



MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

U.S. Pharmacopeia 12601 Twinbrook Parkway Rockville, MD 20852 USA	Emergency telephone: Responsible Party: Hours:	(301) 881-0666 Reference Standards Technical Services 8 a.m. to 5 p.m. M - F
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Product name	ASPIRIN
Catalog number	1044006
Synonyms	Acetylsalicylic acid
Chemical name	Benzoic acid, 2-(acetyloxy)-; Salicylic acid acetate
Product use	USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARDS INFORMATION

Emergency overview	TOXIC ALLERGEN/ IRRITANT REPRODUCTIVE HAZARD
Statements of hazard	TOXIC IF SWALLOWED MAY CAUSE EYE, SKIN, AND RESPIRATORY TRACT IRRITATION MAY CAUSE ALLERGIC REACTIONS IN SUSCEPTIBLE INDIVIDUALS MAY CAUSE HARM TO THE UNBORN CHILD MAY CAUSE HARM TO BREAST-FED CHILDREN
Description	Colorless or White crystals or crystalline powder; Odorless or faint odor
Therapeutic use	Analgesic; Antipyretic; Antirheumatic
Eye effects	May cause severe eye irritation.
Skin effects	May cause skin irritation.
Inhalation effects	Causes irritation and is a known respiratory allergen. See "Known clinical effects," "Other potential health effects," and "Effects of overexposure," below.
Ingestion effects	Accidental ingestion may cause effects similar to those seen in clinical use. See "Known clinical effects," "Other potential health effects," and "Effects of overexposure," below.

SECTION 2 - HAZARDS INFORMATION...continued

Known clinical effects	Adverse effects most commonly include heartburn and nausea or vomiting. Less frequent effects may include troubled breathing, unusual tiredness or weakness, and skin rash. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
Effects of overexposure	Symptoms of mild overdose include ringing or buzzing in ears, headache, temporary hearing loss, change in breathing, severe diarrhea, stomach pain, confusion, dizziness, severe drowsiness, uncontrollable flapping of the hands, fever, increased thirst, continued nausea or vomiting, hyperventilation, dehydration, and vision problems. Severe overdose include bloody urine, convulsions, hallucinations, severe nervousness, excitement, or confusion, breathing difficulties, and unexplained fever.
Other potential health effects	Possible hypersensitization. Long-term administration of high doses can cause the symptoms described under the overdose section above as well as dermatitis, allergic reaction (skin rash, hives, or itching), gastrointestinal ulceration, possibly with bleeding (severe stomach pain, bloody or black, tarry stools, vomiting of blood or material that looks like coffee grounds); and anemia.
GHS classification	Oral - Category 2; Irritant (eye) - Category 2B; Irritant (skin) - Category 2 Toxic to reproduction - Category 2
Route of entry	Inhalation, ingestion, skin contact, or eye contact.
At increased risk from exposure	Hypersensitivity to material, nasal polyps, asthma, thrombocytopenia, erosive gastritis, peptic ulcer, hemophilia or other bleeding problems, severe kidney failure, severe liver insufficiency, and active alcoholism.
Cross sensitivity	Persons sensitive to other salicylates, other nonsteroidal anti-inflammatory agents, or to tartrazine dye may be sensitive to this material also.
Target organ(s)	Liver; Central nervous system
Additional data	For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Aspirin	50-78-2	100%
RTECS number	VO0700000	
EINECS number	200-064-1	
Chemical family	Aromatic carboxylic acid	
EC index number	Not classified in the Annex I of Directive 67/548/EEC	

SECTION 4 - FIRST AID MEASURES

Overview	This material is rapidly and completely absorbed from the gastrointestinal tract. This material can be absorbed through the skin in sufficient amounts to cause systemic effects, especially if skin is broken or exposure is extensive. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
Eyes	Flush with copious quantities of tepid water for 15 minutes. If irritation occurs or persists, get medical attention.
Skin	Remove contaminated clothing and flush exposed area with copious quantities of water. If irritation occurs or persists, get medical attention.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Get medical attention immediately.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Get medical attention.
Note to physician	For treatment of overdose, the following is recommended: <ol style="list-style-type: none">1. Empty the stomach by induced vomiting or gastric lavage (taking care to guard against aspiration).2. Administer repeated oral doses of activated charcoal slurry.3. Monitor and support vital functions; correct for hyperthermia, fluid, electrolyte or acid-base imbalances, ketosis, and plasma glucose concentration as needed.4. Induce forced alkaline diuresis, however, DO NOT administer bicarbonate orally, since it can cause increased salicylate absorption. Also, avoid using acetazolamide.5. For severe poisoning, institute exchange transfusion, hemodialysis, peritoneal dialysis, or hemoperfusion as needed.6. Monitor for pulmonary edema and convulsions and institute appropriate therapy.7. For hemorrhaging, administer blood or vitamin K1.8. Monitor serum salicylate concentration until it is apparent that the concentration is decreasing to the nontoxic range. Prolonged monitoring may be necessary in massive overdose because absorption may be delayed. [USP DI 2004]

