

SAFETY DATA SHEET



Aleve 220 mg Film-coated Tablet

Version 1.3 Revision Date: 05/17/2023 SDS Number: 122000014046 Date of last issue: 06/28/2021
Date of first issue: 03/10/2016

SECTION 1. IDENTIFICATION

Product identifier

Product name : Aleve 220 mg Film-coated Tablet

UI Number : 1600169

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

Use of the Sub-stance/Mixture : Medicinal products

Details of the supplier of the safety data sheet

Company

Bayer HealthCare, LLC
100 Bayer Boulevard PO Box 915
WHIPPANY 07981-0915
UNITED STATES OF AMERICA
(800) 743-5423

Emergency telephone number

In case of emergency: (800) 331-4536
Chemtrec: (800) 424-9300

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4
Skin irritation : Category 2
Eye irritation : Category 2B
Specific target organ toxicity - single exposure : Category 3 (Respiratory system)

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.
H315 + H320 Causes skin and eye irritation.
H335 May cause respiratory irritation.

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Precautionary Statements : **Prevention:**
P261 Avoid breathing dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Naproxen Sodium Salt	26159-34-2	76.2

SECTION 4. 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 : No hazards which require special first aid measures.

In case of eye contact : Flush eyes with water as a precaution.

If swallowed : In case of overdose, contact your regional poison control center or physician immediately. Contact U.S. Poison Control Center at 1-800-222-1222.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
Causes skin and eye irritation.
May cause respiratory irritation.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : No information available.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Any

Unsuitable extinguishing : High volume water jet

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media

- Specific hazards during fire fighting : 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.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Ensure adequate ventilation.
Avoid dust formation.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and 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).

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Avoid dust formation.
No special technical protective measures required.
- Conditions for safe storage : Store at temperatures and conditions as indicated on the product label.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Naproxen Sodium Salt	26159-34-2	SUP	5 mg/m ³ (inhalable fraction)	
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1

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		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Talcum	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable)	2 mg/m ³	NIOSH REL
		TWA (Respirable particulate matter)	2 mg/m ³	ACGIH

Personal protective equipment

- Respiratory protection : 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 : 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.
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : tablet
- Color : blue
- Odor : odourless
- Odor Threshold : No data available
- pH : No data available
- Melting point/range : No data available
- Boiling point/boiling range : No data available

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Flash point : No data available

Evaporation rate : No data available

Burning rate : No data available

Self-ignition : No data available

Burning number : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Bulk density : No data available

Solubility(ies)

 Water solubility : No data available

 Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : No data available

 Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

Impact sensitivity : No data available

Minimum ignition energy : No data available

SECTION 10. STABILITY AND REACTIVITY

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Reactivity : No data available
Chemical stability : No data available
Possibility of hazardous reactions : No data available
Conditions to avoid : No data available
Incompatible materials : Oxidizing agents
Hazardous decomposition products : Carbon monoxide (CO)
Carbon dioxide (CO₂)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate (ATE): 524.93 mg/kg
Method: Calculation method

Components:

Naproxen Sodium Salt:

Acute oral toxicity : LD50 (Rat): ca. 400 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

Naproxen Sodium Salt:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes eye irritation.

Components:

Naproxen Sodium Salt:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

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Respiratory sensitization

Not classified based on available information.

Components:

Naproxen Sodium Salt:

Species : Guinea pig
Result : Does not cause skin sensitization.
Test substance : Data on a comparable substance

Germ cell mutagenicity

Not classified based on available information.

Components:

Naproxen Sodium Salt:

Genotoxicity in vitro : Test Type: Ames test
Result: negative
Test substance: Data on a comparable substance

Test Type: Mouse lymphoma assay
Result: negative
Test substance: Data on a comparable substance

Carcinogenicity

Not classified based on available information.

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 on OSHA's list of regulated carcinogens.

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.

Product:

Effects on fertility : Result: Not classified
Remarks: Expert judgement

Reproductive toxicity - Assessment : No toxicity to reproduction

Components:

Naproxen Sodium Salt:

Reproductive toxicity - Assessment : Suspected human reproductive toxicant

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STOT-single exposure

May cause respiratory irritation.

Components:

Naproxen Sodium Salt:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Further information

Components:

Naproxen Sodium Salt:

Pharmaceutic effects
Remarks : Analgesic
Antirheumatic agent

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Naproxen Sodium Salt:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 690 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 150 mg/l
Exposure time: 48 h

Persistence and degradability

Components:

Naproxen Sodium Salt:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 98 %
Exposure time: 28 d

Bioaccumulative potential

Components:

Naproxen Sodium Salt:

Partition coefficient: n-octanol/water : log Pow: 3.18
Method: Calculation method

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Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of as hazardous waste in compliance with local and national regulations.

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)

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

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SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation
Specific target organ toxicity (single or repeated exposure)

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 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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

Cellulose	9004-34-6
Talcum	14807-96-6
Quartz	14808-60-7

Pennsylvania Right To Know

Cellulose	9004-34-6
Talcum	14807-96-6

Maine Chemicals of High Concern

Quartz	14808-60-7
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Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New York City Hazardous Substances

Titanium dioxide	13463-67-7
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California List of Hazardous Substances

Polyvinylpyrrolidone	9003-39-8
Talcum	14807-96-6

California Permissible Exposure Limits for Chemical Contaminants

Talcum	14807-96-6
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International Regulations

Montreal Protocol : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

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Stockholm Convention (Persistent Organic Pollutants) : Not applicable

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

TSCA : Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

Health - 2 Flammability - 1 Instability - 0 Others -

HMIS® IV:

Health - 2 Flammability - 1 Instability - 0 Others -

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants -
1910.1000
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-
its for Air Contaminants
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Min-
eral Dusts
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour
workday during a 40-hour workweek
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

Revision Date : 05/17/2023

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.

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