prescription - use only as directed. See product packaging for further information concerning adverse effects and drug interaction precautions.

ACUTE EFFECTS OF EXPOSURE.....: Overdose may cause vomiting, pancreatitis, blood disturbances, acid-base disturbances, pulmonary edema, acute hepatic necrosis (severe liver damage), liver failure, kidney failure, myocardial damage and neurologic symptoms including coma. NOTE: Clinical signs and symptoms of acute toxicity may not appear until several days post-ingestion; prompt medical attention is necessary even if symptoms are not apparent.

CHRONIC EFFECTS OF EXPOSURE....: Chronic overexposure to this product may cause effects described under acute exposure. Hepatotoxicity may occur with ingestion of 150 mg/kg acetaminophen.

CARCINOGENICITY.....: The components of this product are not listed by NTP, IARC or regulated as a carcinogen by OSHA.

MEDICAL CONDITIONS

AGGRAVATED BY EXPOSURE.....: Persons with preexisting pulmonary, renal or liver disease may be more susceptible to the effects of this product (acetaminophen), or children and persons with preexisting glaucoma or prostatic hypertrophy (pyrilamine maleate), may be more susceptible to the adverse effects of this product.

4. FIRST AID MEASURES:

FIRST AID FOR EYES.....: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.
FIRST AID FOR SKIN.....: Flush skin with plenty of soap and water. Contact a physician if irritation develops.
FIRST AID FOR INHALATION: Not applicable.
FIRST AID FOR INGESTION.: In case of overdose, contact your regional poison control center or physician immediately. For additional information, contact Bayer Corporation at 1-800-800-4793.

5. FIRE FIGHTING MEASURES:

FLASH POINT.....: Not Applicable
EXTINGUISHING MEDIA.....: All extinguishing media are suitable.
SPECIAL FIRE FIGHTING PROCEDURES: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

6. ACCIDENTAL RELEASE MEASURES:

SPILL OR LEAK PROCEDURES.....: Spills should be swept up and placed in appropriate containers for disposal. Avoid creating dusty conditions.

7. HANDLING AND STORAGE:

STORAGE TEMPERATURE (MIN/MAX): Room temperature.
SHELF LIFE.....: Do not use after expiration date.
SPECIAL SENSITIVITY.....: None known.
HANDLING/STORAGE PRECAUTIONS: Keep this and all drugs out of the reach of children. Avoid contact with eyes and skin. Wash thoroughly after handling. Store in a dry place away from excessive heat. Reseal containers immediately after use. Use normal precautions for storage of a drug.

8. PERSONAL PROTECTION:

EYE PROTECTION REQUIREMENTS.....: None for normal use.
SKIN PROTECTION REQUIREMENTS.....: None for normal use.
VENTILATION REQUIREMENTS.....: Under normal conditions of use, special
ventilation is not required.
RESPIRATOR REQUIREMENTS.....: Under normal conditions of use,
respiratory protection is not required.
WORK PRACTICES.....: Normal clinical practice. Use good
personal hygiene - wash hands and exposed skin thoroughly with soap and
water after each use.
ADDITIONAL PROTECTIVE MEASURES.....: Employers shall provide handwashing
facilities which are readily accessible to employees. Educate and train
employees in the safe use and handling of this product.

9. PHYSICAL AND CHEMICAL PROPERTIES:

PHYSICAL FORM.....: Solid
APPEARANCE.....: Caplet
COLOR.....: Two-tone pink
ODOR.....: Odorless
pH.....: Not Established
BOILING POINT.....: Not Applicable
MELTING/FREEZING POINT.....: Not Applicable
SOLUBILITY IN WATER.....: Soluble
SPECIFIC GRAVITY.....: Not Established
BULK DENSITY.....: Not Established
VAPOR PRESSURE.....: Not Applicable

10. STABILITY AND REACTIVITY:

STABILITY.....: This is a stable material.
HAZARDOUS POLYMERIZATION...: Will not occur.
INCOMPATIBILITIES.....: See product packaging and the Physicians' Desk
Reference (PDR) for drug interaction.
INSTABILITY CONDITIONS.....: None known.
DECOMPOSITION PRODUCTS.....: Not Applicable.

