



SAFETY DATA SHEET according to Regulation (EC) No.  
1907/2006

122000001058

## Aspirin tablets / Standard Mix - Bulk

Version 2.0

Revision Date 11.04.2014

Print Date 12.04.2014

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

#### 1.1 Product identifier

Aspirin tablets / Standard Mix - Bulk

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the : unfinished drug mixture  
Substance/Mixture

#### 1.3 Details of the supplier of the safety data sheet

##### Company

Bayer Pharma AG  
Müllerstr. 178  
D-13353 BERLIN  
Tel.: +49 (0) 214 30 46440  
Mail: msds@bayerhealthcare.com

#### 1.4 Emergency telephone number

In case of emergency: +49 (0) 214 30 99300 (Sicherheitszentrale Bayer)

### 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

GHS-Classification (according to EC 1272/2008):

|| Acute toxicity, Oral, Category 4 (H302)

Classification (67/548/EEC, 1999/45/EC):

Harmful  
Harmful if swallowed.

#### 2.2 Label elements

GHS-Labeling (according to EC 1272/2008):



|| Warning

Hazard statements:

|| H302 Harmful if swallowed.

Precautionary statements:



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Prevention:

- || P264 Wash skin thoroughly after handling.
- || P270 Do not eat, drink or smoke when using this product.

Response:

- || P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
- || P330 Rinse mouth.

Disposal:

- || P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

50-78-2 Acetylsalicylic acid

### Labelling according to EC Directives:

Labelling in accordance with directive 1999/45/EC (preparations) and its amendments and adaptations



R-phrases)

R22 Harmful if swallowed.

S-phrases)

S22 Do not breathe dust.

S60 This material and its container must be disposed of as hazardous waste.

Hazardous components which must be listed on the label:

50-78-2 Acetylsalicylic acid

### 2.3 Other hazards

Other hazards which do not result in classification:

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture within the meaning of Regulation (EC) No. 1907/2006.

### Hazardous components

#### Acetylsalicylic acid

Concentration [Weight percent]  $\geq 50$  -  $\leq 100$

CAS-No.: 50-78-2

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

EINECS-No.: 200-064-1



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Synonyms: ASA, Aspirin active ingredient

### EU - Classification:



Harmful R22

### GHS Classification:



Acute Tox. 4 H302

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For the full text of the H+R-phrases mentioned in this Section, see Section 16.

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## 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

**General advice:** Take off all contaminated clothing immediately.

**If inhaled:** Remove to fresh air. If symptoms persist, call a physician.

**In case of skin contact:** After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact 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:** If swallowed, seek medical advice immediately and show this container or label.

### 4.2 Most important acute symptoms/effects

**Symptoms:** No information available.

**Risks:** No information available.

### 4.3 Indication of any immediate medical attention and special treatment needed

No information available.

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## 5. FIREFIGHTING MEASURES

### 5.1 Extinguishing media

**Suitable extinguishing media:** Any

### 5.2 Special hazards arising from the substance or mixture

**Specific hazards during firefighting:** Fire may cause evolution of: Carbon monoxide (CO) Carbon dioxide (CO<sub>2</sub>)



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**Further information:** Prevent fire extinguishing water from contaminating surface water or the ground water system.

### 5.3 Advice for firefighters

**Special protective equipment for firefighters:** In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.

### 6.2 Environmental precautions

Do not flush into surface water or sanitary sewer system.

### 6.3 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).

### 6.4 Reference to other sections

**Additional advice:** Avoid dust formation. Keep away from/remove sources of ignition.

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## 7. HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Handling:

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

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

### 7.2 Conditions for safe storage, including any incompatibilities

For storage suitable stores with adequate product-reception volume must be used. During handling local official regulations must be observed in order to avert impairment of water by the product.

### 7.3 Specific end use(s)

No statements available.



