

SECTION 1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

SECTION 1.1 Product Identifier

Product Name SEVOFLURANE –100% – (All presentation Volumes)
 Product Type SUBSTANCE
 REACH Registration Not Applicable: Exempt, as substance presented as a pharmaceutical agent.

SECTION 1.2 Relevant Identified Uses, & Uses Advised Against

Identified Uses VETERINARY USE: Induction & maintenance of general anaesthesia with analgesic properties.

SECTION 1.3 Details of the Supplier of the Safety Data Sheet

Company Name Chanelle Pharmaceuticals Manufacturing Ltd.,
 Company Address Dublin Road, Loughrea, Co. Galway, Rep. of Ireland
 Hours of Business 8.30 AM -5.00 PM (GMT)

SECTION 1.4 Emergency Contact Information


Company Telephone +353-(0)-91-841-788 (Reception -during office hours)
 Company Fax +353-(0)-91-841-303
 Company Website <http://www.chanellegroup.ie/>

SECTION 2 HAZARDS IDENTIFICATION

SECTION 2.1 Classification of the Substance/Mixture (ACCORDING TO REGULATION 1272/2008/EC)

Hazard Type	Category	H-Statement	Signal
Eye Damage/Irritation	2A	H319	WARNING
Reproductive Toxicity	2	H361	WARNING
STOT-(SE)	3	H336	WARNING

SECTION 2.2 Label Elements

Labelling According to Regulation 1272/2008/EC [CLP]						
Label	Hazard Statements	Precautionary Statements				
	H319 Causes Serious Eye Irritation H361 Suspected of Damaging Fertility or the Unborn Child H336 May cause Drowsiness or Dizziness	Prevention	Response	Storage	Disposal	
Signal		WARNING	P201	P304+P340	P403+P233	P501
			P202	P305+P351+P338	P405	
		P261	P308+P313			
		P264	P312			
		P271	P313+P337			
		P280				
Refer to Section 16 for Full Expansion of P-Statements Listed.						

SECTION 2.3 Other Hazards

Refer to Section 4 for First Aid Measures; Refer to Section 11 for Toxicological Data.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

SECTION 3.1 Substance ACCORDING TO 1272/2008/EC

SECTION 3.2 Mixture Not Applicable

Component	Type	Concentration	CAS	Classification	Label
SEVOFLURANE	Active	>99%	28523-86-6	As per Section 2.1	As per Section 2.2

SECTION 4 FIRST AID MEASURES

- SECTION 4.1 Description of First Aid Measures (Refers to the Finished Product Mixture)**
General If unconscious, place person on their side in the recovery position; contact medical aid; give access to this SDS.
Inhalation If coughing, dizziness, or irritation develops remove to Fresh Air; Keep Patient Warm; Seek Medical Assistance.
Skin Contact Wash affected area with mild soap & water; if irritation develops contact physician.
Eye Contact Rinse open eye with water for several minutes; Remove Contact Lenses if present. Seek Medical Advice.
Ingestion Rinse Mouth with water; Allow patient (if conscious) to drink water; If any symptoms develop contact medical aid.
- SECTION 4.2 Most Important Symptoms and Effects (Acute & Delayed)**
 Narcotic/CNS Effects &/or irritation of Mucous Membranes and Eyes. Symptoms may include Coughing, Somnolence or Confusion. Slow Heartbeat &/or Arrhythmia may also be observed. May Cause Allergic Reaction.
- SECTION 4.3 Indication of Any Immediate Medical Attention & Special Treatment Needed**
Notes to Medical Physician Only: Accidental Exposure/Overdose (to individuals other than the patient animal):
 Treat Symptomatically & Supportively. Consider administration of charcoal slurry for acute ingestions of large volumes.
 Monitor for hypotension, seizures & electrolyte disturbances.

