



SAFETY DATA SHEET

122000013370

MIDOL Menstrual Gelatin-coated tablet

Version 1.0

Revision Date 08/19/2015

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**Product information**

Product Name: MIDOL Menstrual Gelatin-coated tablet
SDS Number: 122000013370

Use : Medicinal products

Company

BAYER HEALTHCARE LLC
Bayer HealthCare Pharmaceuticals
100 Bayer Boulevard PO Box 915
Whippany, NJ 07981-0915
USA
1888-84-BAYER

In case of emergency: 1888-84-BAYER
Chemtrec: (800) 424-9300

2. HAZARDS IDENTIFICATION**Emergency Overview**

Colour: white **Form:** Caplet **Odour:** odourless.

GHS Classification:

Acute toxicity (Oral) : Category 4

GHS Label element:

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Other hazards which do not result in classification:

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent	Components	CAS-No.
3 - 7%	Starch	9005-25-8

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1 - 5%	Cellulose	9004-34-6
9%	Caffeine	58-08-2
75.9%	Acetaminophen	103-90-2

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately.

ALCOHOL WARNING: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

If inhaled: Not an expected entry route.

In case of skin contact: If skin irritation persists, call a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: In case of accidental ingestion, contact your regional poison center or physician immediately.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Any

Specific hazards during firefighting: Fire may cause evolution of: Carbon monoxide (CO)
Carbon dioxide (CO₂)

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

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Personal precautions: Use personal protective equipment.

Methods for cleaning up: Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

Additional advice: Avoid dust formation.

Further Accidental Release Notes Avoid dust formation.

7. HANDLING AND STORAGE

Handling:

Keep this and all drugs out of the reach of children. Avoid contact with skin, eyes and clothing. Store in a dry place away from excessive heat. Reseal containers immediately after use. Use normal precautions for storage of a drug.

No special protective measures against fire required.

Storage:

Storage temperature: 59 - 86 °F (15 - 30 °C)
Do not use after expiration date.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Starch (9005-25-8)

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 10 mg/m³

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 10 mg/m³ (Total)

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 5 mg/m³ (Respirable.)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Permissible exposure limit: 15 mg/m³ (Total dust.)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Permissible exposure limit: 5 mg/m³ (Respirable fraction.)

Respiratory protection:

Recommended Filter type: HEPA

None required for consumer use of this product.

Hand protection:

Chemically resistant gloves.

None required for consumer use of this product.

Eye protection:

Safety glasses

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None required for consumer use of this product.

Other protective measures:

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	Caplet
Colour:	white
Odour:	odourless
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	No applicable information is available
Bulk density:	No applicable information is available
Vapour pressure:	No applicable information is available
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available
Miscibility with water:	No applicable information is available
Water solubility:	soluble
pH:	No applicable information is available
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	No applicable information is available
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY

Conditions to avoid: No data available

Materials to avoid: Oxidizing agents

Hazardous reactions: None known.

Thermal decomposition:

No data available

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Hazardous decomposition products:Carbon monoxide (CO), Carbon dioxide (CO₂)**Oxidizing properties:**

No statements available.

Impact sensitivity:No data available

11. TOXICOLOGICAL INFORMATION**Acute oral toxicity:**

Starch

The substance or mixture has no acute oral toxicity

Cellulose

LD50 Rat: > 5,000 mg/kg

The substance or mixture has no acute oral toxicity

Caffeine

LD50 Rat: 367 mg/kg

Method: OECD 401

Acetaminophen

LD50 Rat: 1,944 mg/kg

Acute inhalation toxicity:

Cellulose

LC50 Rat: > 5.05 mg/l, 4 h

May be harmful if inhaled.

Caffeine

LC50 Rat: 4.94 mg/l, 4 h

The substance or mixture has no acute inhalation toxicity

Method: OECD 403

Acetaminophen

LC50 Mouse: 0.539 mg/l

The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity:

Cellulose

LD50 Rabbit: > 2,000 mg/kg

May be harmful in contact with skin.

Caffeine

LD50 Rat: > 2,000 mg/kg

The substance or mixture has no acute dermal toxicity

Method: OECD 402

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Acetaminophen

LD50 Rabbit: > 7,940 mg/kg

The substance or mixture has no acute dermal toxicity

Acute toxicity (other routes of administration):

Starch

LD50 intraperitoneal Mouse: 6,600 mg/kg

Acetaminophen

LD50 intraperitoneal Rat: 1,205 mg/kg

LD50 subcutaneous Rat: 310 mg/kg

Skin irritation:

Starch

Rabbit

Result: Mild skin irritation

Method: Draize Test

Cellulose

Rabbit

Result: No skin irritation

Caffeine

Rabbit

Result: No skin irritation

Method: OECD 404

Acetaminophen

Rabbit

Result: No skin irritation

Eye irritation:

Cellulose

Rabbit

Result: No eye irritation

Caffeine

Rabbit

Result: No eye irritation

Method: OECD 405

Sensitisation:

Cellulose

Skin sensitization guinea pig

Result: Did not cause sensitisation on laboratory animals.

