Identification

- 1.1 Product identifier
- Trade name: Aspirin
  - Acetylsalicylic acid
  - Acidum acetylsalicylicum
- Product Code: 100015
- CAS Number: 50-78-2
- EC number: 200-064-1

Application of the substance / the mixture Pharma Active ingredients

1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier:
  Fagron Inc
  2400 Pilot Knob Road
  St. Paul, MN 55120
  www.fagron.us
  QA@fagron.us
- Information department:
  Tel.: 800-423-6967
  Fax: 800-339-1596
- 1.4 Emergency telephone number:
  Emergency Telephone:
  US: 1-800-535-5053
  International: 1-352-323-3500

Hazard(s) identification

2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008
  - GHS07

Acute Tox. 4 H302 Harmful if swallowed.

2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008
- The substance is classified and labeled according to the CLP regulation.
- Hazard pictograms GHS07
- Signal word Warning
- Hazard statements
  - H302 Harmful if swallowed.

Precautionary statements
- P264 Wash thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
- P330 Rinse mouth.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)
Trade name: Aspirin
Acetylsalicylic acid
Acidum acetylsalicylicum

Classification system:
- NFPA ratings (scale 0 - 4)
- HMIS-ratings (scale 0 - 4)

2.3 Other hazards
- Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

Composition/information on ingredients

- 3.1 Chemical characterization: Substances
- CAS No. Description
  50-78-2 Aspirin
  Acetylsalicylic acid
  Acidum acetylsalicylicum
- Identification number(s)
  - EC number: 200-064-1

First-aid measures

- 4.1 Description of first aid measures
  - General information:
    Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
  - After inhalation: Supply fresh air.
  - After skin contact: Generally the product does not irritate the skin.
  - After eye contact: Rinse opened eye for several minutes under running water.
  - After swallowing:
    Rinse out mouth and then drink plenty of water.
    Immediately call a doctor.
- 4.2 Most important symptoms and effects, both acute and delayed: No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed: No further relevant information available.

Fire-fighting measures

- 5.1 Extinguishing media
  - Suitable extinguishing agents:
    Water
    Carbon dioxide
    Foam
    Fire-extinguishing powder
  - Use fire fighting measures that suit the environment.
- 5.2 Special hazards arising from the substance or mixture
  Formation of toxic gases is possible during heating or in case of fire.
5.3 Advice for firefighters
- Protective equipment:
  - Wear self-contained respiratory protective device.
  - Wear fully protective suit.

Accidental release measures
- 6.1 Personal precautions, protective equipment and emergency procedures
  - Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Dispose contaminated material as waste according to item 13.
- 6.4 Reference to other sections
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protection equipment.
  - See Section 13 for disposal information.

Handling and storage
- 7.1 Precautions for safe handling
  - No special precautions are necessary if used correctly.
- 7.2 Conditions for safe storage, including any incompatibilities
  - Storage:
    - Requirements to be met by storerooms and receptacles: No special requirements.
    - Information about storage in one common storage facility: Not required.
- 7.3 Specific end use(s)
  - No further relevant information available.

Exposure controls/personal protection
- 8.1 Control parameters
  - Components with limit values that require monitoring at the workplace:
    - Acetylsalicylic acid
      - Acidum acetylsalicylicum
    - 50-78-2 Aspirin
      - REL Long-term value: 5 mg/m³
      - TLV Long-term value: 5 mg/m³
- Additional information: The lists that were valid during the creation were used as basis.
8.2 Exposure controls
Personal protective equipment:
General protective and hygienic measures:
Do not eat or drink while working.
Use skin protection cream for skin protection.
Keep away from foodstuffs, beverages and feed.
Breathing equipment: Filter P2
Protection of hands:
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Material of gloves
Nitrile rubber, NBR
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
Penetration time of glove material
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye protection: Not required.
Body protection: Protective work clothing

Physical and chemical properties
9.1 Information on basic physical and chemical properties
General Information
Appearance:
Form: Solid
Color: White
Odor: Recognizable
Odor threshold: Not determined.

pH-value (2.5 g/l) at 20 °C (68 °F): ~ 3.5
Change in condition
Melting point/Melting range: 135 - 144 °C (275 - 291 °F)
Boiling point/Boiling range: Undetermined.
Flash point: 250 °C (482 °F)
Flammability (solid, gaseous): Product is not flammable.
Ignition temperature: 500 °C (932 °F)
Decomposition temperature: 140 °C (284 °F)
Auto igniting: Not determined.
Danger of explosion: Product does not present an explosion hazard.
Trade name: Aspirin  
Acetylsalicylic acid  
Acidum acetylsalicylicum

- Explosion limits:  
  Lower: Not determined.  
  Upper: Not determined.
- Vapor pressure: Not applicable.
- Density: Not determined.  
  Relative density Not determined.  
  Vapor density Not applicable.  
  Evaporation rate Not applicable.
- Solubility in / Miscibility with  
  Water at 20 °C (68 °F): 3.3 g/l
- Partition coefficient (n-octanol/water) at 20 °C (68 °F): 1.19 log POW (experimentell (HSDB))
- Viscosity:  
  Dynamic: Not applicable.  
  Kinematic: Not applicable.
- 9.2 Other information  
  No further relevant information available.

