



SAFETY DATA SHEET

1. Identification

Product identifier

EXCEDRIN TABLETS AND CAPLETS

Other means of identification

Synonyms

CIBALENAA * EXCEDRIN CAPLETS * EXCEDRIN EXTRA FUERTE * EXCEDRIN EXTRA STRENGTH * EXCEDRIN EXTRA STRENGTH CAPLETS * EXCEDRIN EXTRA FUERTE COMPRIMIDOS RECUBIERTOS * EXCEDRIN MIGRAINE * EXCEDRIN MIGRAINE CAPLETS * EXCEDRIN MIGRAÑA * EXCEDRIN MIGRAÑA COMPRIMIDOS RECUBIERTOS * VOLTADINE EXTRA STRENGTH AND MIGRAINE * VOLTADINE F. C. TABLETS * 服他定膜衣錠 * 엑세드린엑스트라스트렙스정 * ЭКСЕДРИН * GSK LINCOLN MATERIAL ID 61000000001528 * GSK LINCOLN MATERIAL ID 61000000000777 * MFC1528-1 * ACETYLSALICYLIC ACID, CAFFEINE, PARACETAMOL, FORMULATED PRODUCT

Recommended use

Medicinal Product.

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.

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

Telephone:

VERISK 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:

334878

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
ASPIRIN	BENZOIC ACID, 2-(ACETYLOXY)-SALICYLIC ACID ACETATE ASPIRIN ACETOPHEN 2-(ACETYLOXY)BENZOIC ACID ACETYL SALICYLIC ACID (ASPIRIN)	50-78-2	36.93

Chemical name	Common name and synonyms	CAS number	%
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- N-(4-HYDROXYPHENYL) ACETAMIDE ACETANILIDE, 4'-HYDROXY- 4'-HYDROXYACETANILIDE PARACETAMOL PARA-ACETAMIDOPHENOL 4-ACETAMINOPHENOL PARA-HYDROXYACETANILIDE	103-90-2	36.93
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CRYSTALLINE CELLULOSE	9004-34-6	14.77
CAFFEINE	TRIMETHYLBXANTHINE METHYLTHEOBROMINE CAFFEINE ANHYDROUS	58-08-2	9.6
HYDROXYPROPYL METHYL CELLULOSE	METHOCEL K4M GONIOSOL ISOPRO ALKALINE METHOCEL E,F,K METHOCEL HG METHYL CELLULOSE PROPYLENE GLYCOL ETHER HYPROMELLOSE CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER METHYLHYDROXYPROPYLCELLULOS E PHARMACOAT 603	9004-65-3	1.05
STEARIC ACID	1-HEPTADECANECARBOXYLIC ACID OCTADECANOIC ACID STEAROPHANIC ACID N-OCTADECANOIC ACID	57-11-4	0.37
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	0.2

4. First-aid measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Not established. Dusts may irritate the respiratory tract, skin and eyes.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
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	Move containers from fire area if you can do so without risk.
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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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. Dike the spilled material, where this is possible. Shovel up and place in a container for salvage or disposal. Following product recovery, flush area with water. Small Spills: Pick up and arrange disposal without creating dust. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. Never return spills in original containers for re-use.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation.
Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in a closed container away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Components	Type	Value	Note
ASPIRIN (CAS 50-78-2)	8 HR TWA	1000 mcg/m ³	SKIN
	OHC	2	SKIN
CAFFEINE (CAS 58-08-2)	8 HR TWA	200 mcg/m ³	
	OHC	2	
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1	
PARACETAMOL (CAS 103-90-2)	8 HR TWA	3000 mcg/m ³	

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

Components

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m ³	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
ASPIRIN (CAS 50-78-2)	TWA	5 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
STEARIC ACID (CAS 57-11-4)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
ASPIRIN (CAS 50-78-2)	TWA	5 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	
Appropriate engineering controls	General ventilation normally adequate.
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	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties**Appearance**

Physical state	Solid.
Form	Tablet. Caplet.
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 explosive.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Heat, flames and sparks. Contact with incompatible materials.
Incompatible materials	Not available.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics
Not established. Dusts may irritate the respiratory tract, skin and eyes.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
ASPIRIN (CAS 50-78-2)		
Acute		
Oral		
LD50	Dog	700 mg/kg
	Mouse	1100 mg/kg
	Rabbit	1800 mg/kg
	Rat	1500 mg/kg

