

1. Identification

Product identifier	ADVIL PM REDUCED FILL SOFT GELS (FN-2294-0001)
Other means of identification	
Product code	FN-2294-0001
Synonyms	FN-2294-0001 * ADVIL PM RF (25% RF) * DIPENHYDRAMINE HYDROCHLORIDE 25mg+IBUPROFEN 200mg Capsule, Liquid Filled * ADVIL PM MINI
Recommended use	This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
	Consumer Healthcare Product
	Medicinal Product
Recommended restrictions	No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME	Haleon PLC
Address:	184 Liberty Corner Road, Suite 200 Warren, NJ 07059 USA
Telephone:	+1-908-293-4000 (General Inquiries)
Email:	msds@haleon.com
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EMERGENCY CONTACTS

Telephone:	3E GLOBAL INCIDENT RESPONSE +(1) 760 476 3971 (In country) +(1) 760 476 3962 or +(1) 866 519 4752 (International) 24/7; multi-language response
Contract Number:	335879

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Skin corrosion/irritation	Category 1B
	Serious eye damage/eye irritation	Category 1
	Specific target organ toxicity, single exposure	Category 3 respiratory tract irritation
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 2
	Hazardous to the aquatic environment, long-term hazard	Category 2
OSHA defined hazards	Not classified.	
Label elements		



Signal word Danger

Hazard statement	Harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage. May cause respiratory irritation. Toxic to aquatic life. Toxic to aquatic life with long lasting effects.
Precautionary statement	
Prevention	Avoid breathing vapors. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.
Response	Rinse mouth. If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor/. Specific treatment (see on this label). Take off contaminated clothing and wash it before reuse. Collect spillage.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	23.95% of the mixture consists of component(s) of unknown acute oral toxicity. 63.52% of the mixture consists of component(s) of unknown acute dermal toxicity. 59.95% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 59.95% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
IBUPROFEN	ALPHA-METHYL-4-(2-METHYLPROPYL) BENZENEACETIC ACID HYDRATROPIC ACID, P-ISOBUTYL-	15687-27-1	20 - < 30
POLYETHYLENE GLYCOL (LIQUID)	ALPHA-HYDRO-OMEGA-HYDROXY-POLY(OXY-1,2-ETHANEDIYL) ETHYLENE GLYCOL HOMOPOLYMER ETHYLENE GLYCOL POLYMER GLYCOLS, POLYETHYLENE PEG PEG 1000 PEG 1450 PEG 200 PEG 300 PEG 400 PEG 4000 PEG 600 PEG 6000 POLY(ETHYLENE ETHER)GLYCOL POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-HYDRO.-OMEGA. POLYETHYLENE GLYCOL POLYETHYLENE GLYCOL 1000 POLYETHYLENE GLYCOL 1450 POLYETHYLENE GLYCOL 200 POLYETHYLENE GLYCOL 300 POLYETHYLENE GLYCOL 400 POLYETHYLENE GLYCOL 4000 POLYETHYLENE GLYCOL 600 POLYETHYLENE GLYCOL 6000 POLYETHYLENGLYKOLE (PEG) (MOLMASSE 200-600) RTECS TQ3630000	25322-68-3	20 - < 30
DIPHENHYDRAMINE HYDROCHLORIDE	2-(DIPHENYLMETHOXY)-N,N-DIMETHYLETHYLAMINE HYDROCHLORIDE BENADRYL HYDROCHLORIDE BENZHYDRAMINE HYDROCHLORIDE DIFENHYDRAMINE HYDROCHLORIDE BENADRYL	147-24-0	3 - < 5

Chemical name	Common name and synonyms	CAS number	%
POTASSIUM HYDROXIDE	POTASSIUM HYDRATE POTASSIUM HYDROXIDE, DRY SOLID, FLAKE, BEAD OR GRANULAR POTASSA CAUSTIC POTASH POTASSIUM HYDROXIDE (DRY SOLID, FLAKE, BEAD OR GRANULAR) UN 1813 HKO OHS19431 RTECS TT2100000 KOH GI151106X 184 (GW ACN)	1310-58-3	3 - < 5
FD&C BLUE NO. 1	ALPHAZURINE BRILLIANT BLUE FCF, DISODIUM SALT ERIOGLAUCINE ACID BLUE 9	3844-45-9	< 0.1
Other components below reportable levels			30 - < 40

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a poison center or doctor/physician if you feel unwell.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Call a physician or poison control center immediately. Chemical burns must be treated by a physician. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Burning pain and severe corrosive skin damage. Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Chemical burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
General information	If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water spray. Foam. Powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

This material is classified as a water pollutant under the Clean Water Act and should be prevented from contaminating soil or from entering sewage and drainage systems which lead to waterways.

