SAFETY DATA SHEET

1. Identification

Product identifier **Advil Tablets/Caplets**

Other means of identification

Product code WH-0432-0033, WH-0432-0037, 215 SL0504

Synonyms IBUPROFEN TABLETS * IBUPROFEN CAPLETS

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 ProductMedicinal Product

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2
	Specific target organ toxicity, single exposure	Category 3 respiratory tract irritation
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 2
OSHA defined hazards	Not classified.	

Label elements

Signal word Warning

Hazard statement Harmful if swallowed. Causes serious eye irritation. May cause respiratory irritation. Toxic to aquatic life.

Precautionary statement

Prevention Avoid breathing dust/fume/gas/mist/vapors/spray. 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 eye protection/face protection.

Response	If swallowed: Call a poison center/doctor// if you feel unwell. Rinse mouth. 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. Call a poison center/doctor// if you feel unwell. If eye irritation persists: Get medical advice/attention.
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	25.21% of the mixture consists of component(s) of unknown acute oral toxicity. 58.31% of the mixture consists of component(s) of unknown acute dermal toxicity. 57.31% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 57.31% 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	42
SUCROSE	SUGAR CANE SUGAR BEET SUGAR CONFECTIONER'S SUGAR ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL GRANULATED SUGAR SUCRALOX	57-50-1	30
STARCH	ARROWROOT STARCH CORN STARCH CORN STARCH 400-L NF MAIZE STARCH POTATO STARCH PREGELATINIZED STARCH NF RICE STARCH STARCH 1500	9005-25-8	22.3
CROSCARMELLOSE SODIUM	AC-DI-SOL (R) SODIUM CROSCARMELLOSE AC-DI-SOL (R) CROSCARMELLOSE SODIUM AC-DI-SOL (R) SD-711	74811-65-7	2.1
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 AVICEL 1030W CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CELPHERE CP203 CEOLUS KG-802 CRYSTALLINE CELLULOSE VIVAPUR VIVAPUR 101 VIVAPUR 102 VIVAPUR 112 VIVAPUR 200	9004-34-6	1.9

Chemical name	Common name and synonyms	CAS number	%
POLYVINYLPYRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER 2-PYRROLIDINONE, 1-ETHENYL, HOMOPOLYMER CROSPOVIDONE KOLLIDON 25 KOLLIDON 30 PLASDONE PLASDONE K29/32 POLY(N-VINYLPYRROLIDONE) POLY[1-(2-OXO-1-PYRROLIDINYL)ETHYLENE] Polyplasdone XL POLYVINYLPYRROLIDONE POVIDONE POVIDONE 30 PROVIDONE PVP	9003-39-8	1
STEARIC ACID	1-HEPTADECANECARBOXYLIC ACID OCTADECANOIC ACID STEAROPHANIC ACID N-OCTADECANOIC ACID	57-11-4	0.3
BEESWAX	YELLOW BEESWAX WHITE BEESWAX BEESWAX (WHITE) BEESWAX ABSOLUTE BEESWAX BLEACHED (WHITE), SYNTHETIC 619 BEESWAX OIL, ABSOLUTE BEESWAX YELLOW OHS02556	8012-89-3	0.1
DODECYL SODIUM SULFATE	SODIUM DODECYL SULPHATE DODECYL SULFATE, SODIUM SALT SODIUM LAURYL SULPHATE LAURYL SULFATE SODIUM SALT SLS	151-21-3	0.01
PROPYL PARABEN	PROPYL P-HYDROXYBENZOATE PROTABEN 4-HYDROXYBENZOIC ACID, PROPYL ESTER P-HYDROXYBENZOIC ACID, PROPYL ESTER PASEPTOL PARASEPT PROPYL ASEPTOFORM PROPYL P-OXYBENZOATE PROPYL-4-HYDROXYBENZOATE N-PROPYL P-HYDROXYBENZOATE P-HYDROXYPROPYL BENZOATE Propyl 4-hydroxybenzoate Propyl Parahydroxybenzoate	94-13-3	0.01
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT BENZOATE OF SODA SODUIM BENZOIC ACID	532-32-1	0.01
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	0.01
Other components below reportable levels			0.26

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 Wash off with soap and water. Get medical attention if irritation develops and persists.