SECTION 5 FIREFIGHTING MEASURES

- SECTION 5.1 Extinguishing Media**
Suitable Extinguishing Media Use Suitable Media for Surrounding Fire. (Water Spray/ CO2/Dry Powder)
Unsuitable Extinguishing Media None Known
- SECTION 5.2 Special Hazards (arising from substance/mixture)**
Hazardous Thermal Decomposition Products Product Considered Non Flammable/Non Combustible. However degradation may occur in extreme conditions and could result in emission of toxic gases (-F)
- SECTION 5.3 Advice for Firefighters**
Additional Information: Wear self-contained respiratory protection; Wear Protective Clothing; Evacuate Area.
 Fire Exposure may cause vessel to rupture; Cool containers exposed to flame with water.

SECTION 6 ACCIDENTAL RELEASE MEASURES

- SECTION 6.1 Personal Precautions, Protective Equipment & Emergency Procedures**
For Non-Emergency Personnel Do not walk through, touch or attempt to contain spilled material without PPE. Refer to Section 8 for PPE
 Unnecessary personnel should be removed from area.
For Emergency Personnel Refer to Section 8 for required PPE to contain spillage. Affected area may then be cleaned with water.
- SECTION 6.2 Environmental Precautions**
 Avoid Run-Off to Soil/Waterways in large volumes
- SECTION 6.3 Materials/Methods (for containment and clean-up)**
 Absorb large volumes of spilled material for standard waste disposal.

SECTION 7 HANDLING & STORAGE

- SECTION 7.1 Precautions for Safe Handling (Refer to section 4 for First Aid Protocols)**
 Avoid contact with skin and eyes. Wash Hands after use. Keep container safely secured when not in use. Keep all medicines away from children & pets; Children are particularly at risk from product and may prove harmful. Pets can be overly susceptible to Toxicity therefore; access & exposure to this product should be restricted.
- Finished Product For Persons Administering the Product**
 In all cases of accidental exposure through ingestion, contact medical physician immediately. Avoid contact with Skin & Eyes. Avoid Inhalation of Mists/Vapours.
- SECTION 7.2 Conditions for Safe Storage (including incompatibilities)**
 No special storage conditions. Recommended to be stored under 30°C, dry, & well ventilated area.
 Avoid storing in direct sunlight Do not store in freezing condition.
- SECTION 7.3 Specific End Use(s): Use ONLY as detailed in Section 1.2**

SECTION 8 EXPOSURE CONTROLS/ PERSONAL PROTECTION

SECTION 8.1

Exposure Controls

Sevoflurane CAS: 28523-86-6 TWA 10ppm

Environmental Exposure Controls

None specified; Emissions from processes should meet requirements of environmental protection legislation.

SECTION 8.2

Control Parameters

List of PPE is as follows: Finished Product itself requires no Respiratory Protection under normal conditions of use and a well ventilated environment. Gloves are recommended & wash hands thoroughly after handling product. Eye protection not normally required when handling the finished product, protective eyewear (EN 166) is recommended when working with large or bulk volumes, or where the risk of exposure is increased.

SECTION 9 PHYSICAL & CHEMICAL PROPERTIES

SECTION 9.1

Information on Basic Physical & Chemical Properties

	FINISHED PRODUCT
APPEARANCE: Form/Colour	Clear, Colourless, Volatile Liquid
Odour	Characteristic
Odour Threshold	Not Available
.pH	7.0-7.5
Melting/Freezing Point	Not Available
Boiling Point (Range)	58.6°C (760mm Hg)
Flash Point	Not Available
Evaporation Rate	Not Available
Flammability	Not Flammable
Upper/Lower Explosive Limits	Not Available
Vapour Pressure	209.2 mbar @ 20°C
Vapour Density	6.94 (air = 1)
Relative Density	1.520-1.525 g/cm ³ @ 20°C
Solubility	0.01g/L (Water) , Miscible in Ethanol
Partition Coefficient n-octanol/water	Not Available
Auto-Ignition Temperature	Not Available
Decomposition Temperature	Not Available
Viscosity	Not Available
Explosive properties	Not Available
Oxidising Properties	None