Large Spills: Stop the flow of material, if this is without risk. Following product recovery, flush area with water.

Small Spills: Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Do not get in eyes, on skin, or on clothing. Do not taste or swallow. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Haleon Exposure Limits

Components	Type	Value	Form
DIPHENHYDRAMINE HYDROCHLORIDE (CAS 147-24-0)	8 HR TWA	200 mcg/m3	SKIN
	OHC	2	SKIN
FD&C BLUE NO. 1 (CAS 3844-45-9)	OHC	3	
IBUPROFEN (CAS 15687-27-1)	8 HR TWA	2000 mcg/m3	SKIN
	OHC	1	SKIN
POTASSIUM HYDROXIDE (CAS 1310-58-3)	OHC	1	CORROSIVE

US. ACGIH Threshold Limit Values

Components	Type	Value
POTASSIUM HYDROXIDE (CAS 1310-58-3)	Ceiling	2 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
POTASSIUM HYDROXIDE (CAS 1310-58-3)	TWA	2 mg/m3

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL (LIQUID) (CAS 25322-68-3)	TWA	10 mg/m3	Aerosol.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Wear safety glasses with side shields (or goggles) and a face shield.

Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.
Respiratory protection	Chemical respirator with organic vapor cartridge.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Liquid. Capsule
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.

Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.

Solubility(ies)

Solubility (water)	Not available.
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Partition coefficient (n-octanol/water)	Not available.
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Auto-ignition temperature	Not available.
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Decomposition temperature	Not available.
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Viscosity	Not available.
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Other information

Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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Chemical stability	Material is stable under normal conditions.
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Possibility of hazardous reactions	Hazardous polymerization does not occur.
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Conditions to avoid	Contact with incompatible materials.
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Incompatible materials	Strong oxidizing agents.
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Hazardous decomposition products	No hazardous decomposition products are known.
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11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause irritation to the respiratory system. Prolonged inhalation may be harmful.
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Skin contact Causes severe skin burns.
Eye contact Causes serious eye damage.
Ingestion Causes digestive tract burns. Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Burning pain and severe corrosive skin damage. Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. May cause respiratory irritation.

Information on toxicological effects

Acute toxicity In high concentrations, vapors are anesthetic and may cause headache, fatigue, dizziness and central nervous system effects. Harmful if swallowed.

Components	Species	Test Results
DIPHENHYDRAMINE HYDROCHLORIDE (CAS 147-24-0)		
<u>Acute</u>		
Oral		
LD50	Rat	500 mg/kg
FD&C BLUE NO. 1 (CAS 3844-45-9)		
<u>Acute</u>		
Oral		
LD50	Rat	11.3 g/kg
IBUPROFEN (CAS 15687-27-1)		
<u>Acute</u>		
Oral		
LD50	Rat	1600 mg/kg
NOEL	Dog	50 mg/kg Gastro-intestinal toxicity.
<u>Chronic</u>		
Oral		
NOAEL	Baboon	40 mg/kg/day, 52 weeks Gastro-intestinal toxicity.
	Rat	20 mg/kg/day, 2 years Gastro-intestinal toxicity.
<u>Subchronic</u>		
Oral		
LD	Rat	180 mg/kg/day, 6 months Gastro-intestinal toxicity.
LOAEL	Rat	60 mg/kg/day, 6 months Gastro-intestinal toxicity.
NOAEL	Mouse	75 mg/kg/day Gastro-intestinal toxicity.
POLYETHYLENE GLYCOL (LIQUID) (CAS 25322-68-3)		
<u>Acute</u>		
Oral		
LD50	Rat	> 20 g/kg
POTASSIUM HYDROXIDE (CAS 1310-58-3)		
<u>Acute</u>		
Oral		
LD50	Rat	273 mg/kg

Skin corrosion/irritation Causes severe skin burns and eye damage.

Irritation Corrosion - Skin

IBUPROFEN

0, Supplier data
 Result: Mild irritant
 Species: Human
 Notes: IUCLID

DIPHENHYDRAMINE HYDROCHLORIDE

Acute dermal irritation; OECD 404, Supplier SDS
 Result: Non-irritant
 Species: Rabbit
 Notes: Pfizer SDS

Serious eye damage/eye irritation Causes serious eye damage.

