ALKA SELTZER Original Efferescent Tablet

Version 1.0 Revision Date 01/12/2017



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

Product information

Product Name: ALKA SELTZER Original Efferescent Tablet

SDS Number: 122000012466

Use : Medicinal products

Company

Bayer Inc. 2920 Matheson Boulevard East Mississauga, ON L4W 5R6 CANADA (800) 622-2937

In case of emergency: Chemtrec: (800) 424-9300

CANUTEC: (613) 996-6666

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification according to national GHS implementation:

Eye irritation, Category 2A (H319)

Label elements

Labelling according to national GHS implementation:



Warning

Hazard statements:

H319 Causes serious eye irritation.

Precautionary statements:

Prevention:

P264 Wash skin thoroughly after handling. P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Other hazards

Other hazards which do not result in classification:

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None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture.

Hazardous components

Citric acid

Concentration [Weight percent] >= 30 - < 50

CAS-No.: 77-92-9

CAS name: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-

GHS Classification:



Eye Irrit. 2A H319

Acetylsalicylsäure

Concentration [Weight percent] >= 10 - < 20

CAS-No.: 50-78-2

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

GHS Classification:



Acute Tox. 4 H302

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: If skin irritation persists, call a physician.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation

develops and persists.

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

immediately.

Most important acute symptoms/effects

Indication of any immediate medical attention and special treatment needed

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5. FIREFIGHTING MEASURES

Extinguishing media

Suitable extinguishing media: Any

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. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.

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. Only handle product with local exhaust ventilation. Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.

Conditions for safe storage, including any incompatibilities

Storage temperature: 15 - 30 °C Do not use after expiration date.

Specific end use(s)

No statements available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible	Basis
			concentration	
Acetylsalicylsäure	50-78-2	TWA	5 mg/m3	CA AB OEL
		TWA	5 mg/m3	CA BC OEL
		TWAEV	5 mg/m3	CA QC OEL

Personal protective equipment

Respiratory protection : Recommended Filter type:

HEPA

None required for consumer use of this product.

Hand protection

Material : Chemically resistant gloves.

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.

Wear suitable protective equipment.

For the intake of ready for use pharmaceutials 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: solid, Effervescent Tablet

Colour: white Odour: odourless

Melting point/range: No statements available. Boiling point/boiling range: No statements available. Density: No statements available. Bulk density: No statements available. No statements available. Vapour pressure: Viscosity, dynamic: No statements available. Viscosity, kinematic: No statements available. Flow time: No statements available.

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Surface tension: No statements available.

Water solubility:

Product is highly soluble.

Solubility(ies): No statements available. pH: No statements available.

Partition coefficient Citric acid experimental

(n-octanol/water): log Pow: -1.61

Acetylsalicylsäure log Pow: -1.19

Flash point: Not applicable

Inflammability (solid, gaseous): No statements available. **Explosion limits:** No statements available.

Other information

Miscibility with water: Not applicable

10. STABILITY AND REACTIVITY

Reactivity

No statements available.

Reactions with water / air:

No statements available.

Ignition temperature:

Acetylsalicylsäure

500 °C DIN 51794

Burning number:

Acetylsalicylsäure

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

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

Flammability (solid, gas):

No statements available.

Chemical stability

No statements available.

Thermal decomposition:

No data available

Dust explosion characteristic number:

No statements available.

Dust explosion class:

No data available

Impact sensitivity:

No data available

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Hazardous reactions:

No data available

Explosive properties:

No statements available.

Possibility of hazardous reactions

deflagration ability:

No statements available.

Smoldering combustion:

No statements available.

Conditions to avoid

No data available

Minimum ignition energy:

No data available

Oxidizing properties:

No statements 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): 3,004 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate (ATE): > 5,000 mg/kg

Method: Calculation method

Components:

Citric acid:

Acute oral toxicity : LD50 (Rat): 3,000 mg/kg

Assessment: May be harmful if swallowed.

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD 402

GLP: yes

Assessment: May be harmful in contact with skin.

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Acetylsalicylsäure:

Acute oral toxicity : LD50 (Rat): 1,230 mg/kg

Method: OECD 401

Skin corrosion/irritation

Components:

Citric acid:

Species: Rabbit Exposure time: 72 h

Method: OECD Test Guideline 404

Result: Mild skin irritation

Acetylsalicylsäure:

Species: Rabbit

Result: Mild skin irritation

Serious eye damage/eye irritation

Components:

Citric acid:

Species: Rabbit

Result: Irritating to eyes. Exposure time: 72 h Method: OECD 405

Acetylsalicylsäure:

Species: Rabbit

Result: Mild eye irritation

Respiratory or skin sensitisation

Components:

Citric acid:

Assessment: Causes serious eye irritation., May be harmful if swallowed., May

be harmful in contact with skin.

Germ cell mutagenicity

Components:

Citric acid:

Genotoxicity in vitro : Test Type: Ames test

Result: negative

Acetylsalicylsäure:

Genotoxicity in vitro : Test Type: Ames test

Result: negative

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Components:

Citric acid:

Repeated dose toxicity -

Assessment

: Causes serious eye irritation., May be harmful if swallowed.,

May be harmful in contact with skin.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Citric acid:

: EC0 (Bacteria): 10,000 mg/l Toxicity to bacteria

Method: DIN 38412

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Acetylsalicylsäure:

Toxicity to fish : LC0 (Danio rerio (zebra fish)): > 100 mg/l

Test Type: Acute Fish toxicity

Method: EC C.1.

aquatic invertebrates

Toxicity to daphnia and other : 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

Persistence and degradability

Components:

Citric acid:

Biodegradability : Result: Readily biodegradable.

> Biodegradation: 98 % Exposure time: 2 d Method: OECD 302 B

Biochemical Oxygen

Demand (BOD)

: 575 - 675 mg/g

Chemical Oxygen Demand

(COD)

: 700 - 800 mg/g

Acetylsalicylsäure:

Biodegradability : Biodegradation

Result: rapidly biodegradable

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Biodegradation: 98 % Exposure time: 28 d Method: OECD 301 D

Bioaccumulative potential

Components:

Citric acid:

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n-

octanol/water

: log Pow: -1.61

Method: experimental

Acetylsalicylsäure:

Partition coefficient: n-

octanol/water

: log Pow: -1.19

Mobility in soil

No data available

Other adverse effects

Product:

Results of PBT and vPvB

assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

Additional ecological

information

: Do not allow to enter surface waters or groundwater.

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.

14. TRANSPORT INFORMATION

US Land transport (CFR)

non-regulated

Sea transport (IMDG)

non-regulated

Air transport (IATA)

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non-regulated

Land transport TDG non-regulated

15. REGULATORY INFORMATION

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

DSL All components of this product are on the Canadian DSL

Canadian lists

No substances are subject to a Significant New Activity Notification.

16. OTHER INFORMATION

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

H302 Harmful if swallowed.H319 Causes serious eye irritation.

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.