SECTION 9.2

Other Information; No other information available Refer to Section 10

SECTION 10 STABILITY & REACTIVITY DATA

SECTION 10.1

Reactivity

Considered Stable

SECTION 10.2

Chemical Stability

Stable under Normal Conditions

SECTION 10.3

Possibility of Hazardous Reactions

None Listed or Known

SECTION 10.4

Conditions to Avoid

No Specific Data (Refer to Section 7.2) Avoid Extremes of Light & Heat

SECTION 10.5

Incompatible Materials

Strong Bases; Alkaline Metals.

SECTION 10.6

Hazardous Decomposition Products

Normal Conditions NONE Known: Refer to Section 5 (fire conditions)

SECTION 11 TOXICOLOGICAL INFORMATION

SECTION 11.1 Information on Toxicological Effects

SECTION 11.1.1 Acute Toxicity

Ingredient	LD50	Species	Result
SEVOFLURANE	Oral	Rat	10,800.00 mg/kg
	Inhalation		28,800 ppm (3Hr)
	Oral	Mouse	18,200.00 mg/kg
	Inhalation		28,300 ppm (3Hr)

SECTION 11.1.2 Skin Irritation/Corrosion Data

No Available Data for Finished Product.

SECTION 11.1.3 Eye Irritation/Damage Data

Finished Product Classified as Cat 2A: Causes Serious Eye Irritation

SECTION 11.1.4 Respiratory &/or Skin Sensitisation Data

No Available Data for Finished Product. NO Specific Data for Ingredients.

SECTION 11.1.5 Germ Cell Mutagenicity

Finished Product Not Classified. Contains NO ingredient classified as Mutagenic. Sevoflurane NEGATIVE under Ames, Micronucleus, & Mouse Lymphoma Assays

SECTION 11.1.6 Carcinogenicity

Finished Product Not Classified. Contains NO ingredient classified as Carcinogenic.

SECTION 11.1.7 Reproductive Toxicity

Sevoflurane Classified as Repr. Cat 2 Suspect. Material inhibits uterine contractions during delivery, prolonging labour & increasing blood loss.

SECTION 11.1.8 STOT- Single Exposure

Finished Product Classified under STOT-SE as Cat 3 May Cause Drowsiness or Dizziness (Narcotic Effects).

SECTION 11.1.9 STOT- Repeated Exposure

Finished Product Not Classified. Contains NO ingredient classified under STOT-RE.

SECTION 11.1.10 Aspiration Hazard

Finished Product Not Classified.

SECTION 12 ECOLOGICAL INFORMATION

SECTION 12.1	Toxicity	Not Classified
SECTION 12.2	Persistence & Biodegradability	No Available Data
SECTION 12.3	Bioaccumulative Potential	No Available Data
SECTION 12.4	Mobility in Soil	No Available Data
SECTION 12.5	Results of PBT & vPvB Assessment	No Available Data
SECTION 12.6	Other Adverse Effects	No Available Data

SECTION 13 DISPOSAL CONSIDERATIONS

SECTION 13.1 Waste Treatment Methods

It is recommended that large volumes of this product disposed of in accordance with Local Authority Requirements & National Regulations.

SECTION 14 TRANSPORT INFORMATION

SECTION 14.1 UN Number
UN 3334

SECTION 14.2 UN Proper Shipping Name
Aviation Regulated Liquid, n.o.s. (Sevoflurane)

SECTION 14.3 Transport Hazard Class-(es)
9

SECTION 14.4 Packing Group
III

SECTION 14.5 Environmental Hazard(s)
Not Applicable

SECTION 14.6 Special Precautions for User
Not Applicable/No Specific Data

SECTION 14.7 Transport in Bulk
Not Applicable

Please Note: Sevoflurane does not meet the definition of Dangerous Goods under ADR or IMDG