Eye

IBUPROFEN

0, Supplier data
Result: Irritant
Species: Human
Notes: IUCLID

DIPHENHYDRAMINE HYDROCHLORIDE

Acute ocular irritation; OECD 405, Supplier SDS
Result: Non-Irritating
Species: Rabbit
Notes: Pfizer SDS
REET
Result: Positive

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization

IBUPROFEN

OECD 406 - Maximisation test, Literature data
Result: Negative
Species: Guinea pig
Notes: IUCLID

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

IBUPROFEN

Ames, Literature data
Result: Negative
Notes: IUCLID

DIPHENHYDRAMINE HYDROCHLORIDE

Ames, Literature data
Result: Negative
Notes: NTP study
Chromosomal Aberration Assay In Vitro, CHO cells, Literature data
Result: Positive at concentration toxic to cells
Notes: CCRIS

IBUPROFEN

In vivo cytogenetics, Literature data
Result: Negative
Species: Human
Notes: IUCLID

DIPHENHYDRAMINE HYDROCHLORIDE

L5178Y mouse lymphoma thymidine kinase locus assay, Literature data
Result: Negative
Notes: NTP study

IBUPROFEN

Sister Chromatid Exchange, Literature data
Result: Negative
Species: Human
Test Duration: 2 weeks
Notes: IUCLID

DIPHENHYDRAMINE HYDROCHLORIDE

Sister Chromatid Exchange, Supplier SDS
Result: Negative

Carcinogenicity Not classifiable as to carcinogenicity to humans.

IBUPROFEN

100 - 300 mg/kg/day, 300 mg/kg/day for first 55-weeks. 100 mg/kg/day for remainder.
Result: Negative
Species: Mouse
Notes: IUCLID

DIPHENHYDRAMINE HYDROCHLORIDE

156 - 313 ppm, Dietary study
Species: Mouse
Test Duration: 2 years
Notes: NTP study

IBUPROFEN

20 - 120 mg/kg/day
Result: Negative
Species: Rat

DIPHENHYDRAMINE HYDROCHLORIDE

313 - 635 ppm, Dietary study
Species: Rat
Test Duration: 2 years
Notes: NTP study

Carcinogenicity

IBUPROFEN

60 - 180 mg/kg/day, 180 mg/kg/day for first 55-weeks. 60 mg/kg/day for remainder.

Result: Negative

Species: Rat

Notes: IUCLID

IARC Monographs. Overall Evaluation of Carcinogenicity

FD&C BLUE NO. 1 (CAS 3844-45-9)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects.

Reproductivity

IBUPROFEN

2 - 100 mg/kg/day Embryofetal Development, Literature data

Result: maternal toxicity, no adverse foetal effects.

Species: Rat

Notes: IUCLID

20 - 120 mg/kg/day General reproductive performance

Result: maternal toxicity, no adverse effects on fertility or foetal development.

Species: Rat

Notes: IUCLID

DIPHENHYDRAMINE HYDROCHLORIDE

25 - 100 mg/kg/day Embryo-foetal development, Literature data

Result: Maternal toxicity; adverse foetal effects

Species: Rat

Notes: NTP study

IBUPROFEN

5 - 100 mg/kg/day Embryo-foetal development, Literature data

Result: No adverse foetal effects observed

Species: Mouse

Notes: IUCLID

7.5 - 180 mg/kg/day Embryo-foetal development, Literature data

Result: No adverse foetal effects observed

Species: Rat

Notes: IUCLID

7.5 - 60 mg/kg/day Embryo-foetal development, Literature data

Result: No adverse foetal effects observed

Species: Rabbit

Notes: IUCLID

DIPHENHYDRAMINE HYDROCHLORIDE

80 - 200 Embryo-foetal development, Literature data

Result: Maternal toxicity, Foetotoxicity, some malformations.

Species: Mouse

Notes: NTP study

Specific target organ toxicity - single exposure May cause respiratory irritation.

DIPHENHYDRAMINE HYDROCHLORIDE

Organ: Central Nervous System.

Specific target organ toxicity - repeated exposure Not classified.

IBUPROFEN

Epidemiology, Literature data

Organ: Gastro-intestinal tract

Notes: IUCLID

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged inhalation may be harmful.

