

MSDS for Product Distributed by Zee Medical

Alka-Seltzer® Tablets (Zee #1400, 1401)



MATERIAL SAFETY DATA SHEET

BAYER CORPORATION  
CONSUMER CARE DIVISION  
99 Cherry Hill Road  
Parsippany, NJ 07054-1102

TRANSPORTATION EMERGENCY

CALL CHEMTREC: 800-424-9300  
DISTRICT OF COLUMBIA: 202-483-7616

NON-TRANSPORTATION

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

1. CHEMICAL PRODUCT IDENTIFICATION:

PRODUCT NAME.....: Original ALKA-SELTZER Antacid and Pain Reliever  
PRODUCT CODE.....: 4028,4002,4024,4022,4019,4017,4012,4011  
CHEMICAL FAMILY.....: Effervescent mixture of antacid and pain reliever

2. COMPOSITION/INFORMATION ON INGREDIENTS:

INGREDIENT NAME /CAS NUMBER	EXPOSURE LIMITS	CONCENTRATION (%)
--------------------------------	-----------------	-------------------

\*\*\*\*\* HAZARDOUS INGREDIENTS \*\*\*\*\*

This pharmaceutical product, available without a prescription, is for human consumption. 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 \*\*\*\*\*

Aspirin			
50-78-2	OSHA :	5.00 mg/m3 TWA	Approx. 10%
	ACGIH:	5.00 mg/m3 TWA	

\* See Section 3 for potential health effects.

Sodium Bicarbonate			
144-55-8	OSHA :	Not Established	Approx. 50 %
	ACGIH:	Not Established	

2. COMPOSITION/INFORMATION ON INGREDIENTS (Continued)

INGREDIENT NAME /CAS NUMBER	EXPOSURE LIMITS	CONCENTRATION (%)
Citric Acid 77-92-9	OSHA : Not Established ACGIH: Not Established	30-40 %

3. HAZARDS IDENTIFICATION:

\*\*\*\*\*  
 \* EMERGENCY OVERVIEW \*  
 \* \*  
 \* Over-the-Counter agent in tablet form that poses little or \*  
 \* no immediate hazard. See Potential Health Effects if the \*  
 \* recommended dosage is exceeded. Will burn in a fire. \*  
 \*\*\*\*\*

POTENTIAL HEALTH EFFECTS:

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

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE:

Alka-Seltzer in water contains principally the antacid sodium citrate and the analgesic sodium acetylsalicylate (the soluble ionic form of aspirin). NOTE: This is a pharmaceutical product available without a prescription - use only as directed. See product packaging and the Physicians Desk Reference (PDR) for further information concerning adverse effects and drug interaction precautions.

ACUTE EFFECTS OF EXPOSURE.....: Acute overexposure to this product may cause nausea, vomiting, ringing in the ears, fever, coma, respiratory alkalosis, metabolic acidosis, and convulsions.

CHRONIC EFFECTS OF EXPOSURE...: Chronic overexposure to this product may cause ringing in the ears, diminished hearing, confusion, agitation, lethargy, pulmonary edema, and cardiovascular collapse.

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 ulcers (aspirin), asthma (aspirin), predisposition to bleeding and decreased platelet function (aspirin), women who are pregnant (aspirin), children and teenagers with chicken pox (aspirin), congestive heart failure (sodium), or hypertension (sodium) may be more susceptible to the adverse effects of this product.

EXPOSURE LIMITS.....: FDA -- Aspirin 4000 mg/24 hrs. for 10 days in a 70 kg person; acute toxicity may follow ingestions of 150 mg/kg.

-----  
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 Hayer Corporation at 1-800-800-4793.

-----  
5. FIRE FIGHTING MEASURES:  
-----

FLASH POINT.....: Not Applicable  
AUTO-IGNITION TEMPERATURE.....: Not Applicable  
EXTINGUISHING MEDIA.....: Water  
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.....: Tablet  
COLOR.....: Effervescent white  
ODOR.....: Odorless  
pH.....: Buffered pH 6 - 7  
BOILING POINT.....: Not Applicable  
MELTING/FREEZING POINT.....: Not Applicable  
SOLUBILITY IN WATER.....: Effervesces in water  
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.....: Effervesces in contact with water, producing CO<sub>2</sub>.  
DECOMPOSITION PRODUCTS.....: Not Applicable.

-----  
**11. TOXICOLOGICAL INFORMATION:**  
-----

TOXICITY DATA FOR: Aspirin

ACUTE TOXICITY

ORAL LD50.....: Greater than 1,500 mg/kg (rat)

-----  
**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.....: Effervescent mixture of antacid and pain reliever

PRODUCT LABEL.....: Original ALKA-SELTZER Antacid and Pain Reliever

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
Aspirin 50-78-2	Approx. 10%	PA1, CA, MA, NJ1
Sodium Bicarbonate 144-55-8	Approx. 50 %	PA3, NJ4
Citric Acid 77-92-9	30-40 %	PA3, NJ4

CA = California Proposition 65  
 MA = Massachusetts Hazardous Substance List  
 NJ1 = New Jersey 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.

ADDITIONAL INFORMATION: ACTIVE INGREDIENTS (per tablet): Aspirin 325 mg;

Product Code: 4028,4002,4024,4022,4019,4017,4012,4011  
 Approval date: 03/25/96

MSDS Page 6  
 Continued on next page

15. REGULATORY INFORMATION (Continued)

Sodium Bicarbonate 1916 mg; Citric Acid 1000 mg

16. OTHER INFORMATION:

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

Bayer' 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.....: Revision to Section 11.  
PREPARED BY.....: S. Van Volkenburg  
APPROVED BY.....: Michael C. Porter  
APPROVAL DATE.....: 03/25/96  
SUPERSEDES DATE.....: 12/20/95  
MSDS NUMBER.....: 24440

-----  
This information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of Bayer Inc. The data on this sheet relates only to the specific material designated herein. Bayer Corporation assumes no legal responsibility for use or reliance upon these data.  
-----

Product Code: 4028,4002,4024,4022,4019,4017,4012,4011  
Approval date: 03/25/96

MSDS Page 7  
Last page