



SAFETY DATA SHEET

122000012471

ALKA SELTZER PLUS Cold and Cough Effervescent Tablet

Version 1.0

Revision Date 08/19/2015

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

Product Name: ALKA SELTZER PLUS Cold and Cough Effervescent Tablet
Synonyms: Alka Seltzer Plus Sinus
Alka Seltzer Plus Head Cold
ALKA-SELTZER PLUS Non-Drowsy Cold
SDS Number: 122000012471

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:** Effervescent Tablet **Odour:** like fruit.

GHS Classification:

Eye irritation : Category 2

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

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Weight percent	Components	CAS-No.
10.53%	Acetylsalicylic acid	50-78-2
0.064%	Chlorphenamine hydrogen maleate	113-92-8
15 - 40%	Citric acid	77-92-9
0.32%	Dextromethorphan hydrobromide monohydrate	6700-34-1
0.25%	Phenylephrine Bitartrate	17162-39-9

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately.

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

Acetylsalicylic acid (50-78-2)

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 5 mg/m³

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 5 mg/m³

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

None required for consumer use of this product.

Other 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.

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Wear suitable protective equipment.

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

Form:	Effervescent Tablet
Colour:	white
Odour:	like fruit
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:	No applicable information is available
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: No data available

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:**

Chlorphenamine hydrogen maleate

LD50 Rat: 118 - 306 mg/kg

Toxic if swallowed.

TDL0 Rat: 10 mg/kg

Citric acid

LD50 Rat: 3,000 mg/kg

May be harmful if swallowed.

Phenylephrine Bitartrate

LD50 Rat, female: 2,172 mg/kg

LD50 Rat, male: 1,043 mg/kg

Acetylsalicylic acid

LD50 Rat: 1,230 mg/kg

Method: OECD 401

Acute inhalation toxicity:

Chlorphenamine hydrogen maleate

Rat: 0.61 mg/l, 4 h

No mortality observed at this dose.

Citric acid

The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity:

Chlorphenamine hydrogen maleate

LD50 365 mg/kg

Toxic in contact with skin.

Citric acid

LD50 Rat: > 2,000 mg/kg

May be harmful in contact with skin.

Method: OECD 402

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Acute toxicity (other routes of administration):

Chlorphenamine hydrogen maleate

LD50 subcutaneous Rat: 365 mg/kg

Skin irritation:

Citric acid

Rabbit

Result: Mild skin irritation

Method: OECD 404

Acetylsalicylic acid

Rabbit

Result: Mild skin irritation

Eye irritation:

Chlorphenamine hydrogen maleate

Classification: Causes serious eye irritation.

Citric acid

Rabbit

Result: Causes serious eye irritation.

Method: OECD 405

Acetylsalicylic acid

Rabbit

Result: Mild eye irritation

Genotoxicity in vitro:

Phenylephrine Bitartrate

Ames test

Result: negative

Acetylsalicylic acid

Ames test

Result: negative

Pharmaceutic effects:

Chlorphenamine hydrogen maleate

anti-allergic agent

Phenylephrine Bitartrate

Vasoconstrictor

Acetylsalicylic acid

Analgesic Anti-inflammatory (Antiphlogistic) antipyretic

Carcinogenicity:

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

STOT - single exposure:

No data available

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STOT - repeated exposure:No data available

12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Acetylsalicylic acid

Acute Fish toxicity: LC0 > 100 mg/l

Test species: Danio rerio (zebra fish)

Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates:

Citric acid

EC50 120 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 72 h

Acetylsalicylic acid

EC50 > 100 mg/l

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

Toxicity to algae:

Citric acid

640 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 168 h

Toxicity to bacteria:

Citric acid

EC0 10,000 mg/l

tested on: Bacteria

Method: DIN 38412

Acetylsalicylic acid

EC50 > 10,000 mg/l

tested on: activated sludge micro-organism

Method: OECD 209

Biodegradability:

Citric acid

98 %, 2 d rapidly biodegradable

Method: OECD 302 B

Dextromethorphan hydrobromide monohydrate

0 %,

Method: OECD 302 B

Phenylephrine Bitartrate

100 %, 28 d Readily biodegradable

Method: None known.

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Acetylsalicylic acid
98 %, 28 d rapidly biodegradable
Method: OECD 301 D

Bioaccumulation:

Citric acid

Does not bioaccumulate.

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 non-regulated
IMDG non-regulated

15. REGULATORY INFORMATION

Other regulations: No statements available.

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

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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.
7 - 13%	Acetylsalicylic acid	50-78-2

California Prop. 65**Warning! This product contains chemical(s) known to the State of California to be**

Weight percent	Components	CAS-No.
7 - 13%	Acetylsalicylic acid	50-78-2

OSHA Hazcom Standard RatingNot 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.