Components	Species	Test Results
<u>Subchronic</u>		
Oral		
LOAEL	Rat	375 mg/kg/day Stomach ulcers
CAFFEINE (CAS 58-08-2)		
<u>Acute</u>		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD50	Rat	192 mg/kg
<u>Subchronic</u>		
Oral		
NOAEL	Mouse	167 - 179 mg/kg/day Dosed in drinking water - Continuous
	Rat	151 - 174 mg/kg/day Dosed in drinking water - Continuous
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
<u>Acute</u>		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
<u>Subacute</u>		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
<u>Subchronic</u>		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
Other		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous
STEARIC ACID (CAS 57-11-4)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
<u>Acute</u>		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg

Components	Species	Test Results
<u>Chronic</u>		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
<u>Subacute</u>		
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.
<u>Subchronic</u>		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.
Skin corrosion/irritation	Health injuries are not known or expected under normal use.	
Irritation Corrosion - Skin		
TITANIUM DIOXIDE	0, Literature data Result: Non-irritant Species: Guinea pig	
CAFFEINE	0, Literature data Result: Non-irritant Species: Human	
ASPIRIN	0, Literature data Result: Non-irritant Species: Rabbit	
TITANIUM DIOXIDE	Acute dermal irritation; OECD 404 Result: Slightly irritating Species: Rabbit	
ASPIRIN	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit	
	Result: Irritating to skin Species: Human Notes: IUCLID data	
Irritation Corrosion - Skin: P.I.I. value		
PARACETAMOL	OECD 404, Literature data Result: Slight irritant Species: Rabbit	
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.	
Eye		
CAFFEINE	0, Literature data Result: Not likely to be a severe irritant Species: Rabbit	
ASPIRIN	Acute ocular irritation; OECD 405 Result: Moderate Irritant Species: Rabbit	
PARACETAMOL	Notes: IUCLID data OECD 405 Result: Slight irritant Species: Rabbit	

Eye		
	TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit
Eye / Initial pain reaction score		
	PARACETAMOL	0, Literature data
Respiratory or skin sensitization		
Respiratory sensitization	Based on available data, the classification criteria are not met.	
Skin sensitization	Due to partial or complete lack of data the classification is not possible.	
Maximisation assay (Magnusson and Kligman)		
	HYDROXYPROPYL METHYL CELLULOSE	Result: Negative Species: Guinea pig
Sensitization		
	CAFFEINE	0, Literature data Result: Negative Species: Mouse
	TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure Patch test, Literature data Result: Negative Species: Human
	ASPIRIN	Result: Equivocal Species: Human Notes: IUCLID data Result: Negative Species: Guinea pig Notes: IUCLID data
Germ cell mutagenicity	Based on available data, the classification criteria are not met.	
Mutagenicity		
	CAFFEINE	25 - 100 mg/kg Chromosomal Aberration Assay In Vivo Result: Positive Species: Mouse 25 - 100 mg/kg Micronucleus Assay Result: Negative Species: Mouse Ames Result: Negative
	ASPIRIN	Ames Result: Negative Notes: NTP study
	PARACETAMOL	Ames, Literature data Result: Negative
	TITANIUM DIOXIDE	Ames, Literature data Result: Negative
	ASPIRIN	BlueScreen mammalian cell mutation assay Result: Negative
	CAFFEINE	Chromosomal Aberration Assay In Vitro Result: Positive
	ASPIRIN	Chromosomal Aberration Assay In Vitro Result: Positive Notes: Snyder 2001
	PARACETAMOL	Chromosomal Aberration Assay In Vitro, Literature data Result: Positive HPRT gene mutation in human lymphocytes, Literature data Result: Negative
	ASPIRIN	In vitro cytogenetics assay Result: Negative Notes: Snyder 2001
	CAFFEINE	In vivo Micronucleus Result: Positive
	PARACETAMOL	In vivo Micronucleus, Literature data Result: Negative Species: Mouse

Mutagenicity

CAFFEINE

L5178Y mouse lymphoma thymidine kinase locus assay

Result: Positive

TITANIUM DIOXIDE

Micronucleus Assay in vitro, CHO cells, Literature data

Result: Negative

Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data

Result: Positive

Syrian Hamster Embryo (SHE) cell transformation assay

Result: Negative

WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell

lymphoblastoid, Literature data

Result: Positive

Carcinogenicity

Based on available data, the classification criteria are not met. Carcinogenic effects are not expected as a result of occupational exposure. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. Carcinogenicity has been reported in humans or animals at doses equal to, or greater than recommended for therapeutic use.

PARACETAMOL

0, Literature data

Result: Equivocal. Increase in adenomas at toxic dose.

Species: Mouse

0, Literature data

Result: Equivocal. Liver and bladder neoplasms at toxic doses.

Species: Rat

0, Literature data

Result: Negative

Species: Mouse

0, Literature data

Result: Negative

Species: Rat

CAFFEINE

0.1 - 0.2 %, Dosed in drinking water

Result: Negative

Species: Rat

Test Duration: 78 weeks

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

ASPIRIN

1.4 % 18 month bioassay, Dietary study with aspirin, phenacetin and caffeine in females.

