



MATERIAL SAFETY DATA SHEET

BAYER HEALTHCARE LLC

Consumer Care
36 Columbia Road
Morristown, NJ 07962-1910

TRANSPORTATION EMERGENCY

CALL CHEMTREC.....: (800) 424-9300
INTERNATIONAL.....: (703) 527-3887

NON-TRANSPORTATION

BAYER EMERGENCY PHONE : (412) 923-1800
BAYER INFORMATION PHONE: (800) 662-2927

Section 1: Product and Company Identification

Product Name: Alka-Seltzer Plus® Cold Formula Sparkling Original Effervescent Tablets

Section 2: Hazards Identification

EMERGENCY OVERVIEW

Form: Solid Effervescent Tablet

Color: White

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. Do not use this product if the safety seal bearing "Sealed for your protection" under cap is torn or missing.

POTENTIAL HEALTH EFFECTS

Route(s) of Entry: Appropriate route of entry: Ingestion

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

Ingestion Hazards

Acute Ingestion Hazards:

Allergy Alert: Aspirin may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock. **Do not use** if you are allergic to aspirin or any other pain reliever/fever reducer, if you are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product, in children under 12 years of age.

Chronic Effects of Exposure

Chronic overexposure to this product may cause effects as noted under Acute overexposure.

Carcinogenic Components:

NTP: None

IARC: None

OSHA: None

Medical Conditions**Aggravated by Exposure:**

Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Stomach Bleeding Warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you are age 60 or older, have had stomach ulcers or bleeding problems, take blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others), have 3 or more alcoholic drinks every day while using this product, or take for a longer time than directed. **Sore Throat Warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Ask a doctor before use if: the stomach bleeding warning applies to you, you have a history of stomach problems, such as heartburn, you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, you are taking a diuretic, you have asthma, diabetes, thyroid disease, glaucoma, difficulty in urination due to enlargement of the prostate gland, a breathing problem such as emphysema or chronic bronchitis, a sodium-restricted diet. **Ask a doctor or pharmacist before use if you are** taking a prescription drug for gout, diabetes or arthritis, taking sedatives or tranquilizers.

**Human Health Effects
Postnote:**

Do not use to sedate children. Phenylketonurics: Contains Phenylalanine. This is a pharmaceutical material available without a prescription. Use only as directed. See carton for full directions and warnings. For additional product information, contact Bayer at 1-800-353-3343.

Section 3: Composition/Information on Ingredients**HAZARDOUS INGREDIENTS****Ingredient Name/****CAS Number****Exposure Limits****Concentration****Min. Max.**

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

Label Ingredients:

Aspirin, Chlorpheniramine Maleate, Phenylephrine Bitartrate, Acesulfame Potassium, Anhydrous Citric Acid, Aspartame, Calcium Silicate, Dimethylpolysiloxane, Docusate Sodium, Flavors, Mannitol, Povidone, Sodium Benzoate, Sodium Bicarbonate.

OTHER INGREDIENTS

The ingredients listed below are provided for informational purposes.

<u>Ingredient Name / CAS Number</u>	<u>Exposure Limits</u>		<u>Concentration</u>	
	<u>OSHA (PEL):</u>	<u>ACGIH (TLV):</u>	<u>Min.</u>	<u>Max.</u>
Acetylsalicylic Acid 50-78-2	Not Established	Not Established	10%	
Chlorpheniramine Maleate 113-92-8	Not Established	Not Established		1%
Phenylephrine Bitartrate 17162-39-9	Not Established	Not Established		1%

Section 4: First Aid Measures

- First Aid for Eye:** In case of contact, flush with copious amounts of water for at least 15 minutes. Call a physician.
- First Aid for Skin:** Not applicable.
- First Aid for Inhalation:** Not applicable.
- First Aid for Ingestion:** **When using this product: do not exceed recommended dosage;** excitability may occur, especially in children; you may get drowsy; avoid alcoholic drinks; alcohol, sedatives, and tranquilizers may increase drowsiness; be careful when driving a motor vehicle or operating machinery. In case of overdose, contact your regional poison control center or physician immediately. Contact U.S. Poison Control Center at 1-800-222-1222.
- First Aid Other:** **Stop use and ask a doctor if :** an allergic reaction occurs, Seek medical help right away; you experience any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better; pain or nasal congestion gets worse or lasts more than 7 days; fever gets worse or lasts more than 3 days; redness or swelling is present; new symptoms occur; ringing in the ears or loss of hearing occurs; nervousness, dizziness, or sleeplessness occurs. **If pregnant or breast feeding,** ask a health professional before use. **It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.**
- Keep this product out of reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

