Issue date: 05-November-2014 Revision date: 05-November-2014

Version number: 02



### SAFETY DATA SHEET

#### 1. Identification

**Product identifier VOLIBRIS TABLETS** 

Other means of identification

**Synonyms** VOLIBRIS 5 MG TABLETS \* VOLIBRIS 10 MG TABLETS \* AMBRISENTAN, FORMULATED

**PRODUCT** 

Recommended use of the chemical and restrictions on use

Medicinal Product. Recommended use

> This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant

to medicinal use of the product. In this instance patients should consult prescribing

information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate

safety data sheet for each ingredient.

No other uses are advised. Restrictions on use

### Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia 1061 Mountain Highway Melbourne, Victoria 3155

Australia

Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS

(available 24hrs/7days: multi-language response)

Australia Toll Free +(61) 2 9037 2994 International Toll Call +(1) 703 527 3887

### 2. Hazard(s) identification

#### Classification of the hazardous chemical

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

### Label elements, including precautionary statements

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

### Other hazards which do not result in classification

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

### 3. Composition/information on ingredients

#### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	
MICROCRYSTALLINE CELLULOSE	9004-34-6	ingredients < 25
AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE	3004-34-0	1 20
AVICEL PH101 AVICEL PH102		
AVICEL PH103 AVICEL PH105		
AVICEL PH112 AVICEL PH200 CELLUI OSE (8CIOCI)		
CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE		
CRYSTALLINE CELLULOSE		

Material name: VOLIBRIS TABLETS

AMBRISENTAN	177036-94-1	3.4 - < 7
(S)-2-(4,6-DIMETHYL-PYRIMIDIN-2-YLOXY)-3-METHOXY-3,3-DIPHENYLPR OPANOIC ACID BSF 208075 GSK1325760		
MAGNESIUM STEARATE STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	< 1
Talc TALCUM, NON-ASBESTOS FORM Talc HYDROUS MAGNESIUM SILICATE	14807-96-6	<1
Titanium dioxide  TITANIUM OXIDE  TITANIUM(IV) OXIDE  TITANIUM PEROXIDE (TiO2)  PIGMENT WHITE 6	13463-67-7	< 1
Other components below reportable levels		60 - < 70

#### 4. First-aid measures

### Description of necessary 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.

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large Ingestion

amount does occur, call a poison control centre immediately. Do not induce vomiting without

advice from poison control center.

Personal protection for first-aid

responders

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.

None known. Symptoms caused by exposure

The following adverse effects have been noted with therapeutic use of this material: headache;

flushing; dizziness.

Medical attention and special

treatment

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.

### 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

Water. 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 fire fighters

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.

Not available. **Hazchem Code** 

General fire hazards No unusual fire or explosion hazards noted.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

Material name: VOLIBRIS TABLETS

### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency

personnel

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate

protective clothing. For personal protection, see section 8.

For emergency responders

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the

SDS.

**Environmental precautions** 

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

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.

### 7. Handling and storage

Precautions for safe handling

Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

### 8. Exposure controls and personal protection

**Control parameters** 

Components

Talc (CAS 14807-96-6)

Follow standard monitoring procedures.

#### Occupational exposure limits

**GSK** 

Components	Туре	Value	Note
AMBRISENTAN (CAS 177036-94-1)	8 HR TWA	20 mcg/m3	
	OHC	3	Reproductive hazard
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1	

## Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Туре	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	Inhalable fibers.
Talc (CAS 14807-96-6)	TWA	2.5 mg/m3	
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	Inhalable dust.

### Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational **Environment)**

Type

**TWA** 

MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inspirable dust.
MICROCRYSTALLINE	TWA	10 mg/m3	Inspirable dust.
CELLULOSE (CAS			
9004-34-6)			

#### Titanium dioxide (CAS **TWA** 10 mg/m3 Inspirable dust. 13463-67-7)

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US. ACGIH Threshold Limit Values				
Components	Туре	Value	Form	
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3		
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3		
Talc (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.	
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3		

Material name: VOLIBRIS TABLETS

**Form** 

Value

2.5 mg/m3

**UK. EH40 Workplace Exposure Limits (WELs)** 

Components	Туре	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	STEL	20 mg/m3	Inhalable dust.
·	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.
Talc (CAS 14807-96-6)	TWA	1 mg/m3	Respirable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
•		10 mg/m3	Inhalable

**Biological limit values** 

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

**Exposure guidelines** 

Appropriate engineering General ventilation normally adequate.

controls

Individual protection measures, for example personal protective equipment (PPE)

If contact is likely, safety glasses with side shields are recommended. Eye/face protection

Skin protection

**Hand protection** For prolonged or repeated skin contact use suitable protective gloves.

Wear suitable protective clothing as protection against splashing or contamination. Other

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate

certified respirators.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures 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. 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. Colour Not available. Odour Not available. **Odour threshold** Not available. Not available. рH Not available. Melting point/freezing point Initial boiling point and boiling Not available. range Flash point Not available. Not available. **Evaporation rate** 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.

Vapour pressure Not available. Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

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 oxidising agents. Fluorine.

**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 possible routes of exposure

InhalationUnder normal conditions of intended use, this material is not expected to be an inhalation hazard.Skin contactHealth 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 exposure None known.

The following adverse effects have been noted with therapeutic use of this material: headache;

flushing; dizziness.

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

Components Species Test results

AMBRISENTAN (CAS 177036-94-1)

**Acute** Oral

LD50 Rat >= 3160 mg/kg

MAGNESIUM STEARATE (CAS 557-04-0)

Acute

Oral

LD50 Rat > 2000 mg/kg

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

Acute

Dermal

LD50 Rabbit > 2000 mg/kg

Oral

LD50 Rat > 2000 mg/kg

Titanium dioxide (CAS 13463-67-7)

**Acute** 

Inhalation

LC50 Rat 6820 mcg/m3

Oral LD50

Rat > 24 g/kg

Material name: VOLIBRIS TABLETS SDS AUSTRALIA

Components	Species	Test results
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

<sup>\*</sup> 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. Prolonged skin contact may cause

temporary irritation.

Irritation Corrosion - Skin

TITANIUM DIOXIDE 0. Literature data Result: Non-irritant

Species: Guinea pig 0, Literature data Result: Non-irritant Species: Human

Acute dermal irritation; OECD 404, Literature data

Result: Non-irritant Species: Rabbit

Reconstituted Human Epidermis (RHE) **AMBRISENTAN** 

Result: Negative - Not likely to be a significant irritant.

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE 0

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

tissue.

Eve

TITANIUM DIOXIDE OECD 405, Literature data

Result: Mild irritant Species: Rabbit

**AMBRISENTAN** Reconstituted Human Corneal Epithelium (HCE)

Result: Negative; not likely to be a severe irritant

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE

Recovery Period: 2 days

Respiratory or skin sensitisation

Respiratory sensitisation Not available.

Skin sensitisation Health injuries are not known or expected under normal use.

Material name: VOLIBRIS TABLETS 131821

Sensitisation

TITANIUM DIOXIDE 5 % Optimisation Test, Literature data - Vehicle: petrolatum

Result: negative Species: Guinea pig

Test Duration: 48 hour exposure

AMBRISENTAN OECD 429 / Local Lymph Node Assay, Maximum

concentration = 50%; vehicle = DMF

Result: negative Species: Mouse

TITANIUM DIOXIDE Patch test, Literature data

Result: negative Species: Human

Germ cell mutagenicity

Health injuries are not known or expected under normal use. No data available to indicate product

or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

TITANIUM DIOXIDE

AMBRISENTAN Ames Assay, GLP assay

Result: negative Ames, Literature data Result: negative

AMBRISENTAN Chromosomal Aberration Assay In Vitro

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

AMBRISENTAN Micronucleus Assay, GLP assay

Result: negative Species: Rat

TITANIUM DIOXIDE Syrian Hamster Embryo (SHE) cell transformation assay

Result: negative

AMBRISENTAN Unscheduled DNA Synthesis in vivo

Result: negative Species: Rat

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

lymphoblastoid, Literature data

Result: positive

Carcinogenicity

Health injuries are not known or expected under normal use. 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 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

**ACGIH Carcinogens** 

MAGNESIUM STEARATE (CAS 557-04-0)

Talc (CAS 14807-96-6)

A4 Not classifiable as a human carcinogen. A4 Not classifiable as a human carcinogen.

