



Bayer Genuine Aspirin Film-Coated Tablet 325mg

Version 1.1

Revision Date 10/05/2018

122000006025
Print Date 10/21/2020

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product information

Product Name: Bayer Genuine Aspirin Film-Coated Tablet 325mg
Synonyms: BAYER ASPIRIN CAPLETS 325MG
SDS Number: 122000006025
UI Number: 1600643
Product Number: 12408

Use : Medicinal products

Company

Bayer HealthCare, LLC
Consumer Health
100 Bayer Boulevard PO Box 915
Whippany, NJ 07981-0915
UNITED STATES OF AMERICA

In case of emergency: (800) 331-4536
Chemtrec: (800) 424-9300
BAYER INFORMATION PHONE:(800) 331-4536 OR (800) 743-5423

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification according to national GHS implementation:

Acute toxicity, Oral, Category 4 (H302)

Label elements

Labelling according to national GHS implementation:



Warning

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

Prevention:

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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Hazardous components which must be listed on the label:

Components:	CAS-No.
Acetylsalicylic acid	50-78-2

Other hazards

Other hazards which do not result in classification:
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture.

Hazardous components

Acetylsalicylic acid

Concentration [Weight percent] 83.33

CAS-No.: 50-78-2

CAS name: Benzoic acid, 2-(acetyloxy)-

GHS Classification:



Acute Tox. 4 H302

contains

Starch

Concentration [Weight percent] 8.25

CAS-No.: 9005-25-8

CAS name: Starch

Cellulose

Concentration [Weight percent] 8.25

CAS-No.: 9004-34-6

CAS name: Cellulose

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

Description of first aid measures

General advice: No hazards which require special first aid measures.

If inhaled: Not an expected entry route.

In case of skin contact: No hazards which require special first aid measures.

In case of eye contact: Flush eyes with water as a precaution.

If swallowed: In case of overdose, contact your regional poison control center or physician

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immediately. Contact U.S. Poison Control Center at 1-800-222-1222.

Most important acute symptoms/effects

Symptoms: No information available.

Risks: No information available.

Indication of any immediate medical attention and special treatment needed

No information available.

5. FIREFIGHTING MEASURES

Extinguishing media

Suitable extinguishing media: Any

Unsuitable extinguishing media: High volume water jet

Special hazards arising from the substance or mixture

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

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

Advice for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

Environmental precautions

Methods and materials for containment and cleaning up

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).

Reference to other sections

Additional advice: Avoid dust formation.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling:

Industrial uses: Avoid dust formation. No special technical protective measures required.

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|| No special protective measures against fire required.

Conditions for safe storage, including any incompatibilities

Store at temperatures and conditions as indicated on the product label.

Specific end use(s)

No statements available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Acetylsalicylic acid	50-78-2	TWA	5 mg/m3	ACGIH
			5 mg/m3	NIOSH REL
			5 mg/m3	OSHA P0
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
			5 mg/m3	NIOSH REL
		TWA (Respirable)		
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
			5 mg/m3	NIOSH REL
			5 mg/m3	NIOSH REL
			10 mg/m3	NIOSH REL
			15 mg/m3	OSHA Z-1
			5 mg/m3	OSHA Z-1
		TWA (Total inhalable dust.)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0

Personal protective equipment

Respiratory protection : Recommended Filter type:
HEPA

None required for consumer use of this product.

Hand protection

Material : Chemically resistant gloves.

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Remarks	: None required for consumer use of this product.
Eye protection	: Safety glasses None required for consumer use of this product.
Protective measures	: No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients. For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet. Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form:	tablet
Colour:	white
Odour:	No statements available.
Melting point / range:	No statements available.
Boiling point/boiling range:	No statements available.
Density:	No statements available.
Bulk density:	No statements available.
Vapour pressure:	No statements available.
Viscosity, dynamic:	No statements available.
Viscosity, kinematic:	No statements available.
Flow time:	No statements available.
Surface tension:	No statements available.
Water solubility:	No statements available.
Solubility(ies):	No statements available.
pH:	No statements available.
Corrosive to metal:	No statements available.
Partition coefficient (n-octanol/water):	Acetylsalicylic acid log Pow: -1.19
Ignition temperature:	No data available
Flash point:	Not applicable
Inflammability (solid, gaseous):	No statements available.
Explosion limits:	No statements available.