Section 5: Fire Fighting Measures

Flash Point: Not Applicable

Flammable Limits:

**Upper Explosion Limit
(UEL %):** Not Established

Lower Explosion Limit (LEL %):	Not Established
Auto-ignition Temperature:	Not Applicable
<u>Extinguishing Media:</u>	
Suitable:	Any
Special Fire Fighting Procedures:	Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

Section 6: Accidental Release Measures

Spill or Leak Procedures:	Spills should be swept up and placed in appropriate containers for disposal. Avoid creating dusty conditions.
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Section 7: Handling and Storage

Storage Temperature:	Room Temperature
Shelf Life:	Do not use after expiration date.
Special Sensitivity:	None known.
Handling/Storage Precautions:	Keep out of reach of children. Avoid contact with eyes. Avoid excessive contact with skin or clothing. Wash thoroughly after handling. Avoid excessive heat.

Section 8: Exposure Controls/Personal Protection

Personal Protective Equipment

Eye Protection Requirements:	None for normal use.
Skin Protection Requirements:	No special skin protection requirements during normal handling and 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.

Section 9: Physical and Chemical Properties

Physical Form:	Solid
Appearance:	Effervescent Tablets
pH:	Not Applicable
Boiling Point:	Not Applicable
Melting/Freezing Point:	Not Established
Solubility in Water:	Not Applicable
Specific Gravity:	Not Applicable
Bulk Density:	Not Applicable
Vapor Pressure:	Not Applicable

Section 10: Stability and Reactivity

Stability:	Stable
Hazardous Polymerization:	Will not occur
Substances to Avoid:	See carton for full directions and warnings.
Conditions to Avoid:	None known.
Decomposition Products:	None known.

Section 11: Toxicological Information

Toxicity Data for :Alka-Seltzer Plus® Cold Formula Sparkling Original Effervescent Tablets

Toxicity Note: No data available for this product.

Toxicity Data for Acetylsalicylic acid

Acute oral toxicity:	LD50 = 1,230 mg/kg (Rat)
Skin Irritation:	Mild skin irritation (Rabbit)
Eye Irritation:	Mild eye irritation (Rabbit)
Genotoxicity in vitro:	Result: Negative (Ames Test)

Section 12: Ecological Information

General Advice: Do not allow to enter surface waters or groundwater.

Ecological Data for :Alka-Seltzer Plus® Cold Formula Sparkling Original Effervescent Tablets

Ecological Note: No data available for this product.

Ecological Data for Acetylsalicylic acid

	<u>Result</u>	<u>Test Species</u>	<u>Method</u>
Toxicity to fish:	LC0>100 mg/l	Danio rerio / Brachydanio rerio	Directive 67/548/EEC
Toxicity to daphnia:	EC50>100mg/l	Daphnia magna (water flea)	Duration of test: 48 hrs
Toxicity to bacteria:	EC50>10,000mg/l	Activated sludge micro-organism	OECD TG 209
Biodegradability:	98%	28 d Readily biodegradable	OECD TG 301 D

Section 13: Disposal Considerations

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

Section 14: Transportation Information

Technical shipping name: Nonprescription drug

Domestic Surface Transportation (DOT)

Hazard Class or Division: Non-Regulated

Marine Transportation (IMO / IMDG)

Hazard Class Division Number: Non-Regulated

Air Transportation (ICAO / IATA)

Hazard Class Division Number: Non-Regulated

Section 15: Regulatory Information

United States Federal Regulations

OSHA Hazcom Standard Rating: Not subject to OSHA

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

CERCLA Hazardous Substance:

Component(s)
None

Reportable Quantity

SARA Title III

SARA Section 302 Extremely Hazardous Substances:

Component(s)/
CAS Number
Exempt

Concentration
Min. Max.

SARA Section 311/312 Hazard Categories: Exempt from SARA Section 311/312

SARA Section 313 Toxic Chemicals:

Component(s)/
CAS Number
Exempt

Reporting
Threshold

Concentration
Min. Max.

RCRA Status: If discarded in its purchased form, this product would not be a

Material Name: Alka-Seltzer Plus® Cold Formula Sparkling Original Effervescent Tablets

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.

State Right-to-Know Information

<u>Component(s)/ CAS Number</u>	<u>State Code</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
Acetylsalicylic acid	MA, NJ, PA	10%	

Section 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 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.

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