Result: Equivocal carcinogenic effects.

Species: Rat

Notes: NTP study

1.4 % 18 month bioassay, Dietary study with aspirin, phenacetin and caffeine in males.

Result: Negative

Species: Rat

Notes: NTP study

1.4 % 18 month bioassay, Dietary study with aspirin, phenacetin and caffeine.

Result: Negative - dietary

Species: Mouse

Notes: NTP study

TITANIUM DIOXIDE

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

CAFFEINE

200 - 2000 mg/L, Dosed in drinking water

Result: Negative

Species: Rat

Test Duration: 2 years

TITANIUM DIOXIDE

25000 - 50000 ppm, Dietary study - Literature data.

Result: Negative

Species: Rat

Carcinogenicity

TITANIUM DIOXIDE

25000 - 50000 ppm, Dietary study
 Result: Negative
 Species: Mouse
 7.2 - 14.8 mg/m³, Literature data
 Result: Lung tumour
 Species: Rat
 Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

CAFFEINE (CAS 58-08-2)

3 Not classifiable as to carcinogenicity to humans.

PARACETAMOL (CAS 103-90-2)

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

Based on available data, the classification criteria are not met.

Reproductivity

PARACETAMOL

<= 1400 mg/kg/day Pre- and Post-natal development,
 Literature data
 Result: reduced weight gain during nursing.
 Species: Rat

CAFFEINE

>= 301 mg/day Epidemiology
 Result: delayed conception
 Species: Human

ASPIRIN

100 mg/kg/day Embryofetal Development
 Result: Maternal toxicity; adverse foetal effects
 Species: Rat
 187 mg/kg/day Embryo-foetal development
 Result: Reduced viable foetuses and malformations.
 Species: Rat

Notes: IUCLID data
 200 mg/kg/day Embryo-foetal development
 Result: Foetal NOAEL
 Species: Rabbit
 Notes: IUCLID data
 200 mg/kg/day One generation study
 Result: Maternal NOAEL
 Species: Rat

CAFFEINE

Notes: IUCLID data
 25 mg/kg Embryofetal Development
 Result: No effect
 Species: Rat

PARACETAMOL

250 mg/kg/day Embryofetal Development, Literature data
 Result: Foetal NOAEL
 Species: Rat

ASPIRIN

250 mg/kg/day Embryo-foetal development
 Result: Foetal lethality
 Species: Rabbit
 Notes: IUCLID data

30 mg/kg/day Fertility, Male
 Result: Reduced spermatogenesis.
 Species: Rat

Notes: IUCLID data
 300 mg/kg/day Fertility, Female
 Result: Reduced ovulation.
 Species: Rabbit

CAFFEINE

Notes: IUCLID data
 300 mg/kg/day
 Result: testicular toxicity
 Species: Rat

PARACETAMOL

Test Duration: 75 Day
 387 mg/kg/day Embryofetal Development, Literature data
 Result: Negative
 Species: Mouse

Reproductivity

ASPIRIN

50 mg/kg/day Embryo-foetal development

Result: Developmental abnormalities.

Species: Cat

Notes: IUCLID data

50 mg/kg/day One generation study

Result: Foetal NOAEL

Species: Rat

Notes: IUCLID data

600 mg/kg/day Fertility

Result: Foetal toxicity, no viable litters.

Species: Rat

Notes: IUCLID data

62.5 mg/kg/day Embryo-foetal development

Result: NOAEL

Species: Rat

Notes: IUCLID data

PARACETAMOL

750 mg/kg/day Embryofetal Development, Literature data

Result: decrease in foetal weight, minor skeletal abnormalities.

Species: Rat

ASPIRIN

800 - 1200 mg/kg/day Fertility

Result: Increased foetal mortality.

Species: Mouse

Notes: IUCLID data

CAFFEINE

87.5 mg/kg/day Embryofetal Development

Result: Maternal toxicity; adverse foetal effects

Species: Mouse

PARACETAMOL

Epidemiology, Literature data

Result: No clear association with therapeutic use.

Species: Human

Specific target organ toxicity - single exposure

Based on available data, the classification criteria are not met.

CAFFEINE

0, Literature data

Organ: Nervous system; Cardiovascular system

PARACETAMOL

Species: Human

Organ: Liver

Specific target organ toxicity - repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Not likely, due to the form of the product.

Chronic effects

Not available.

Further information

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information**Ecotoxicity**

There is insufficient information to determine the scope of the environmental effects this material may cause. Avoid contaminating soil or water and entry into drainage or sewer systems. It should not be released into the environment.

