



MATERIAL SAFETY DATA SHEET

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First Issue: Sept 30 2004 (Dainippon); March 17 2011 (Eisai)

Revised: 17th March 2011


Version Number: 1.0

Prepared by: Joanna Wood

Section 1 Chemical Product and Company Identification

Chemical Name	1,2-benzisoxazole-3-methanesulfonamide
Drug Substance Name	Zonisamide
Development Code or Other Names	None
CAS Number	68291-97-4
Recommended Use	Pharmaceutical API
Manufacturer/Supplier	Dainippon Pharmaceutical Co. Ltd (Supplier: Eisai Co Ltd)
Telephone Number	Dainippon: +81-6-6454-8176/+81-6-6458-8640 Eisai: 877-873-4724
Email Address / Website	eisai_ehs@eisai.com www.eisai.com
24 Hour Emergency Number	CHEMTREC 800-424-9300 Internationally 703-527-3887
Fax Number	Eisai: 732-791-1399

Section 2 Hazards Identification

GHS Classification	Specific target organ toxicity, repeated exposure Cat.1 Reproductive toxicity cat 1B	
GHS Label Element(s)		
Signal Word(s)	Danger	
GHS Hazard Statement(s)	H360	May damage fertility or the unborn child.
	H372	Causes damage to organs through prolonged or repeated exposure.
Precautionary Statement(s)	P202	Do not handle until all safety precautions have been read and understood.
	P264	Wash thoroughly after handling.
	P281	Use personal protective equipment as required
	P308 & P313	IF exposed or concerned: Get medical advice/attention.
	P501	Dispose of contents/container in



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		accordance with local/regional/national/international regulation
Health Risk Statement(s)	R61	May cause harm to unborn child
	R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed

Other Hazards

Health	
Route of Entry	Ingestion, Inhalation, Skin contact/absorption, Eye contact
Inhalation	No information available
Eye Contact	No information available
Skin Contact	Sulfonamides may cause hypersensitization reactions
Ingestion	No information available
Fire & Explosion	
No information available	
Environment	
No information available	

Section 3 Composition/ Information on Ingredients

Chemical Name	1,2-benzisoxazole-3-methanesulfonamide
Synonyms	Zonisamide
CAS #	68291-97-4
Molecular Formula	C ₈ H ₈ N ₂ O ₃ S
Molecular Weight	212.23
Purity	98-102%
NIOSH/RTECS NO.	None
EU Classification	MU, H360/372

Section 4 First Aid Measures

Short-term toxic effects of this compound in humans are unknown. The following general precautions should be observed.

Ingestion	Seek medical attention immediately. Never give anything by mouth to someone who is unconscious or convulsing. Never
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	attempt to induce vomiting.
Inhalation	Using appropriate personal protective equipment (PPE), move person to fresh air and keep them warm and calm. If not breathing, administer artificial respiration. Seek immediate medical attention.
Eye contact	Flush eyes with clean running water for at least 15 minutes. Seek medical attention.
Skin contact	Using appropriate personal protective equipment (PPE), remove contaminated clothing and rinse the site of contact with plenty of water. Seek medical attention if skin reaction occurs, which may be immediate or delayed.
Notes To Health Professional	
Medical treatment	Treat according to locally accepted protocols

Section 5 Fire Fighting Measures

Fire & Explosion Hazards	No information available
Suitable Extinguishing Media	Use dry chemical, foam or water spray as appropriate for the surrounding fire and materials.
Special Fire Fighting Procedures	Wear protective clothing and self-contained breathing apparatus as appropriate for surrounding fire. Firefighters Should Wear Proper Protective Equipment And Self-Contained Breathing Apparatus With Full Facepiece Operated In Positive Pressure Mode.
Specific hazards arising from the material	
By Products	None determined
Decomposition Products	None determined

Section 6 Accidental Release Measures

For spillages, cordon the area off and use personal protective equipment according to local protocols and any guidance provided in section 8 of this SDS. Clean up spills in a manner that does not disperse dust into the air. Do not allow materials to enter service drainage systems or sewers.

Powder form:

1. Wet the spilled area with paper towels saturated in methanol first to reduce airborne powder generation.



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2. Continue to wipe the area until large amounts of material have been removed. Follow by washing area with water.
3. Discard all clean-up materials as hazardous waste as per local, state and federal regulations.

Section 7 Handling and Storage

Conditions for Safe Storage	This compound should be stored in a closed container.
General requirements:	<ol style="list-style-type: none">1. Substance should be in non-dusty form (e.g., solution or suspension) prior to removal from ventilated hood or enclosure or within secondary containment.2. Equipment and work surfaces should be cleaned daily (wet-wiping of potentially contaminated surfaces with a suitable solvent until visible clean at minimum). If lab bench absorbent paper is used, it should be changed at least daily3. Wet methods or a HEPA filtered vacuum system should be used for spill containment and clean up.4. Depending on the scale of the operation use of appropriate exhaust ventilation is recommended to provide routine control of fire and explosion hazards during handling of this material5. General good hygiene practices should be followed at all times whilst handling the chemical
Protective Systems	An assessment of the operations should be made to determine the suitability of any protective systems used as precautionary measures against health or physical chemical properties.