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. Get medical attention if irritation develops and persists.

Ingestion	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause respiratory irritation. Coughing.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. 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. Alcohol resistant foam. Powder. Carbon dioxide (CO2).
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.
Methods and materials for containment and cleaning up	Prevent product from entering drains. 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 taste or swallow. Avoid contact with eyes. 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.

GSK

Components	Type	Value	Form
BEESWAX (CAS 8012-89-3)	OHC	1	
CROSCARMELLOSE SODIUM (CAS 74811-65-7)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL

GSK

Components	Type	Value	Form
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	1	>1000 - ≤5000 mcg/m3
IBUPROFEN (CAS 15687-27-1)	8 HR TWA	2000 mcg/m3	SKIN
	OHC	1	SKIN
PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m3	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
STARCH (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
STEARIC ACID (CAS 57-11-4)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3	
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

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. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Other	Wear suitable protective clothing.
Respiratory protection	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment.
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	Solid.
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	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
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.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not available.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Acids.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause irritation to the respiratory system. Prolonged inhalation may be harmful.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Causes serious eye irritation.
Ingestion	Harmful if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause respiratory irritation. Coughing.

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
BEESWAX (CAS 8012-89-3)		
Acute		
Oral		
LD50	Rat	> 5 g/kg
CROSCARMELLOSE SODIUM (CAS 74811-65-7)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LCLo	Rat	> 0.1 mg/l
Oral		
LD50	Rat	5050 mg/kg
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Acute		
Oral		
LD50	Rat	1288 mg/kg
IBUPROFEN (CAS 15687-27-1)		
Acute		
Oral		
LD50	Rat	1600 mg/kg
NOEL	Dog	50 mg/kg Gastro-intestinal toxicity.
Chronic		
Oral		
NOAEL	Baboon	40 mg/kg/day, 52 weeks Gastro-intestinal toxicity.
	Rat	20 mg/kg/day, 2 years Gastro-intestinal toxicity.
Subchronic		
Oral		
LD	Rat	180 mg/kg/day, 6 months Gastro-intestinal toxicity.

Components	Species	Test Results
LOAEL	Rat	60 mg/kg/day, 6 months Gastro-intestinal toxicity.
NOAEL	Mouse	75 mg/kg/day Gastro-intestinal toxicity.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
POLYVINYLPYRROLIDONE (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
PROPYL PARABEN (CAS 94-13-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
SODIUM BENZOATE (CAS 532-32-1)		
Acute		
Oral		
LD50	Rat	2000 mg/kg
STEARIC ACID (CAS 57-11-4)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
		4.6 g/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.

Components	Species	Test Results
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

SODIUM BENZOATE	OECD 404 Result: Negative Species: Rabbit

Irritation Corrosion - Skin

TITANIUM DIOXIDE	0, Literature data Result: Non-irritant Species: Guinea pig 0, Literature data Result: Non-irritant Species: Human
IBUPROFEN	0, Supplier data Result: Mild irritant Species: Human Notes: IUCLID
TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit

Serious eye damage/eye irritation Causes serious eye irritation.

Eye

IBUPROFEN	0, Supplier data Result: Irritant Species: Human Notes: IUCLID
SODIUM BENZOATE	Acute ocular irritation; OECD 405 Result: Mild irritant Species: Rabbit
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

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

Sensitization

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure
SODIUM BENZOATE	Local lymph node assay Result: Negative Species: Mouse
IBUPROFEN	OECD 406 - Maximisation test, Literature data Result: Negative Species: Guinea pig Notes: IUCLID
TITANIUM DIOXIDE	Patch test, Literature data Result: Negative Species: Human

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

Mutagenicity

SODIUM BENZOATE	Ames Result: Negative
TITANIUM DIOXIDE	Ames, Literature data Result: Negative