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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

##### Components with workplace control parameters (Europe)

Substance	CAS-No.	Basis	Type:	Value	Ceiling Limit Value	Remarks
Acetylsalicylic acid	50-78-2	EH40 WEL	VLA-ED	5 mg/m <sup>3</sup>		
Starch	9005-25-8	EH40 WEL	VLA-ED	4 mg/m <sup>3</sup>		Respirable.
Starch	9005-25-8	EH40 WEL	VLA-ED	10 mg/m <sup>3</sup>		Inhalable
Cellulose microcrystalline	9004-34-6	EH40 WEL	VLA-ED	4 mg/m <sup>3</sup>		Respirable dust.
Cellulose microcrystalline	9004-34-6	EH40 WEL	VLA-ED	10 mg/m <sup>3</sup>		Inhalable dust.
Cellulose microcrystalline	9004-34-6	EH40 WEL	STEL	20 mg/m <sup>3</sup>		Inhalable dust.

##### Components with workplace control parameters (internationally)

Substance	CAS-No.	Basis	Type:	Value	Ceiling Limit Value	Remarks
Acetylsalicylic acid	50-78-2	EH40 WEL	VLA-ED	5 mg/m <sup>3</sup>		
Starch	9005-25-8	EH40 WEL	VLA-ED	4 mg/m <sup>3</sup>		Respirable.
Starch	9005-25-8	EH40 WEL	VLA-ED	10 mg/m <sup>3</sup>		Inhalable

#### 8.2 Exposure controls

##### Personal protective measures:

##### Respiratory protection:

Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

##### Hand protection:

Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear



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Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

### Eye protection:

Safety glasses

### Hygiene measures:

Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

### Other protective measures:

Wear suitable protective equipment.

The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Form:	solid, powder, tablet
Colour:	white to yellow
Odour:	nearly odourless
Melting point/range:	No statements available.
Boiling point/boiling range:	Acetylsalicylic acid 140 °C at 1,013 hPa
Density:	No statements available.
Bulk density:	No statements available.
Vapour pressure:	No statements available.
Viscosity, dynamic:	No statements available.
Viscosity, kinematic:	No statements available.
Flow time:	No statements available.
Surface tension:	No statements available.
Water solubility:	slightly soluble
Solubility(ies):	No statements available.
pH:	No statements available.
Partition coefficient (n-octanol/water):	Acetylsalicylic acid log Pow: -1.19
pH:	No statements available.
Flash point:	Acetylsalicylic acid Not applicable
inflammability (solid, gaseous):	No statements available.
Explosion limits:	No statements available.



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### 9.2 Other information

Miscibility with water: Not applicable

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

No statements available.

#### reaction with Water / Air

No statements available.

#### Ignition temperature:

##### Acetylsalicylic acid

500 °C DIN 51794

##### Burning number:

##### Acetylsalicylic acid

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.

### 10.2 Chemical stability

No statements available.

#### Thermal decomposition:

no data available

#### Dust explosion characteristic number:

GLP: No information available.

#### Dust explosion class:

no data available

#### Explosive properties:

No statements available.

#### Impact Sensitivity:

no data available

#### Hazardous reactions:

None known.



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### 10.3 Possibility of hazardous reactions

#### deflagration ability:

No statements available.

#### Smoldering combustion:

No statements available.

### 10.4 Conditions to avoid

no data available

#### Oxidizing properties:

No statements available.

#### Minimum ignition energy:

no data available

### 10.5 Incompatible materials

#### Materials to avoid:

no data available

### 10.6 Hazardous decomposition products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

#### Further information:

The following applies in general to flammable organic substances and preparations: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

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## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute oral toxicity:

##### Aspirin tablets / Standard Mix - Bulk

Acute toxicity estimate (ATE) 1,476 mg/kg

Method: Calculation method

##### Acetylsalicylic acid

LD50 rat: 1,230 mg/kg

Method: OECD Test Guideline 401

#### Acute inhalation toxicity:

No statements available.

#### Acute dermal toxicity:

No statements available.

#### Acute toxicity (other routes of administration):





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No statements available.

**Corrosivity:**

No statements available.

**Skin irritation:**

**Acetylsalicylic acid**

rabbit

Result: Mild skin irritation

**Eye irritation:**

**Acetylsalicylic acid**

rabbit

Result: Mild eye irritation

**Sensitisation:**

No statements available.