Other information

Miscibility with water:	Not applicable
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10. STABILITY AND REACTIVITY

Reactivity

No statements available.

Reactions with water / air:

No statements available.

Ignition temperature:

No data available

Burning number:

Acetylsalicylic acid

2 at 20 - 100 °C The product is flammable but not readily ignited.

Chemical stability

No data available

Thermal decomposition:

No data available

Dust explosion characteristic number:

No statements available.

Dust explosion class:

No data available

Heating under defined confinement:

Note: No data available

Impact sensitivity:

No data available

Hazardous reactions:

No data available

Explosive properties:

No statements available.

Possibility of hazardous reactions

deflagration ability:

No data available

Smoldering combustion:

No data available

Conditions to avoid

No data available

Minimum ignition energy:

No data available

Volume resistivity:

No data available

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Oxidizing properties:

No data available

Incompatible materials

Materials to avoid:

Oxidizing agents

Hazardous decomposition products

Carbon monoxide (CO), Carbon dioxide (CO₂)

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate (ATE): 1,476 mg/kg
Method: Calculation method

Acute toxicity estimate (ATE): 1,477 mg/kg
Method: Calculation method

Components:

Acetylsalicylic acid:

Acute oral toxicity : LD50 (Rat): 1,230 mg/kg
Method: OECD 401
Assessment: The component/mixture is moderately toxic after single ingestion.

Skin corrosion/irritation

Components:

Acetylsalicylic acid:

Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation

Components:

Acetylsalicylic acid:

Species: Rabbit
Assessment: The available study results do not lead to a GHS classification

Germ cell mutagenicity

Components:

Acetylsalicylic acid:

Genotoxicity in vitro : Test Type: Ames test
Result: negative



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Carcinogenicity

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Further information

Components:

Acetylsalicylic acid:

Pharmaceutic effects

Remarks: Analgesic

Anti-inflammatory (Antiphlogistic)
antipyretic

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Acetylsalicylic acid:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to bacteria : EC50 (activated sludge micro-organism): > 10,000 mg/l
Method: OECD 209

Ecotoxicology Assessment

Acute aquatic toxicity : slightly water endangering

Persistence and degradability

Components:

Acetylsalicylic acid:

Biodegradability : Biodegradation
Result: rapidly biodegradable
Biodegradation: 98 %
Exposure time: 28 d
Method: OECD 301 D

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Bioaccumulative potential

Components:

Acetylsalicylic acid:

Partition coefficient: n-octanol/water : log Pow: -1.19

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : Ecological injuries are not known or expected under normal use.

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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)

14. TRANSPORT INFORMATION

US Land transport (CFR)

non-regulated

Sea transport (IMDG)

non-regulated

Air transport (IATA)

non-regulated

15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

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SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Acute toxicity (any route of exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

Acetylsalicylic acid	50-78-2
Cellulose	9004-34-6

Pennsylvania Right To Know

Acetylsalicylic acid	50-78-2
Starch	9005-25-8
Cellulose	9004-34-6

New York City Hazardous Substances

Acetylsalicylic acid	50-78-2
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California List of Hazardous Substances

Acetylsalicylic acid	50-78-2
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California Permissible Exposure Limits for Chemical Contaminants

Acetylsalicylic acid	50-78-2
Starch	9005-25-8

The components of this product are reported in the following inventories:

TSCA : On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

16. OTHER INFORMATION

Full text of H-Statements mentioned in chapters 2 and 3

H302 Harmful if swallowed.

Further information

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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.