12. Ecological information**Ecotoxicity**

Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
DIPHENHYDRAMINE HYDROCHLORIDE (CAS 147-24-0)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	0.35 mg/l, 96 hours Measured
	NOEC	Algae	0.26 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	2.3 mg/l, 48 hours Measured
	NOEC	Daphnia	< 0.56 mg/l
Fish	EC50	Rainbow trout (Juvenile Oncorhynchus mykiss)	2.8 mg/l, 96 hours Static renewal test
	NOEC	Rainbow trout (Juvenile Oncorhynchus mykiss)	1.1 mg/l

FD&C BLUE NO. 1 (CAS 3844-45-9)

Aquatic

Acute

Crustacea	EC50	Water flea (Daphnia magna)	> 97 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 96 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	> 96 mg/l, 96 hours Static test

IBUPROFEN (CAS 15687-27-1)

Aquatic

Acute

Algae	EC50	Green algae (Selenastrum capricornutum)	> 30 mg/l, 96 hours Static test
Crustacea	EC50	Water flea (Daphnia magna)	9.06 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	3.37 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	173 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	10 mg/l, 96 hours Static test

Chronic

Algae	NOEC	Green algae (Selenastrum capricornutum)	0.01 mg/l, 72 hours
Crustacea	EC10	Water flea (Daphnia magna)	2.04 mg/l, 14 days
	NOEC	Water flea (Daphnia magna)	20 mg/l, 14 days
			20 mg/l, 21 days

POLYETHYLENE GLYCOL (LIQUID) (CAS 25322-68-3)

Aquatic

Acute

Fish	LC50	Atlantic salmon (Salmo salar)	> 1000 mg/l, 96 hours
		Crucian carp (Carassius carassius)	> 20000 mg/l, 96 hours
		Rainbow trout, donaldson trout (Oncorhynchus mykiss)	> 20000 mg/l, 96 hours

POTASSIUM HYDROXIDE (CAS 1310-58-3)

Aquatic

Acute

Fish	EC50	Mosquito fish (Adult Gambusia affinis)	80 mg/l, 96 hours Static test
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Persistence and degradability No data is available on the degradability of this product.

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

DIPHENHYDRAMINE HYDROCHLORIDE < 1 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Biodegradability	
Percent degradation (Aerobic biodegradation-ready)	
IBUPROFEN	31.1 %, 28 days Closed bottle test, Activated sludge
Bioaccumulative potential	Not available.
Partition coefficient n-octanol / water (log Kow)	
DIPHENHYDRAMINE HYDROCHLORIDE	3.27 (Measured).
IBUPROFEN	3.97
Bioconcentration factor (BCF)	
IBUPROFEN	3 Estimated
Mobility in soil	No data available.
Adsorption	
Soil/sediment sorption - log Koc	
IBUPROFEN	3.53 Estimated
Mobility in general	
Volatility	
Henry's law	
IBUPROFEN	0 atm m ³ /mol Estimated
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Dispose of this material and its container to hazardous or special waste collection point. Incinerate the material under controlled conditions in an approved incinerator. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT	
UN number	UN3077
UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (DIPHENHYDRAMINE HYDROCHLORIDE), MARINE POLLUTANT
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	
Marine pollutant	Yes
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Special provisions	8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33
Packaging exceptions	155
Packaging non bulk	213
Packaging bulk	240
Read safety instructions, SDS and emergency procedures before handling.	
IATA	
UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (DIPHENHYDRAMINE HYDROCHLORIDE)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packaging group	III
Labels required	Not available.

Environmental hazards Yes
ERG Code 9L
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Other information

Passenger and cargo aircraft Allowed with restrictions.
Cargo aircraft only Allowed with restrictions.

IMDG

UN number UN3077
UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DIPHENHYDRAMINE HYDROCHLORIDE), MARINE POLLUTANT

Transport hazard class(es)

Class 9
Subsidiary risk -
Packing group III

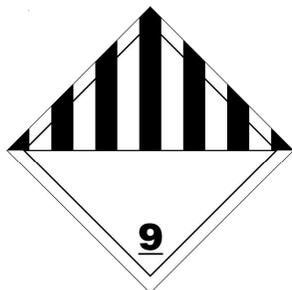
Environmental hazards

Marine pollutant Yes
EmS F-A, S-F

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
274,335,966,967,969

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

DOT; IATA; IMDG



Marine pollutant



General information IMDG Regulated Marine Pollutant. DOT Regulated Marine Pollutant.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

POTASSIUM HYDROXIDE (CAS 1310-58-3) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Classified hazard categories Yes
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 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	10-16-2023
Revision date	02-15-2024
Version #	02
HMIS® ratings	Health: 3 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 3 Flammability: 0 Instability: 0

Disclaimer Haleon cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.