Mutagenicity

IBUPROFEN	Ames, Literature data Result: Negative Notes: IUCLID
SODIUM BENZOATE	Chromosomal aberration assay Result: Negative Species: Rat
IBUPROFEN	In vivo cytogenetics, Literature data Result: Negative Species: Human Notes: IUCLID
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
IBUPROFEN	Sister Chromatid Exchange, Literature data Result: Negative Species: Human Test Duration: 2 weeks Notes: IUCLID
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: Negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive

Carcinogenicity Not classifiable as to carcinogenicity to humans. Contains a material (Titanium dioxide) classified as a carcinogen by external agencies. Carcinogenic effects are not expected as a result of occupational exposure.

TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: Negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: Negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months
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
SODIUM BENZOATE	2 year study, Male + Female Result: Negative - dietary Species: Rat
IBUPROFEN	20 - 120 mg/kg/day Result: Negative Species: Rat
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study - Literature data. Result: Negative Species: Rat 25000 - 50000 ppm, Dietary study Result: Negative Species: Mouse
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
TITANIUM DIOXIDE	7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

POLYVINYLPYRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic 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 5 - 100 mg/kg/day Embryo-foetal development, Literature dat a 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
SODIUM BENZOATE	Embryofetal Development Result: Negative Reproduction/Fertility Study Result: Negative Species: Rat

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

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.

Components		Species	Test Results
DODECYL SODIUM SULFATE (CAS 151-21-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.6 mg/l, 96 hours Flow-through test
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-though Test

Components		Species	Test Results
Fish	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days Flow-through 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
POLYVINYLPYRROLIDONE (CAS 9003-39-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
SODIUM BENZOATE (CAS 532-32-1)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/L, 96 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	484 mg/L, 96 hours Flow-through test
STEARIC ACID (CAS 57-11-4)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 32 mg/l, 47 hours EU Method C.2
Fish	LC0	Carp (Cyprinus carpio)	1000 mg/l, 48 hours OECD 203
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Fish	LC50	Mummichog (Fundulus heteroclitus)	> 1000 mg/l, 96 hours
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

STEARIC ACID	17 Hours Estimated

UV/visible spectrum wavelength

STEARIC ACID	210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

POLYVINYLPYRROLIDONE	0 %, 28 days Modified MITI test, Activated sludge
STEARIC ACID	77 %, 28 days BOD
SUCROSE	69 % BOD5

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

DODECYL SODIUM SULFATE	95 % OECD 301 B
IBUPROFEN	31.1 %, 28 days Closed bottle test, Activated sludge
SODIUM BENZOATE	100 %, 28 days Modified OECD Screening Test (OECD 301E), Sea water 90 %, 7 days Modified Sturm test., Activated sludge
STEARIC ACID	95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

STEARIC ACID	50 %, 13 days

Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE	93 %, 7 days Other degradation test system, Mixed Residential/Industrial

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

DODECYL SODIUM SULFATE	1.6
IBUPROFEN	3.97
PROPYL PARABEN	3.04
SODIUM BENZOATE	1.89 -2.27
STEARIC ACID	8.23 8.42
SUCROSE	-3

Bioconcentration factor (BCF)

IBUPROFEN	3 Estimated
STEARIC ACID	> 9999 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

IBUPROFEN	3.53 Estimated
SODIUM BENZOATE	1.16 Calculated
STEARIC ACID	5.86 Estimated

Mobility in general

Volatility

Henry's law

IBUPROFEN	0 atm m^3/mol Estimated
STEARIC ACID	0.000051 Estimated
SUCROSE	< 0 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN	3.04

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 Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

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)

Not 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 Yes

Classified hazard categories 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

WARNING: This product can expose you to TITANIUM DIOXIDE, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

PROPYL PARABEN (CAS 94-13-3)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

Country(s) or region	Inventory name	On inventory (yes/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)	No
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 10-02-2019

Revision date 02-02-2022

Version # 05

HMIS® ratings Health: 2
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 2
Flammability: 0
Instability: 0

Disclaimer GlaxoSmithKline 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.

Revision information Composition / Information on Ingredients: Ingredients