

Aggrenox®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000026359 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 1. IDENTIFICATION

Product name : Aggrenox®
Synonyms : Active ingredient: Dipyridamol and Acetylsalicylic acid
Aggrenox® Capsules 25 mg/200 mg

Product code : 000000026359

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated

Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368

Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours

Routine Contact Number : (203) 778-7759

Recommended use of the chemical and restrictions on use

Recommended use : Mixture for production of finished medicinal products.

Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Not a hazardous substance or mixture.

Other hazards

None known.

Aggrenox®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000026359 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Pure substance

Chemical Name	CAS-No.	Concentration (%)
Acetylsalicylic acid	50-78-2	< 4
Dipyridamol	58-32-2	<= 33

SECTION 4. FIRST AID MEASURES

- General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Move to fresh air.
Call a physician immediately.
- In case of skin contact : Wash off immediately with plenty of water.
Cover wound with sterile dressing.
Call a physician immediately.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
Call a physician immediately.
- If swallowed : Rinse mouth.
Drink plenty of water.
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Foam
Dry chemical
Carbon dioxide (CO₂)
- Specific hazards during fire- : In case of fire and/or explosion do not breathe fumes.
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Aggrenox®

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000026359	Date of first issue: 06/03/2015

fighting	Can be released in case of fire: Carbon oxides Nitrogen oxides (NO _x)
Further information	: Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment for firefighters	: Self-contained breathing apparatus (EN 133) complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Wear personal protective equipment. Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Knock down dust with water spray jet.
Environmental precautions	: Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	: Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Clean-up methods - large spillage Dampen, pick up mechanically and dispose of. Clean-up methods - small spillage Use approved industrial vacuum cleaner for removal. Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	: Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Avoid dust formation.
Advice on safe handling	: Provide sufficient air exchange and/or exhaust in work rooms. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Minimize dust generation and accumulation. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Breathing must be protected when large quantities are decanted without local exhaust ventilation. Keep container closed when not in use.
Conditions for safe storage	: Keep tightly closed in a dry and cool place. Keep in a well-ventilated place. Protect from heat and direct sunlight.

Aggrenox®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000026359 Date of last issue: -
Date of first issue: 06/03/2015

Jointless smooth floor

Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	Basis	Factor	Catergory	Values	Remark
2,6-Bis-(diethanolamino)-4,8-dipiperidino-pyrimido-(5,4-d)-pyrimidine 58-32-2	ECL		1	1,000 µg/m ³	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Components	Basis	Factor	Catergory	Values	Remark
O-acetylsalicylic acid 50-78-2	ECL		1	2,000 µg/m ³	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Contains no substances with occupational exposure limit values.

Engineering measures : It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection : Respirator with a dust filter particle filter P3 (EN 143)
Use NIOSH approved respiratory protection.

Hand protection Material : Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
Directive : Protective gloves against chemicals and micro-organisms

Eye protection : Safety glasses with side-shields
(Not necessary when using full face mask)

Aggrenox®

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000026359	Date of first issue: 06/03/2015

- Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.
- Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
- Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : solid
- Colour : No data available
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/range : No data available
- Boiling point/boiling range : Not applicable
- Flash point : Not applicable
- Evaporation rate : No data available
- Flammability (solid, gas) : No data available
- Upper explosion limit : No data available
- Lower explosion limit : No data available
- Vapour pressure : No data available
- Relative vapour density : Not applicable
- Relative density : No data available
- Bulk density : No data available
- Solubility(ies)

Aggrenox®

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000026359	Date of first issue: 06/03/2015

Water solubility	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, dynamic	:	Not applicable
Explosive properties	:	Not tested
Oxidizing properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	Extremes of temperature and direct sunlight.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
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Components:**Acetylsalicylic acid:**

Acute oral toxicity	:	LD50 (Rat): = 1,460 mg/kg LD50 (Rabbit): = 1,010 mg/kg
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Acute inhalation toxicity	:	Remarks: No data available
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Acute dermal toxicity	:	Remarks: No data available
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Dipyridamol:

Acute oral toxicity	:	LD50 (Rat): > 12,000 mg/kg LD50 (Mouse): > 12,000 mg/kg
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Aggrenox®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000026359 Date of last issue: -
Date of first issue: 06/03/2015

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Not classified based on available information.

