



SAFETY DATA SHEET

1. Identification

Product identifier	RETROVIR TABLETS
Other means of identification	Not available.
Synonym(s)	RETROVIR TABLETS 300 MG * ZIDOVUDINE, 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

Manufacturer

ViiV Healthcare
Five Moore Drive
Research Triangle Park
North Carolina, USA
27709-3398
US General Information (normal business hours): +1-877-844-8872 (+1 877 ViiVUSA)
Email Address: msds@gsk.com
Website: www.viivhealthcare.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

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

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
ZIDOVUDINE	3'-AZIDO-3'-DEOXYTHYMIDINE 509U81 AZIDOTHYMIDINE ERYTHRO-3'-THYMIDINE GR 63367X ZDV	30516-87-1	60 - < 70

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ABICEL ALPHA-CELLULOSE ARBOCEL ARBOCELL B 600/30 ARBOCELL BC 200 AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 BETA-AMYLOSE CELLEX MX CELLULOSE (8CI9CI) CELLULOSE 248 CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CELUFI CRYSTALLINE CELLULOSE EMOCEL MCC MICROCRYSTALLINE CELLULOSE POWDERED CELLULOSE RTECS FJ5691460 SOLKA FLOC BW200 CELLULOSA (FIBRA PAPEL) CELLULOSE (PAPER FIBRES) CELLULOSE-PAPER FIBER CELULOSA (FIBRA PAPEL) TSELLULOOS	9004-34-6	5 - < 10
POLYVINYLPIRROLIDONE	2-PYRROLIDINONE, 1-ETHENYL, HOMOPOLYMER 1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER 2-PYRROLIDINONE, 1-VINYL-, POLYMERS 1-VINYL-2-PYRROLIDINONE POLYMERS POLY(VINYLPYRROLIDINONE) POLY(N-VINYLPYRROLIDINONE) POLY(1-VINYLPYRROLIDINONE) POLY(VINYLPYRROLIDONE) POLY(N-VINYLPYRROLIDONE) POVIDONE PVP VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDONE HOMOPOLYMER VINYLPYRROLIDONE POLYMER N-VINYLPYRROLIDONE POLYMER RTECS TR8370000 PLASDONE PLASDONE K29/32 POLY-1-VINYL-2-PYRROLIDON POLYVINYL-PYRROLIDONE PROVIDONE	9003-39-8	3 - < 5

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
TITANIUM DIOXIDE	ANATASE BROOKITE RUTILE TITANIUM OXIDE TITANIUM DIOXIDE (TiO ₂) C.I. PIGMENT WHITE 6 C.I. 77891 TITANIUM(IV) OXIDE TITANIUM(4+) OXIDE TITANIUM PEROXIDE (TiO ₂) TITANIA (TiO ₂) PIGMENT WHITE 6 TITANIA KRONOS TITANIC OXIDE O2Ti OHS23510 RTECS XR2275000 DIOXIDO DE TITANIO TITANOKSIID	13463-67-7	1 - < 3
MAGNESIUM STEARATE	OCTADECANOIC ACID, MAGNESIUM SALT STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE OCTADECANOIC ACID MAGNESIUM SALT MAGNESIUM OCTADECANOATE C36H70MGO4 OHS13505 RTECS WI4390000 MAGNESIUMDISTEARAT	557-04-0	< 1

Other components below reportable levels

20 - < 30

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

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

Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

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.

Most important symptoms/effects, acute and delayed

Prolonged exposure may cause chronic effects.
The following adverse effects have been noted with therapeutic use of this material: anaemia; headache; nausea; vomiting; anorexia.

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 centre.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

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

In the event of fire, cool tanks with water spray.

Specific methods

Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. 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 MSDS.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1	
ZIDOVUDINE (CAS 30516-87-1)	8 HR TWA	350 mcg/m3	
	OHC	2	CARCINOGEN

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.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	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

Biological limit values

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

Appropriate engineering controls

An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Good general ventilation (typically 10 air changes per hour) 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.

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.

Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	When using, do not eat, drink or smoke. 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. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
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)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

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	Strong oxidizing agents. Fluorine.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Adverse effects might occur with repeated ingestion.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

Symptoms related to the physical, chemical and toxicological characteristics

The following adverse effects have been noted with therapeutic use of this material: anaemia; headache; nausea; vomiting; anorexia.
Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; lymph nodes; spleen; thymus. Assessment based upon information from animal studies.

Information on toxicological effects

Acute toxicity Adverse effects might occur with repeated ingestion.

Components	Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m ³
<i>Oral</i>		
LD50	Rat	> 24 g/kg
Chronic		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m ³ , 1 years, TiO ₂ accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m ³ , 2 years, Highest dose 5 mg/m ³ , 24 months
Subacute		
<i>Inhalation</i>		
LOEL	Rat	0.1 - 35 mg/m ³ , 4 weeks, Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m ³ , 3 weeks, No evidence of significant inflammation in respiratory tract.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.

