



SAFETY DATA SHEET

1. Identification

Product identifier

RETROVIR CAPSULES

Other means of identification

Synonyms

RETROVIR CAPSULES 100 MG * RETROVIR CAPSULES 250 MG * NDC NO 0173-0108-55 *
NDC NO 0173-0108-56 * 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

Chemical name	Common name and synonyms	CAS number	%
ZIDOVUDINE	3'-AZIDO-3'-DEOXYTHYMIDINE * 509U81 * AZIDOTHYMIDINE * ERYTHRO-3'-THYMIDINE * GR 63367X * ZDV	30516-87-1	43.6 - < 60
MAIZE STARCH	STARCH, EDIBLE * STARCH (CORN)	9005-25-8	20 - < 30
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	15

Chemical name	Common name and synonyms	CAS number	%
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	< 1

Other components below reportable levels

5 - < 10

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

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	None known. 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 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. Keep out of low areas. 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	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 SDS.
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 prolonged exposure. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
ZIDOVUDINE (CAS 30516-87-1)	8 HR TWA	350 mcg/m3	CARCINOGEN
	OHC	2	CARCINOGEN

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

Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
MAIZE STARCH (CAS 9005-25-8)	TWA	10 mg/m3
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MAIZE STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
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	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	
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.

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. Peroxides. Isocyanates. Amides. Fluorine. Phenols.
Hazardous decomposition products	None known. 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. Dust or powder may irritate the skin.
Eye contact	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics	None known. The following adverse effects have been noted with therapeutic use of this material: anaemia; headache; nausea; vomiting; anorexia.
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Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use. May be harmful if swallowed.
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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
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

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. Direct contact with eyes may cause temporary irritation.

Eye

ZIDOVUDINE

Acute ocular irritation
Result: Moderate Irritant
Species: Rabbit

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE

4

Recovery Period: 2 days

Respiratory or skin sensitization

Respiratory sensitization

Not available.

Skin sensitization

Health injuries are not known or expected under normal use.

Germ cell mutagenicity

The ingredient zidovudine has caused genetic toxicity in laboratory studies.

Mutagenicity

ZIDOVUDINE

Ames Assay, GLP assay
Result: Positive
Chromosomal Aberration Assay In Vitro, human lymphocytes
Result: Positive
GreenScreen Assay
Result: Positive (+ S9 only)
Micronucleus Assay
Result: Positive
Species: Mouse
Micronucleus Assay
Result: Positive
Species: Rat
Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay
Result: Positive
Sister Chromatid Exchange
Result: Positive

Carcinogenicity

Contains a material (zidovudine) classified as a carcinogen by external agencies.

Carcinogenicity
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

IARC Monographs. Overall Evaluation of Carcinogenicity

ZIDOVUDINE (CAS 30516-87-1)

2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

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

Reproductivity

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
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 available.

Chronic effects

Prolonged exposure may cause chronic effects. May cause damage to organs through prolonged or repeated exposure.

Further information

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

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
ZIDOVUDINE (CAS 30516-87-1)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours OECD 209

Components		Species	Test Results
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)

ZIDOVDINE 9.04 Hours Measured, pH 7 Buffer Solution

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

ZIDOVDINE 266 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

ZIDOVDINE > 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD

ZIDOVDINE 50 %, 3 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ZIDOVDINE 0.06

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ZIDOVDINE 1.34 Measured, pH 7

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 m³/mol, 25 C 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	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 dangerous goods.
IMDG	Not regulated as dangerous goods.
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

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 1910.1001-1050)	Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical No

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

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)	Not listed.
US. Massachusetts RTK - Substance List	MAIZE STARCH (CAS 9005-25-8) MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
US. New Jersey Worker and Community Right-to-Know Act	MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

US. Pennsylvania Worker and Community Right-to-Know Law

MAIZE STARCH (CAS 9005-25-8)

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

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

ZIDOVUDINE (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	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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	01-21-2015
Revision date	01-21-2015
Version #	12
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 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	This document has undergone significant changes and should be reviewed in its entirety.