11. TOXICOLOGICAL INFORMATION:

TOXICITY DATA FOR: Acetaminophen
ACUTE TOXICITY

ORAL LD50.....: 2404 mg/kg (rat) (1)
DERMAL LD50.....: Greater than 7940 mg/kg (rabbit) (1)

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12. ECOLOGICAL INFORMATION:

NO ECOLOGICAL INFORMATION AVAILABLE

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD.....: Waste disposal should be in accordance with
existing federal, state and local environmental control laws.

14. TRANSPORTATION INFORMATION:

TECHNICAL SHIPPING NAME.....: Analgesic
PRODUCT LABEL.....: MIDOL (R) Maximum PMS Geicaps

DOT (DOMESTIC SURFACE)

HAZARD CLASS OR DIVISION: Non-Regulated

IMO / IMDG CODE (OCEAN)

HAZARD CLASS DIVISION NUMBER...: Non-Regulated

ICAO / IATA (AIR)

HAZARD CLASS DIVISION NUMBER...: Non-Regulated

15. REGULATORY INFORMATION:

OSHA STATUS.....: This material is not subject to the OSHA Hazard Communication Standard as noted in 29 CFR 1910.1200(b)(6)(vii).

TSCA STATUS.....: This product is exempt from TSCA Regulation under Section 3 (2)(B)(vi) when used for pharmaceutical application.

CERCLA REPORTABLE QUANTITY...: None

SARA TITLE III:

SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES...: None

SECTION 311/312 HAZARD CATEGORIES.....: Exempt from SARA Section 311/312

SECTION 313 TOXIC CHEMICALS.....: None

RCRA STATUS.....: If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

COMPONENT NAME /CAS NUMBER	CONCENTRATION	STATE CODE
Acetaminophen 103-90-2	Greater than 25 %	PA3, NJ4
Starch, Pregelatinized 9005-25-8	1 - 5 %	PA1, MA, NJ4
Panabrom 606-04-2	1 - 5 %	PA3, NJ4
Cellulose, Microcrystalline 9004-34-6	5 - 10 %	PA1, MA
Croscarmellose Sodium 7440-23-5	1 - 5 %	PA1, PA4, MA, NJ1, NJ3
Magnesium Stearate 557-04-0	Less than 1 %	NJ3
Pyridamine Maleate 59-33-6	1 - 5 %	PA3, NJ4

15. REGULATORY INFORMATION (Continued)

- MA - Massachusetts Hazardous Substance List
- NJ1 = New Jersey Hazardous Substance List
- NJ3 = New Jersey Special Health Hazardous Substance List
- NJ4 = New Jersey Other - included in 5 predominant ingredients > 1%
- PA1 = Pennsylvania Hazardous Substance List
- PA3 = Pennsylvania Non-hazardous present at 3% or greater.
- PA4 = Pennsylvania Environmental Hazardous Substance List.

ADDITIONAL INFORMATION: ACTIVE INGREDIENTS: 500 mg Acetaminophen, 25 mg Pamabrom, 15 mg Pyrilamine Maleate per caplet. INACTIVE INGREDIENTS: Croscarmellose Sodium, D&C Red #27 Lake, EDTA Disodium, FD&C Blue #1, FD&C Red #40, Gelatin, Glycerin, Hydroxypropyl Methylcellulose, Iron Oxide, Magnesium Stearate, Microcrystalline Cellulose, Starch, Stearic Acid, Titanium Dioxide, Triacetin.

16. OTHER INFORMATION:

HMIS RATINGS: Health Flammability Reactivity
 1 0 0
 0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

Bayer's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS ratings are provided by Bayer as a customer service.

REASON FOR ISSUE.....: Revise section 3
 PREPARED BY.....: R. Ruppel-Kerr
 APPROVED BY.....: Llew C. Williams
 APPROVAL DATE.....: 07/31/97
 SUPERSEDES DATE.....: 09/19/96
 MSDS NUMBER.....: 26684

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