

SAFETY DATA SHEET

According to Regulation (EC). No.1272/2008[CLP]

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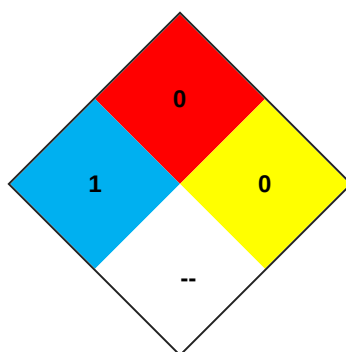
SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

1.1 PRODUCT IDENTIFIERS

Product Name : Macitentan
Synonyms : ACT-064992; ACT 064992; ACT064992; Macitentan; brand name: Opsumit
CAS No. : 441798-33-0
Molecular Weight : 588.27 g/mol
Molecular Formula : C₁₉H₂₀Br₂N₆O₄S

NFPA Rating

Health (Blue);
Flammability (Red);
Reactivity (Yellow);
Specific (White);



NFPA RATING			
Rating	NFPA-Blue	NFPA-Red	NFPA-Yellow
0	None	None	None
1	Very Low	Very Low	Very Low
2	Low	Low	Low
3	High	High	High
4	Very High	Very High	Very High
White (symbol & nature)			
OXY - Oxidizer	W - Use No Water		
ACID - Acid	☢ - Radiation Hazard		
ALK - Alkali	SA - Simple Asphyxiant		
COR - Corrosive	-- - Not Applicable		

1.2 CONTACT INFORMATION

Corporate Office : Laurus Labs Limited, 2nd Floor, Serene Chambers, Road No # 7, Banjara Hills, Hyderabad-500034. Telangana, India. Tel: 040-39804333
Registered Office : Laurus Enclave, Plot Office 01, E.Bonangi Village, Parawada Mandal, Anakapalli District - 531021. Andhra Pradesh, India. Tel: +91 891 682 1101, +91 891 682 1102

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

Hazard Code	Hazard Category	Hazard Description
H360	Category 1A	Reproductive toxicity

2.2 LABEL ELEMENTS:

Pictogram(s):



Signal word: Warning

Hazard Statements:

Hazard Code	Hazard Description
H360	May damage fertility or the unborn child

Precautionary Statements:

Precautionary Code**Precautionary Description**

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container to location in accordance with local/regional/national/international regulations.

2.3 OTHER HAZARDS:

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: COMPOSITION/ INFORMATION ON INGREDIENTS

CAS #	Chemical name	Percent
441798-33-0	Macitentan	NLT 98.0 & NMT 102.0

SECTION 4: FIRST AID MEASURES**4.1 DESCRIPTION OF NECESSARY FIRST-AID MEASURES:****Eye contact:**

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention immediately.

Skin contact:

In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient / Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately / Loosen tight clothing such as a collar, tie, belt or waistband.

4.2 MOST IMPORTANT SYMPTOMS/ EFFECTS - ACUTE AND DELAYED:

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED:

No data available

SECTION 5: FIREFIGHTING MEASURES**5.1 EXTINGUISHING MEDIA:**

Suitable extinguishing media: Water,Foam (AFFF),Special Chemical Powder,ABC Powder,Carbon Dioxide

Unsuitable extinguishing media: For this substance/ mixture no limitations of extinguishing agents are given.

5.2 SPECIFIC HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

Carbon oxides, Nitrogen oxides (NOx), Sulfur oxides, Hydrogen bromide gas and Combustible.

5.3 ADVICE FOR FIRE FIGHTERS:

Wear self contained breathing apparatus for firefighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 PERSONAL PRECAUTIONS PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 ENVIRONMENTAL PRECAUTIONS:

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

During handling wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:

Stored in a well closed container at a temperature not more than 25°C

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 CONTROL PARAMETERS:

No Data available

8.2 EXPOSURE CONTROLS:

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3 PERSONAL PROTECTIVE EQUIPMENT :



Eye & Face protection:

Use personal protective equipment such as Nose mask, goggles & gloves as described by the Indian standard and/or international standard.