Section 8 Exposure Controls/Personal Protection

Eisai Occupational Exposure Band (OEB)	Not Applicable. OEL established
Eisai Occupational Exposure Limit (OEL)	400µg/m ³ 8 hour Time Weighted Average
Eisai Acceptable Surface Limit (ASL)	Not determined



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Occupational Hygiene Air/Surface Monitoring Methods	An occupational/industrial hygiene monitoring method has not yet been developed for this material. For further advice, seek guidance from a qualified environment, health and safety professional
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Engineering Controls

Containment / Ventilation	Open handling of powders should be avoided. Appropriate containment and/or ventilation should be utilized wherever possible in accordance with Eisai's chemical entity handling guidelines If the procedures have a potential for aerosolization, they should be handled in a vented safety enclosure or with local exhaust ventilation.
Administrative	Controlled access to the working area should be in place in accordance with Eisai's chemical entity handling guidelines. Procedures should be adopted to prevent exposure and contamination of the working area.

Personal Protective Equipment

Respiratory Protection	Where containment or local ventilation is not available or sufficient, a protective dust mask should be worn by all personnel in the immediate area.
Eye Protection	Approved Safety glasses with sideshields.
Skin protection	Protective garments (for example, laboratory coat or disposable suit) and gloves are recommended. Gloves that are appropriate for the process being undertaken should be selected and must take into account any solvents or other hazards present.



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Section 9 Physical and Chemical Properties

Appearance (Colour and physical form)	White to pale yellow crystals or crystalline powder
Odor	Not determined
Odor Threshold	Not determined
pH (Aqueous)	6.96
Melting point/Freezing Point	Melting point 164-168°C
Initial Boiling Point and Boiling Range	Not determined
Flashpoint	Not determined
Evaporation Rate	Not determined
Flammability (solid, gas)	Not determined
Upper/lower flammability or explosive limits	Not determined
Vapor Pressure(Mm Hg)	Not determined
Vapor Density(Air=1)	Not determined
Relative density	Not determined
Solubility	Freely soluble in acetone Sparingly soluble in methanol Slightly soluble in ethanol Very slightly soluble in water Very slightly soluble in ether Very slightly soluble in chloroform
Partition coefficient: n-octanol/water	Log P=3.24
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Specific Gravity	Not determined
Viscosity	Not determined
Hygroscopicity	Not determined
% Volatiles By Volume	Not determined
Oxidizing properties	Not determined
Minimum Ignition Energy	Not determined
Dust Explosion Properties	Not determined
Group	
Pmax	
Kst	
St Class	



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Section 10 Stability and Reactivity Data

Stability	Stable under normal storage and handling conditions
Hazardous Polymerization	Not determined
Conditions To Avoid	Not determined
Decomposition Products	Not determined
Incompatible materials	Not determined

Section 11 Toxicological Information

Toxicity:	<u>Acute toxicity:</u> LD ₅₀ p.o mouse: ca 2000mg/kg LD ₅₀ p.o rat: ca 2000mg/kg LD ₅₀ p.o dog: ca. 1000mg/kg <u>Subacute Toxicity:</u> No effective dose in p.o. administration 20mg/kg/day in rats (3 months) 10mg/kg/day in dogs (2 months) <u>Chronic Toxicity:</u> No effective dose in p.o. administration 10mg/kg/day in rats (9 months) 10mg/kg/day in dogs (12 months)
Carcinogenicity:	No carcinogenic response in rats (80mg/kg/day for 2 years)
Mutagenicity	Negative
Teratogenicity	No effective dose in Seg II (rat, p.o) 200mg/kg/day in dams 20mg/kg/day in fetus No effective dose in Seg II (dogs, p.o) 30mg/kg/day in dams 10mg/kg/day in fetus No effective dose in Seg. III (rat, p.o) 60mg.kg.day in dams and pups
Reproductive Toxicity	No effective dose in Seg. I (rat, p.o) 20mg/kg/day in dams and fetus



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Effects Of Overexposure	No information at this time
Target Organs	Central nervous system, liver, kidney, bladder, brain, blood
Routes of Exposure	Possible routes of exposure may include Ingestion, Inhalation, Skin contact/absorption, eye contact
Medical Conditions Generally Aggravated By Exposure	No information at this time
Other Adverse Effects	No information at this time

Section 12 Ecological Information

Summary:

No environmental testing has been conducted at this time, therefore, no information is currently available

Ecotoxicity:	
Fish Toxicity	No data available
Other Aquatic Toxicity	No data available
Persistence & Degradability	
Biodegradability	No data available
Bio accumulative Potential	No data available
Other Adverse Effects	No data available

Section 13 Disposal Considerations

Disposal Procedure: Dispose of API and associated packaging in accordance with all applicable federal, state, and local environmental regulations.

Section 14 Transportation Data And Additional Information

This Material Safety Data Sheet should accompany all shipments for reference in the event of spillage or accidental release.



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DOMESTIC (D.O.T.):

UN Proper shipping name: Not restricted

UN Classification number:

Hazard Class:

Packing Group:

Special Considerations:

INTERNATIONAL (IATA):

UN Proper shipping name: Not restricted

UN Classification number:

Hazard Class:

Packing Group:

Special Considerations:

If the compound is classed in scope of the EU Classification, Labeling & Packaging (CLP) regulations then labeling for transportation must meet these requirements. Contact EH&S for further advice.

Section 15 Regulatory Information

Non-regulated

Section 16 Other Information

Emergency Contact Information:

In case of overexposure or accidental release, please contact CHEMTREC 800-424-9300, Internationally 703-527-3887

References:

- Dainippon MSDS, Number 10120-1 (September 30 2004)
- GHS-CLP and EU DSD Classification for Zonisamide (prepared by TOXDOC1, LLC, January 24, 2011)
- Zonegran Prescribing Information Limit (revised November 2009)
- Eisai Occupational Exposure Limit Report (August 17, 2004)

Risk Phrases(s)

R61	May cause harm to unborn child
R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed



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SDS Sections Updated:

Section Updated	Sub section Updated
New Eisai Safety Data Sheet to meet EU GHS regulatory requirements	

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