Components:**Acetylsalicylic acid:**

Species: Rabbit

Result: Mild skin irritation

Dipyridamol:

Remarks: No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Acetylsalicylic acid:**

Result: Mild eye irritation

Dipyridamol:

Remarks: No data available

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**Acetylsalicylic acid:**

Result: Did not cause sensitisation on laboratory animals.

Remarks: May cause sensitisation of susceptible persons.

Dipyridamol:

Remarks: No data available

Germ cell mutagenicity

Not classified based on available information.

Components:**Acetylsalicylic acid:**

Genotoxicity in vitro : Test Type: Ames-test
Result: negative

Genotoxicity in vivo : Remarks: No data available

Dipyridamol:

Genotoxicity in vitro : Test Type: Ames-test
Result: negative
Remarks: The substance was not mutagenic in bacteria.

Genotoxicity in vivo : Test Type: Micronucleus test

Aggrenox®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000026359 Date of last issue: -
Date of first issue: 06/03/2015

Species: Mouse
Result: negative
Remarks: No mutagenic effects reported.

Test Type: Cytogenetic assay
Species: Chinese hamster
Result: negative
Remarks: No mutagenic effects reported.

Carcinogenicity

Not classified based on available information.

Components:**Acetylsalicylic acid:**

Remarks: Did not show carcinogenic effects in animal experiments.

Dipyridamol:

Species: Rat

Exposure time: 142 weeks

Dose: 75 mg/kg/day

Remarks: Did not show carcinogenic effects in animal experiments.

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****Acetylsalicylic acid:**

Species: Rat

NOAEL: < 217 mg/kg

Application Route: Oral

Exposure time: 28-day

Target Organs: toxic effect to:, Liver, Blood

Aggrenox®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000026359 Date of last issue: -
Date of first issue: 06/03/2015

Aspiration toxicity

Not classified based on available information.

Components:**Acetylsalicylic acid:**

No data available

Experience with human exposure**Components:****Acetylsalicylic acid:**

Inhalation : Target Organs: Upper respiratory tract

Ingestion : Target Organs: Mucous membranes
Symptoms: Bruising and haemorrhage formation

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Acetylsalicylic acid:**

Toxicity to fish : LC50 (golden orfe): > 1,000 mg/l
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): = 330 mg/l
Exposure time: 24 h

Toxicity to algae : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): = 1 mg/l
Exposure time: 21 d

Toxicity to bacteria : Remarks: No data available

Dipyridamol:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 3.15 mg/l
Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 203
Remarks: The statement of the toxic effect relates to the analytically determined concentration
No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Aggrenox®

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000026359	Date of first issue: 06/03/2015

Remarks: The statement of the toxic effect relates to the analytically determined concentration
No toxicity at the limit of solubility

Toxicity to algae : EC50 (Desmodesmus subspicatus (green algae)): > 2.36 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: The statement of the toxic effect relates to the analytically determined concentration
No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to bacteria : NOEC (activated sludge, industrial): = 1,000 mg/l
Method: OECD 209

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Acetylsalicylic acid:**

Partition coefficient: n-octanol/water : log Pow: 1.19

Dipyridamol:

Partition coefficient: n-octanol/water : log Pow: 3.6 (25 °C)
Method: OECD Test Guideline 117

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Aggrenox®

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	06/03/2015	000000026359	Date of first issue: 06/03/2015

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION**International Regulation****Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

National Regulations**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know Act**

SARA 311/312 Hazards : No SARA Hazards

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Non-hazardous galenic excipients	Not Assigned	50 - 70 %
Dipyridamol	58-32-2	30 - 50 %
Acetylsalicylic acid	50-78-2	1 - 5 %

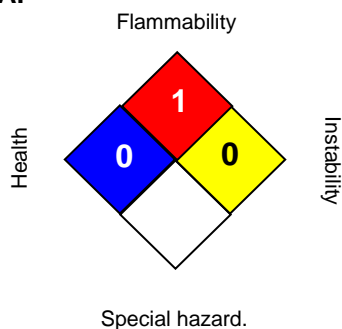
New Jersey Right To Know

Aggrenox®

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000026359 Date of last issue: -
Date of first issue: 06/03/2015

Non-hazardous galenic excipients	Not Assigned	50 - 70 %
Dipyridamol	58-32-2	30 - 50 %
Acetylsalicylic acid	50-78-2	1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Revision Date : 06/03/2015

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.