Components**Species****Test Results**

ASPIRIN (CAS 50-78-2)

Acute

IC50

Activated sludge

> 101 mg/l, 3 hours Nominal

NOEC

Activated sludge

100

Aquatic*Acute*

Algae

EC50

Green algae (Desmodesmus subspicatus)

106.7 mg/l, 72 hours OECD 201

Crustacea

EC50

Water flea (Daphnia magna)

88.1 mg/l, 48 hours OECD 202

Fish

EC50

Golden ide/orfe (Adult Leuciscus idus)

> 1000 mg/l, 48 hours OECD 203

Chronic

Crustacea

EC50

Water flea (Daphnia magna)

61 - 68 mg/l, 21 days EPA Method

Components	Species		Test Results
CAFFEINE (CAS 58-08-2)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours Nominal, OECD 209
	NOEC	Residential sludge	1000
Algae	EC50	Green algae (Desmodesmus subspicatus)	> 100 mg/l, 72 hours OECD 201
		Green algae (Scenedesmus subspicatus)	> 100 mg/l, 72 hours Measured, OECD 201
	NOEC	Algae	100 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	182 mg/l, 48 hours German std DIN 38412
Fish	LC50	Fathead minnow (Adult Pimephales promelas)	151 mg/l, 96 hours OECD 203
		Golden ide/orfe (Adult Leuciscus idus)	87 mg/l, 96 hours German std DIN 38412 Part 15
<i>Chronic</i>			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	6.25 mg/l, 72 hours OECD 201
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Fish	> 100 mg/L, 96 hours
PARACETAMOL (CAS 103-90-2)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
STEARIC ACID (CAS 57-11-4)			
Aquatic			
<i>Acute</i>			
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
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test
Persistence and degradability	Not available.		
Photolysis			
Half-life (Photolysis-atmospheric)			
ASPIRIN	19.8 Days Estimated		
CAFFEINE	2.5 Hours Estimated		
STEARIC ACID	17 Hours Estimated		
UV/visible spectrum wavelength			
CAFFEINE	227 nm		
STEARIC ACID	210 nm		

Hydrolysis

Half-life (Hydrolysis-acidic)

ASPIRIN 12.5 Days Measured

Half-life (Hydrolysis-basic)

ASPIRIN 1.2 Hours Measured

Half-life (Hydrolysis-neutral)

ASPIRIN 6.3 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

PARACETAMOL 99 %, 5 days Modified Zahn-Wellens, Activated sludge

STEARIC ACID 77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

CAFFEINE 90 - 100 % , OECD 301A, 22 days, DOC removal

STEARIC ACID 95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

STEARIC ACID 50 %, 13 days

Percent degradation (Anaerobic biodegradation)

ASPIRIN 90 %, 56 days

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

ASPIRIN 1.19

CAFFEINE -0.07

-0.0907

HYDROXYPROPYL METHYL CELLULOSE -5

PARACETAMOL 0.36

STEARIC ACID 8.23

8.42

Bioconcentration factor (BCF)

ASPIRIN 4.7 - 5.4 Calculated

CAFFEINE 0.52 - 2.25 Estimated

HYDROXYPROPYL METHYL CELLULOSE 3.2 Estimated

STEARIC ACID > 9999 Estimated

Mobility in soil Not available.

Adsorption

Soil/sediment sorption - log Koc

ASPIRIN 1.6 - 2 Calculated

CAFFEINE 1.25 - 1.34 Estimated

STEARIC ACID 5.86 Estimated

Mobility in general Not available.

Volatility

Henry's law

ASPIRIN 0 atm m³/mol Calculated, 25 C

CAFFEINE 0 atm m³/mol Estimated

HYDROXYPROPYL METHYL CELLULOSE 0 atm m³/mol Estimated

PARACETAMOL 0 atm m³/mol Estimated

STEARIC ACID 0.000051 Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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). Avoid discharge into water courses or onto the ground.

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.

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

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
Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation
Carcinogenicity
Reproductive toxicity

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 Proposition 65 - CRT: Listed date/Carcinogenic substance

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

California Proposition 65 - CRT: Listed date/Developmental toxin

ASPIRIN (CAS 50-78-2) Listed: July 1, 1990

California Proposition 65 - CRT: Listed date/Female reproductive toxin

ASPIRIN (CAS 50-78-2) Listed: July 1, 1990

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

ASPIRIN (CAS 50-78-2)
TITANIUM DIOXIDE (CAS 13463-67-7)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*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	04-17-2018
Revision date	11-21-2019
Version #	03
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Revision information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Accidental release measures: Methods and materials for containment and cleaning up Regulatory Information: United States