SAFETY DATA SHEET

1. Identification

Product identifier **RETROVIR I.V. INFUSION**

Other means of identification

Synonyms RETROVIR IV INFUSION 10 MG/ML * RETROVIR INJECTION 10 MG/ML * RETROVIR SOLUTION INJECTABLE * NDC NO 0173-0107-93 * 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	1
Other components below reportable levels			99

*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 not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention if symptoms occur.

Skin contact Immediately flush skin with plenty of water. Get medical attention if symptoms occur. Take off contaminated clothing and wash before reuse.

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	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. Show this safety data sheet to the doctor in attendance. 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	Foam. Dry chemical powder. Carbon dioxide (CO2). Water.
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	This product is expected to be non-combustible.

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 breathe mist or vapor. 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	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). 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 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. Do not breathe mist or vapor. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Should be handled in closed systems, if possible. Pregnant or breastfeeding women must not handle this product. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.
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 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	
	OHC	2	CARCINOGEN

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	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. 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.

Individual protection measures, such as personal protective equipment

Eye/face protection	Not normally needed.
Hand protection	Wear appropriate chemical resistant gloves. 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.
Skin protection	
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	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. 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	Liquid.
Form	Vial.
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.

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.

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.

Information on toxicological effects

Acute toxicity Adverse effects might occur with repeated ingestion.

Components	Species	Test Results
ZIDOVUDINE (CAS 30516-87-1)		
Acute		
Oral		
LD50	Rat	3083 - 3683 mg/kg
Subchronic		
Oral		
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

Serious eye damage/eye irritation Health injuries are not known or expected under normal use.

Eye

ZIDOVUDINE
Acute ocular irritation
Result: Moderate Irritant
Species: Rabbit

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)

Mutagenicity

ZIDOVUDINE

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.

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 May cause damage to organs through prolonged or repeated exposure.

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental effects.

Components		Species	Test Results
ZIDOVUDINE (CAS 30516-87-1)			
Aquatic			
Acute			
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
Chronic			
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

UV/visible spectrum wavelength

ZIDOVUDINE — 266 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

ZIDOVUDINE — > 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

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

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ZIDOVUDINE — 0.06

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ZIDOVUDINE — 1.34 Measured, pH 7

Soil/sediment sorption - log Koc

ZIDOVUDINE — 1.1, pH 7 Estimated

Mobility in general

Volatility

Henry's law

ZIDOVUDINE — 0 atm m^3/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 allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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).
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 One or more components are not listed on 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 1910.1001-1050)

Not listed.

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

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. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

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	07-04-2014
Revision date	07-04-2014
Version #	13
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	This document has undergone significant changes and should be reviewed in its entirety.