**Stability and reactivity**

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability  
  Thermal decomposition / conditions to be avoided: To avoid thermal decomposition do not overheat.
- 10.3 Possibility of hazardous reactions  
  Reacts with strong acids.  
  Reacts with alkali (lyes).  
  Reacts with strong oxidizing agents.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

**Toxicological information**

- 11.1 Information on toxicological effects  
  Acute toxicity: Harmful if swallowed.
- LD/LC50 values that are relevant for classification:  
  Oral [LD50] 1124 mg/kg (Rat)
- Primary irritant effect:  
  on the skin: Based on available data, the classification criteria are not met.  
  on the eye: Based on available data, the classification criteria are not met.  
  Sensitization: Based on available data, the classification criteria are not met.
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Acetylsalicylic acid
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· Additional toxicological information:
  · Carcinogenic categories
  · IARC (International Agency for Research on Cancer) Substance is not listed.
  · NTP (National Toxicology Program) Substance is not listed.
  · OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

Ecological information

· 12.1 Toxicity
  · Aquatic toxicity: No further relevant information available.
· 12.2 Persistence and degradability Easily biodegradable
· 12.3 Bioaccumulative potential
  Due to the distribution coefficient n-octanol/water a worth-mentioning accumulation in organisms is not expected.
· 12.4 Mobility in soil No further relevant information available.
· Additional ecological information:
  · General notes:
    Water hazard class 1 (Assessment by list): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· 12.5 Results of PBT and vPvB assessment
  · PBT: Not applicable.
  · vPvB: Not applicable.
· 12.6 Other adverse effects No further relevant information available.

Disposal considerations

· 13.1 Waste treatment methods
  · Recommendation:
    Must be specially treated adhering to official regulations.
    Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
  · Uncleaned packagings:
    · Recommendation: Disposal must be made according to official regulations.
    · Recommended cleansing agent: Water, if necessary with cleansing agents.

Transport information

· 14.1 UN-Number
  · DOT, ADR, IMDG, IATA
    UN2811

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Safety Data Sheet
acc. to OSHA HCS

Trade name: Aspirin
Acetylsalicylic acid
Acidum acetylsalicylicum

(Contd. of page 6)

14.2 UN proper shipping name
- DOT
  Toxic solids, organic, n.o.s. (Aspirin Acetylsalicylic acid Acidum acetylsalicylicum)
- ADR
  2811 Toxic solids, organic, n.o.s. (Aspirin Acetylsalicylic acid Acidum acetylsalicylicum)
- IMDG, IATA
  TOXIC SOLID, ORGANIC, N.O.S. (Aspirin Acetylsalicylic acid Acidum acetylsalicylicum)

14.3 Transport hazard class(es)
- DOT
  Class
  Label
  6.1 Toxic substances
  6.1
- ADR, IMDG, IATA
  Class
  Label
  6.1 Toxic substances
  6.1

14.4 Packing group
- DOT, ADR, IMDG, IATA
  III

14.5 Environmental hazards:
- Marine pollutant:
  No

14.6 Special precautions for user
- EMS Number:
  F-A,S-A
- Stowage Category
  A

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
- Not applicable.

Transport/Additional information:
- Not dangerous according to the above specifications.

UN "Model Regulation":
- UN 2811 TOXIC SOLIDS, ORGANIC, N.O.S. (ASPIRIN ACETYLSALICYLIC ACID ACIDUM ACETYLSALICYLICUM), 6.1, III

(Contd. on page 8)
Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  
  No further relevant information available.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company’s knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

- **Department issuing SDS:**
  
  Fagron US
  
  Quality Assurance

- **Contact:** QA@fagron.us

- **Date of preparation / last revision** 07/18/2016 / 41

- **Abbreviations and acronyms:**
  
  RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  
  ICAO: International Civil Aviation Organisation
  
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  
  IMDG: International Maritime Code for Dangerous Goods
  
  DOT: US Department of Transportation
  
  IATA: International Air Transport Association
  
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  
  EINECS: European Inventory of Existing Commercial Chemical Substances
  
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  
  NFPA: National Fire Protection Association (USA)
  
  HMIS: Hazardous Materials Identification System (USA)
  
  LC50: Lethal concentration, 50 percent
  
  LD50: Lethal dose, 50 percent
  
  PBT: Persistent, Bioaccumulative and Toxic
  
  vPvB: very Persistent and very Bioaccumulative
  
  OSHA: Occupational Safety & Health
  
  TLV: Threshold Limit Value
  
  PEL: Permissible Exposure Limit
  
  REL: Recommended Exposure Limit
  
  Acute Tox. 4: Acute toxicity – Category 4

- * Data compared to the previous version altered.