Subacute, subchronic and prolonged toxicity:

Acetaminophen

NOEL 530 mg/kg, Rat Oral, Exposure time 90 d

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Genotoxicity in vitro:

Cellulose

Ames test

Result: negative

Caffeine

In vitro tests showed mutagenic effects which were not observed with in vivo test.

Acetaminophen

Ames test Salmonella typhimurium

Result: negative

Micronucleus test

Result: positive

Chromosome aberration test in vitro

Result: positive

Genotoxicity in vivo:

Cellulose

Mouse

Result: No indication of mutagenic effects.

Carcinogenicity:

Caffeine

Result: No indication on the basis of the available data.

Reproductive toxicity:

Caffeine

Application Route: Oral

Result: Animal studies have produced evidence a fertility-reducing effect.

Teratogenicity:

Caffeine

Result: Did not show teratogenic effects in animal experiments.

Pharmaceutic effects:

Analgesic

Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

Experience with human exposure:**Components:****103-90-2 :**

Chronic exposure may cause permanent damage of health., Liver disorders

STOT - single exposure:

No data available

STOT - repeated exposure:No data available

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12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Cellulose

Acute Fish toxicity: LC50 > 100 mg/l

Test species: *Oncorhynchus mykiss* (rainbow trout) Duration of test: 96 h

Caffeine

Acute Fish toxicity: LC50 87 mg/l

Test species: *Leuciscus idus* (Golden orfe) Duration of test: 96 h

Method: DIN 38412

nominal concentration

Acetaminophen

Acute Fish toxicity: LC50 378 mg/l

Test species: *Danio rerio* (zebra fish) Duration of test: 48 h

flow-through test: LC50 334.15 mg/l

Test species: *Pimephales promelas* (fathead minnow) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:

Cellulose

LC50 > 100 mg/l

Test species: *Daphnia magna* (Water flea) Duration of test: 48 h

Caffeine

EC50 182.12 mg/l

Test species: *Daphnia magna* (Water flea) Duration of test: 48 h

nominal concentration

Acetaminophen

EC50 50 mg/l

Test species: *Daphnia magna* (Water flea) Duration of test: 48 h

static test LC50 5,305.71 mg/l

Duration of test: 24 h

LC50 269.153 mg/l

Test species: *Daphnia magna* (Water flea) Duration of test: 24 h

Method: OECD 202

Toxicity to algae:

Cellulose

EC50 > 100 mg/l

Duration of test: 96 h

NOEC 12.5 mg/l

Duration of test: 96 h

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Caffeine

EC50 > 100 mg/l

tested on: *Desmodesmus subspicatus* (green algae) Duration of test: 72 h

Method: OECD 201

Acetaminophen

134 mg/l

tested on: *Scenedesmus capricornutum* (fresh water algae) Duration of test: 72 h**Toxicity to bacteria:**

Caffeine

EC10 1,530 mg/l

tested on: *Pseudomonas putida*

Duration of test: 17 h

EC50 3,490 mg/l

tested on: *Pseudomonas putida*

Duration of test: 17 h

Method: DIN 38412

Acetaminophen

EC50 112 mg/l

tested on: Bacteria

Duration of test: 48 h

IC50 189.0017 mg/l

tested on: *Tetrahymen pyriformis*

Duration of test: 46 h

Toxicity on soil-dwelling organisms

Acetaminophen 82 mg/kg

Duration of test: 7 d

Biodegradability:

Cellulose

inherently degradable

Acetaminophen

57 %, 28 d Not rapidly biodegradable

Method: OECD 301 F

99 %, 5 d Partially biodegradable.

Method: OECD 302 B

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Bioaccumulation:

Caffeine

Bioaccumulation is unlikely.

Acetaminophen

Bioconcentration factor (BCF)

3,162

(calculated) Bioaccumulation is unlikely.

Photodegradation:

Acetaminophen

Air

half-life time (direct Photolysis): 0.92 d

13. DISPOSAL CONSIDERATIONS

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)

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

14. TRANSPORT INFORMATION**Land transport (CFR)**

non-regulated

US Sea transport (IMDG)

non-regulated

US Air transport (ICAO / IATA cargo aircraft only)

non-regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)

non-regulated

International IATA

IMDG

non-regulated

non-regulated

15. REGULATORY INFORMATION

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Other regulations: No statements available.

US. Toxic Substances Control Act This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)

Components

None

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required

Components

None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components

None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
3 - 7%	Starch	9005-25-8
1 - 5%	Cellulose	9004-34-6

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Not subject to OSHA

16. OTHER INFORMATION**Further information**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.