SECTION 5 - FIRE FIGHTING MEASURES

Fire fighting instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use caution in approaching fire.
Extinguishing media	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Hazardous combustion products	Emits toxic fumes of carbon monoxide and carbon dioxide.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General	Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Avoid generating airborne dust.
Spill cleanup methods	Wear approved respiratory protection, chemically-compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

General handling	As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.
Storage conditions	Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Avoid excessive heat. Protect from freezing.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Aspirin	ACGIH	TWA-8 HR	5 mg/m ³
	OSHA	TWA-8 HR	5 mg/m ³
	NIOSH	TWA-10 HR	5 mg/m ³
	Australia	TWAs	5 mg/m ³
	Australia	STEL	10 mg/m ³ (inhalable fraction)

Engineering controls	Engineering controls such as exhaust ventilation are recommended. Do not breathe dust.
Eye protection	Safety glasses or goggles
Skin protection	Use protective clothing (lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Hand protection	Chemically-compatible gloves
Respiratory protection	Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask is recommended.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form/ Appearance	Crystals or Crystalline powder
Color	Colorless or White
Odor	Odorless or Faint odor
Molecular weight	180.16
Molecular formula	C ₉ H ₈ O ₄
pH	n/f
pK_a	3.49 @ 25° C
Boiling point/boiling range	140° C (decomposes)
Melting point/melting range	135° C (rapid heating)
Specific gravity	1.4
Vapor pressure	2.52 x 10 ⁻⁵ mm Hg
Water solubility	Slightly soluble in water
Solvent solubility	Freely soluble in alcohol
Flash point	n/f
Autoignition	490 °C
Flammability limits	n/f
Explosive properties	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.
Log K_{ow} (octanol/water partition coefficient)	1.19

SECTION 10 - STABILITY AND REACTIVITY

Stability	Stable
Conditions to avoid	n/f
Incompatibilities	Oxidizing agents; Alkali hydroxide solutions; Carbonate solutions
Hazardous decomposition products	When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.
Hazardous polymerization	Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Aspirin	LD ₅₀	Oral	Rat	200 mg/kg
	LD ₅₀	Oral	Mouse	250 mg/kg

Ingestion The acute oral LD₅₀ for the active substance is greater than 25 mg/kg and less than or equal to 200 mg/kg. Oral - Category 3 (LD₅₀ > 50 but ≤ 300 mg/kg bodyweight); See acute toxicity table, above.

Mutagenicity n/f

Skin corrosion/irritation Slightly irritating (rabbit)

Skin/Respiratory sensitization Non-sensitizing

Eye irritation Moderately irritating (rabbit)

Chronic effects/ carcinogenicity Long-term toxicity studies to evaluate the carcinogenic potential of this material in mice and rats revealed no evidence of carcinogenesis.

OSHA carcinogen No

NTP carcinogen Not classified

IARC carcinogen Not classified

Reproductive effects n/f

Teratogenicity Studies in animals have shown that salicylates cause birth defects including fissure of the spine and skull, facial clefts, eye defects and malformations of the CNS. Administration of aspirin in large doses from day 6 of pregnancy onwards caused very high incidences of fetal deaths in mice and rats.

Additional information Studies in animals have shown that salicylates cause birth defects. Controlled studies in humans have not shown any evidence that moderate therapeutic doses cause fetal damage. Use of aspirin, particularly at high doses, during the third trimester has been associated with risk of hemorrhage, pulmonary hypertension, heart failure, complicated delivery, and possibly death. This material crosses the placenta. This material is distributed into breast milk.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview The proper use and/or disposal of this substance, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment. See aquatic toxicity data, below.

Aquatic toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Dosage</u>
Aspirin	EC ₅₀ /48h	Daphnia magna	> 100 mg/L

SECTION 13 - DISPOSAL INFORMATION

Disposal procedure Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions This material is regulated for transport under US DOT, EU ADR, IATA, and IMDG regulations.

Proper shipping name Toxic solids, organic, n.o.s. (aspirin)

UN number 2811

Hazard class/Division 6.1

Packing group PG III

SECTION 15 - REGULATORY INFORMATION

EU classification Toxic; Irritant
Substances toxic to reproduction; Category 3

EU labelling T

Risk phrases R25 - Toxic if swallowed.
R36/37/38 - Irritating to eyes, respiratory system and skin.
R63 - Possible risk of harm to the unborn child.
R64 - May cause harm to breastfed babies.

Safety phrases S22 - Do not breathe dust.
S24/25 - Avoid contact with skin and eyes.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
S53 - Avoid exposure - obtain special instructions before use.


TSCA status Listed

SARA section 302 No

SARA section 313 No

WHMIS classification Class D1B - Poisonous; Toxic Material
Class D2A - Reproductive Toxicant
Class D2B - Skin/Eye Irritant

California proposition 65 THIS PRODUCT IS OR CONTAINS CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE DEVELOPMENTAL AND FEMALE REPRODUCTIVE TOXICITY. (aspirin)

EU label pictogram(s) 

SECTION 15 - REGULATORY INFORMATION...continued

WHMIS symbol(s)**NOHSC - Australia labelling**

Toxic "T"

NOHSC - Australia classificationToxic; Irritant; Substance toxic to reproduction; Category 3
R25, R36/37/39, R63, R64

SECTION 16 - OTHER

Disclaimer

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