Skin & Body protection:

Long sleeved clothing. Gloves must be inspected prior to use.

Respiratory protection:

For nuisance exposures use respirator cartridges. Use respirators and components tested and approved under appropriate government standards.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

Physical state & Appearance	: Solid
Colour	: White to off-white
Odor	: No data available
Odour threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Boiling point / range	: No data available
Flash point	: No data available
Flammability (solid, gas)	: No data available
Flammability or explosive limits - Upper	: No data available
Flammability or explosive limits - Lower	: No data available
Evaporation rate	: No data available
Vapour pressure	: No data available
Vapour density	: No data available
Relative density	: No data available

Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Specific gravity	:	No data available.
Oxidizing properties	:	No data available
Viscosity	:	No data available
Others	:	
Others 1	:	
Others 2	:	

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY:

No data available

10.2 CHEMICAL STABILITY:

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

Violent reactions possible with: Strong oxidizing agents

10.4 CONDITIONS TO AVOID:

No data available.

10.5 INCOMPATIBLE MATERIALS:

No data available.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

Carbon oxides, Nitrogen oxides (NOx), Sulfur oxides, Hydrogen bromide gas and Combustible.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

Acute Toxicity:

Type	Species	Value	Unit	Any other
LD50, Oral	Rat	2000	mg/kg	--
LD50, Oral	Mouse	2000	mg/kg	--

Skin corrosion/irritation:

No data available.

Serious eye damage/eye irritation:

No data available.

Respiratory or skin sensitization:

No data available.

Germ cell mutagenicity:

No data available.

Carcinogenicity:

IARC: No component of this product presents at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Reproductive toxicity:

No data available.

Specific target organ toxicity - single exposure:

No data available.

Specific target organ toxicity - repeated exposure:

No data available.

Aspiration hazard:

No data available.

11.2 ADDITIONAL INFORMATION:

The toxicological properties have not been fully investigated.

SECTION 12: ECOLOGICAL INFORMATION**12.1 ECO-TOXICITY:**

No data available.

Toxicity to algae:

No data available.

12.2 PERSISTENCE AND DEGRADABILITY:**Biodegradability:**

No data available.

12.3 BIOACCUMULATIVE POTENTIAL:

No data available.

12.4 MOBILITY IN SOIL:

No data available.

12.5 OTHER ADVERSE EFFECTS:

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal methods -Waste must be segregated, stored and disposed of in accordance with central, state and local environmental control regulations.

SECTION 14: TRANSPORT INFORMATION

	TRANSPORT	ADR/RID	IMDG	IATA
14.1	UN NUMBER	--	--	--
14.2	UN PROPER SHIPPING NAME	Not a dangerous goods	Not a dangerous goods	Not a dangerous goods
14.3	TRANSPORT HAZARD CLASS(ES)	--	--	--
14.4	PACKING GROUP	--	--	--
14.5	ENVIRONMENTAL HAZARD	--	--	--
14.6	SPECIAL PRECAUTIONS FOR USER	--	--	--
14.7	SYMBOL	--		

SECTION 15: REGULATORY INFORMATION**Safety, health and environmental regulations specific for the substance or mixture**

This safety datasheet complies with the requirements of Regulation (EC) No. 1272/2008.

SECTION 16: OTHER INFORMATION**DISCLAIMER:**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

Revision log:

Revision No.	Reason for Revision	Effective Date
0.0	First Issue	09 Aug 2017
1.0	SDS modified as latest format.	08 Jul 2021
2.0	Changed into new template and sections 1,3,7 & 9 modified	08 Oct 2022
3.0	Sections 2 and 11 Updated as per the reference SDS	07 Dec 2023
4.0	Section 11 Toxicological data included.	25 Jul 2024

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END OF SAFETY DATA SHEET

----- This is an electronically generated SDS, and hence need not be signed -----