Components	Species	Test Results
Subchronic <i>Inhalation</i> LOEC	Rat	3.2 - 20 mg/m ³ , 8 min, Accumulation of TiO ₂ in macrophages and evidence of pulmonary inflammation.
ZIDOVUDINE (CAS 30516-87-1)		
Acute <i>Oral</i> LD50	Rat	3083 - 3683 mg/kg
Subchronic <i>Oral</i> LOEL	Monkey	35 mg/kg/day, 6 month study
* Estimates for product may be based on additional component data not shown.		
Skin corrosion/irritation	Health injuries are not known or expected under normal use.	
Irritation Corrosion - Skin ZIDOVUDINE		Acute dermal irritation, Primary Irritation Index: 0; abraded and non-abraded sites Result: Negative Species: Rabbit
TITANIUM DIOXIDE		Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human
Irritation Corrosion - Skin: P.I.I. value MAGNESIUM STEARATE		0
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.	
Eye ZIDOVUDINE		Acute ocular irritation Result: Moderate Irritant Species: Rabbit
TITANIUM DIOXIDE		OECD 405, Literature data Result: Mild irritant Species: Rabbit
Eye / Kay and Calandra class - Intact MAGNESIUM STEARATE		4 Recovery Period: 2 days
Respiratory sensitization	Not available.	
Skin sensitization	Health injuries are not known or expected under normal use.	
Sensitization 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
Germ cell mutagenicity	The ingredient zidovudine has caused genetic toxicity in laboratory studies.	
ZIDOVUDINE		Ames Assay, GLP assay Result: Positive
TITANIUM DIOXIDE		Ames, Literature data Result: Negative
ZIDOVUDINE		Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Positive GreenScreen Assay Result: Positive (+ S9 only) Micronucleus Assay Result: Positive Species: Mouse

ZIDOVUDINE	Micronucleus Assay Result: Positive Species: Rat
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
ZIDOVUDINE	Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Positive Sister Chromatid Exchange Result: Positive
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

Contains a material (zidovudine) classified as a carcinogen by external agencies.
Contains a material (titanium dioxide) classified as a carcinogen by external agencies.
Carcinogenic activity was seen in inhalation studies using laboratory animals. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

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
ZIDOVUDINE	2 year bioassay, vaginal tumours in females at doses of 24X the equivalent of human therapeutic dose; no effect in males Result: Positive Species: Rat 2 year bioassay, vaginal tumours in females at doses of 3X or more the equivalent of human therapeutic dose; no effect in males Result: Positive Species: Mouse 25000 - 50000 ppm, Dietary study Result: Negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: Negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: Negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: Negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

POLYVINYLPIRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.
ZIDOVUDINE (CAS 30516-87-1)	2B Possibly carcinogenic to humans.

Reproductive toxicity

The ingredient zidovudine has caused adverse effects on the development of unborn offspring in animal studies.

ZIDOVUDINE	Embryo-foetal development - Oral Result: Foetal and maternal NOAEL = 150 mg/kg/day; with 500 mg/kg/day evidence of foetal toxicity (increased incidence of resorptions); no foetal malformations with any dose up to maximum of 450 mg/kg/day Species: Rabbit Embryo-foetal development - Oral Result: Foetal and maternal NOAEL = 50 mg/kg/day; with 150 mg/kg/day or more evidence of foetal toxicity (increased incidence of resorptions); no foetal malformations with any dose up to maximum of 450 mg/kg/day Species: Rat
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ZIDOVUDINE

Fertility
 Result: Negative
 Species: Rat
 Peri- and Post-natal development
 Result: NOAEL = 450 mg/kg/day (maximum dose)
 Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure.

ZIDOVUDINE

Repeat dose non-clinical studies
 Organ: bone marrow; blood; lymph nodes; spleen; thymus.

Aspiration hazard Not likely, due to the form of the product.

Chronic effects May cause damage to organs through prolonged or repeated exposure.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components	Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes) 130 mg/l, 96 hours
Microtox	EC50	Microtox 12.5 mg/l, 15 minutes
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours, Static test
Aquatic		
<i>Acute</i>		
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
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) > 1000 mg/l, 48 hours, Static test
ZIDOVUDINE (CAS 30516-87-1)		
Aquatic		
<i>Acute</i>		
Activated Sludge Respiration	IC50	Residential sludge > 1000 mg/l, 3 hours, OECD 209
Crustacea	EC50	Water flea (Daphnia magna) > 100 mg/l, 48 hours, Static test, OECD 202
Microtox	MIC	Aspergillus flavus 250 mg/l
		Azotobacter chroococcum > 1000 mg/l
		Chaetomium globosum > 1000 mg/l
		Nostoc sp. > 1000 mg/l
		Pseudomonas fluorescens > 1000 mg/l
<i>Chronic</i>		
Crustacea	LOEC	Water flea (Daphnia magna) 40 mg/l, 21 days, Static renewal test, OECD 211
	NOEC	Water flea (Daphnia magna) 16 mg/l, 21 days, Static renewal test

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ZIDOVUDINE 9.04 Hours Measured, pH 7 Buffer Solution

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

Photolysis

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm
ZIDOVDINE	266 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

ZIDOVDINE	> 1 Years Measured
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Biodegradability

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days
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Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ZIDOVDINE	0.06
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Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated
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Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ZIDOVDINE	1.34 Measured, pH 7
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Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated
ZIDOVDINE	1.1, pH 7 Estimated

Mobility in general

Volatility

Henry's law

ZIDOVDINE	0 atm m ³ /mol, 25 C Estimated
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Other adverse effects Not available.

13. Disposal considerations

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. 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

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

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

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

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

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
 Delayed Hazard - Yes
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

NFPA ratings Health: 1
 Flammability: 1
 Instability: 0

HMIS® ratings Health: 1*
 Flammability: 1
 Physical hazard: 0

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.

Food and Drug Administration (FDA) Not regulated.

US state regulations**US. Massachusetts RTK - Substance List**

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

ZIDOVIDINE (CAS 30516-87-1)

Listed: December 18, 2009

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)	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

Country(s) or region	Inventory name	On inventory (yes/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	12-12-2013
Revision date	12-12-2013
Version #	09
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1* Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 1 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: Undisclosed Ingredient Statement Other information, including date of preparation or last revision: Further information