SECTION 15 OTHER REGULATORY INFORMATION

SECTION 15.1 Safety, Health & Environmental Regulations/Legislation
(Specific for the substance/mixture) Data Not Available

SECTION 15.2 Chemical Safety Assessment
Data Not Available

SECTION 16 OTHER INFORMATION

Document History Version 1 (Created 13th-May-2019)
Revised Sections Not Applicable
Prepared by Materials Safety Data Officer, Chanelle Pharmaceuticals Ltd.
Information Source(s) Supplier SDS, Pharmacopeia Databases and Equivalent Finished Product SDS.
Abbrev. Legend Listed in alphabetical order.

• ADR	: "Accord-Dangereuses-Route" Dangerous Goods by Road; European Agree	• IBC	: Intermediate Bulk Container
• ATE	: Acute Toxicity Estimate	• IMDG	: International Maritime code for Dangerous Goods
• API	: Active Pharmaceutical Ingredient	• LCS0	: Lethal Concentration 50 %
• BCF	: Bio-concentration Factor	• LD50	: Lethal Dose, 50%
• CAS	: Chemical Abstracts Service	• LQ	: Limited Quantity (stated in ADR-LQ)
• EINECS	: European Inventory of Existing Chemical Substances	• MARPOL 73/78	: International Convention for the Prevention of Pollution from Ships
• EmS	: Emergency Schedule (Code of Emergency Labelling)	• NOEC	: No Observable Effect Concentration
• GHS	: Globally Harmonised System (of Classification and Labelling of Chemicals)	• N.O.S	: "Not Otherwise Specified"
• IATA	: International Air Transport Association	• UN	: United Nations

Continued →

Section 16: continued from previous page.

Precautionary Statements [From Section 2]			
Prevention	Response	Storage	Disposal
P201-Obtain Special Instructions Before Use	P304+P340-IF INHALED: Remove Person to Fresh Air and Keep Comfortable for Breathing.	P403+P233 Store in a Well-Ventilated Place. Keep Container Tightly Closed	P501 – Dispose of contents/container to details listed in Section 13.1
P202- Do Not Handle until all Safety Precautions have been Read and Understood	P305+P351+P338- IF IN EYES: Rinse Cautiously with Water for Several Minutes. Remove Contact Lenses, if present, and easy to do. Continue Rinsing.	P405-Store Locked Up	
P261-Avoid breathing mist/spray	P308 + P313 – IF exposed or concerned: Get medical advice/attention.		
P264-Wash [Hands] thoroughly after handling.	P312 Call a POISON CENTER/ doctor/physician if you feel unwell		
P271-Use outdoors or in a well-ventilated area	P313+P337-If Eye Irritation Persists: Get Medical Advice/Attention.		
P280-Wear protective gloves/protective clothing/eye protection/ face protection			

IMPORTANT NOTICE:

All Information contained herein is accurate to the best of our knowledge, however the above named supplier, nor any of its subsidiaries nor affiliates assumes any liability whatsoever for the accuracy, completeness, or absence of the information contained herein. All materials contained by this document may present their own hazards and should be used with caution. Neither the Chanelle group, subsidiaries, nor affiliates guarantee that the information contained by this SDS is complete, nor do they provide any guarantee, contract or liability that other hazards exist. Final determination of the suitability of any material or information supplied rests solely with the user. No guarantee or warranty of any kind is offered either express or implied with respect to the information and recommendations contained herein. We accept no responsibility and disclaim all liability for any harmful effects that may be caused by (Incorrect) use, handling, purchase, resale or exposure to our product. Customers and users of our product must comply with all applicable health and safety laws, regulations and orders. In particular they are under an obligation to carry out a risk-assessment for the particular work place and to take adequate risk management measures in accordance with the national implementation legislation of EU directive 89/391/98 – 24.

Prepared by: 
Material Safety Data Officer

Date of Approval: 13/05/2019

END OF SDS