Material name: VOLIBRIS TABLETS

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Titanium dioxide (CAS 13463-67-7)

A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Titanium dioxide (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Specific target organ toxicity -

None known.

single exposure

Specific target organ toxicity -

repeated exposure

None known.

Aspiration hazard

Not available.

Chronic effects

Prolonged exposure may cause chronic effects.

Other 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
AMBRISENTAN (CAS 177	(036-94-1)		
Aquatic			
Acute			
Algae	EC50	Algae	10 - 100 mg/l, 96 hours QSAR Estimate
Crustacea	EC50	Daphnia	10 - 100 mg/l, 48 hours QSAR Estimate
Fish	EC50	Fish	10 - 100 mg/l, 96 hours QSAR Estimate
MAGNESIUM STEARATE	(CAS 557-04-0)		
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
Talc (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test
Titanium dioxide (CAS 134	63-67-7)		
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

<sup>\*</sup> Estimates for product may be based on additional component data not shown.

### Persistence and degradability

**Photolysis** 

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE 95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential

**Partition coefficient** 

n-octanol / water (log Kow)

AMBRISENTAN 1.2 (Measured).

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**Bioconcentration factor** 

(BCF)

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil No data available for this product.

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

Not available. Mobility in general Not available. Other adverse effects

### 13. Disposal considerations

Disposal methods 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.

Residual waste 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

#### **ADG**

Not regulated as dangerous goods.

**RID** 

Not regulated as dangerous goods.

Not regulated as dangerous goods.

**IMDG** 

Not regulated as dangerous goods.

Transport in bulk according to Not available.

Annex II of MARPOL 73/78 and

the IBC Code

### 15. Regulatory information

### Safety, health and environmental regulations

This Material Safety Data Sheet was prepared in accordance with the Australia National Code of **National regulations** 

Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

#### Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

### Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

### Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

### Australia Medicines & Poisons Appendix D

AMBRISENTAN (CAS 177036-94-1)

for human use Poisons available only from or on the order of a specialist physician and for which the prescriber must, where the patient is a woman of child bearing age: (a) ensure that the possibility of pregnancy has been excluded prior to

commencement of treatment; and (b) advise the patient to avoid becoming pregnant during or for a period of 3 months after

completion of treatment.

### Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Appendix F

AMBRISENTAN (CAS 177036-94-1)

applies to all preparations in any concentration WARNING - Causes Birth Defects., See a doctor if you are pregnant or diabetic., Do not become pregnant during use or within (Insert number of months as per approved product information) month(s) of stopping treatment.

#### Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

### Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

### Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

### Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

#### Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Schedule 7**

Poisons schedule number not allocated.

### Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

### Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

### **High Volume Industrial Chemicals (HVIC)**

Talc (CAS 14807-96-6)

Titanium dioxide (CAS 13463-67-7)

100000 - 999999 TONNES See the regulation for additional information.

100000 - 999999 TONNES See the regulation for additional information.

### Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

#### National Pollutant Inventory (NPI) substance reporting list

Not listed.

### **Prohibited Carcinogenic Substances**

Not regulated.

# Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed

### Resricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

### **Restricted Carcinogenic Substances**

Not regulated.

### International regulations

#### **Stockholm Convention**

Not applicable.

### **Rotterdam Convention**

Not applicable.

### **Kyoto protocol**

Not applicable.

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### **Montreal Protocol**

Not applicable. **Basel Convention** Not applicable.

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
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

<sup>\*</sup>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).

Toxic Substances Control Act (TSCA) Inventory

### 16. Other information

United States & Puerto Rico

05-November-2014 Issue date **Revision date** 05-November-2014

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

No

the suitability of the material or product for any particular purpose.

Product and Company Identification: Product and Company Identification **Revision Information** 

Composition / Information on Ingredients: Ingredients

Exposure Controls / Personal Protection:

Physical & Chemical Properties: Regulatory Information: United States

GHS: Classification

Material name: VOLIBRIS TABLETS

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