**Phototoxicity:**

No statements available.

**Subacute, subchronic and prolonged toxicity:**

No statements available.

**STOT - single exposure:**

No statements available.

**STOT - repeated exposure:**

No statements available.

**Aspiration toxicity:**

No statements available.

**Genotoxicity in vitro:**

**Acetylsalicylic acid**

Ames test

Result: negative

**Genotoxicity in vivo:**

No statements available.

**Carcinogenicity:**

No statements available.

**Fertility:**

No statements available.

**Developmental toxicity:**

No statements available.

**Human experience:**

No statements available.



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### Neurotoxicity:

No statements available.

### Neurological symptoms:

No statements available.

### Pharmaceutic effects:

#### Acetylsalicylic acid

analgetic Anti-inflammatory (Antiphlogistic) antipyretic

## 12. ECOLOGICAL INFORMATION

### Ecotoxicology Assessment

No statements available.

#### 12.1 Toxicity

##### 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:

###### Acetylsalicylic acid

EC50 > 100 mg/l

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

##### Toxicity to algae:

No statements available.

##### Toxicity to bacteria:

###### Acetylsalicylic acid

EC50 > 10,000 mg/l

Test species: activated sludge micro-organism

Method: OECD TG 209

##### Toxicity to fish (Chronic toxicity):

No statements available.

##### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

No statements available.

##### Toxicity on soil-dwelling organisms:

No statements available.

##### Toxicity on other terrestrial non-mammal:

No statements available.



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### 12.2 Persistence and degradability

#### Biodegradability:

##### Acetylsalicylic acid

98 %, 28 d rapidly biodegradable

Method: OECD Test Guideline 301D

#### Biochemical Oxygen Demand (BOD):

No statements available.

#### Chemical Oxygen Demand (COD):

No statements available.

#### BSB in proportion to CSB:

No statements available.

#### Dissolved organic carbon (DOC):

No statements available.

#### Adsorbed organic bound halogens (AOX):

No statements available.

#### Theoretical biological oxygen requirement:

No statements available.

#### BSB in proportion to ThSB:

No statements available.

#### Total organic carbon (TOC):

No statements available.

#### Physico-chemical removability:

No statements available.

#### Stability in water:

No statements available.

#### Additional degradation pathways:

No statements available.

#### Photodegradation:

No statements available.

#### M-Factor:

No statements available.

### 12.3 Bioaccumulative potential

#### Bioaccumulation:

No statements available.

#### Partition coefficient (n-octanol/water):

##### Acetylsalicylic acid

log Pow: -1.19



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### 12.4 Mobility in soil

**Environmental distribution:**

No statements available.

**Surface tension:**

No statements available.

**Stability in soil:**

No statements available.

### 12.5 Results of PBT and vPvB assessment

No statements available.

### 12.6 Other adverse effects

**General advice:**

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Do not allow to enter surface waters or groundwater.

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## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Transport to suitable incinerator with reduced non-air emission.

Contaminated packaging: Contaminated, empty containers are to be treated in the same way as the contents.

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## 14. TRANSPORT INFORMATION

ADR/RID	--
GGVS/GGVE	--
ADNR	--
IATA	--
IMDG	--



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### 14.6 Special precautions for user

For personal protection see section 8.

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

not applicable

Other information : No dangerous cargo  
Keep dry  
Keep separated from foodstuffs

## 15. REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

#### National legislation

#### Guidelines and information sheets issued by the Chemical Industry Employers' Insurance Association:

M 053 /BGI 660 ("Protective measures when handling hazardous substances at work"),  
Employers' Liability Insurance Association leaflet (BGI) 5151, Working safely in the pharmaceutical industry (April 2009).

#### Other regulations:

No statements available.

### 15.2 Chemical Safety Assessment

No statements available.

## 16. OTHER INFORMATION

### Full text of R-phrases referred to under sections 2 and 3

R22 Harmful if swallowed.

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

H302 Harmful if swallowed.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.



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### 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.