



# SWATI SPENTOSE PVT. UNIT-I

Manufacturing Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India

## Safety Data Sheet

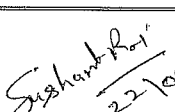

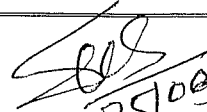
Document No.: FP/SDS/005/02	Revision No.: 02
Effective Date: 25/09/2018	Supersede No.: 01
Product Name: Meloxicam	Page 1 of 13

### 1) Product Information & Company Identification

GHS Product Identifier	Meloxicam
CAS Number	71125-38-7
EC Number	Not available
RTECS #	DL0702000
Molecular Formula	C14H13N3O4S2
Catalog Codes	Not available
Other means of Identification	4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-1,1-dioxide-2h-H-1,2-benzothiazine-3-carboxamide
Recommended use of the chemical and restrictions on use.	Non-steroidal anti-inflammatory drug
Supplier Details Including name, address, phone number etc.)	<b>Swati Spentose Pvt. Ltd.</b> <b>Corporate Office:</b> 114, Marine Chambers, 11 New Marine Lines, Mumbai-400020, India <b>Manufacturing Unit:</b> A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396195, Gujarat, India
Emergency Phone Number	0260-2433133

### 2) Hazards Identification

GHS Classification of the substance/mixture and any regional information	<b>GHS Hazards Classification (According to EU Regulation 1272/2008 and US OSHA 1910.1200)</b> Acute toxicity Oral (Category 3) Skin corrosion/irritation (Category 2) Serious eye damage/eye irritation (Category 2A) Reproductive toxicity (Category 2) Specific target organ toxicity (single exposure) (Category 3)
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Activity	Prepared By	Checked By	Approved By
Sign & Date	 22/09/18	 24/09/18	 25/09/18
Name & Designation	Mr. Sushant Rai Officer-EHS	Mr. Jitendra Varma Project & MNT - Head	Mr. S. K. Srivastava Corporate Head QA & QC

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### Potential Acute Health Effect:

Skin Contact: May cause skin irritation. Eye Contact: Contact with eyes may cause irritation. Inhalation: May cause irritation of respiratory tract. Ingestion: Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting, and diarrhoea. May cause abdominal pain. May cause central nervous system effects. May affect the blood. It may affect the kidneys. May affect the liver. May affect the cardiovascular system.

### Potential Chronic Health Effect:

**Target Organs:** Gastrointestinal tract. Cardiovascular system. Central nervous system. Liver. Kidney

**Carcinogen Status:** Information not available.

**Mutagenic Effects:** Information not available.

**Teratogenic Effects:** Information not available.

**Aggravated Medical Conditions:** Information not available.

### PICTOGRAM



GHS06



GHS07

GHS label elements, including precautionary statements

Signal word Danger

Hazard statements

H301 Toxic if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTRE/ doctor.

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**P305+P351+P338 IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Swati Spentose Pvt. Ltd.  
A-1/2102 & 2103, Phase-III, G.I.D.C  
Vapi-396195, Gujarat, India  
Ph. No: 0260-2433133

Other hazards which do not covered by GHS.

Not Applicable

### 3) Composition/Information on Ingredients

Chemical Identity	<b>Chemical Name:</b> -4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-1,1-dioxide-2h-H-1,2-benzothiazine-3-carboxamide <b>Chemical Formula:</b> -C <sub>14</sub> H <sub>13</sub> N <sub>3</sub> O <sub>4</sub> S <sub>2</sub>
Common Name Synonym	Meloxicam
CAS No.	71125-38-7
Impurities and Stabilizing additives which are themselves classified and which contribute to the classification of the substance.	<b>Impurity:</b> <ul style="list-style-type: none"><li>Ethyl 4- hydroxy-2-methyl-2H-1,2-benzothiazine-3-carboxylate 1,1-dioxide</li><li>2-Amino, 5-methylthiazole</li><li>N-[(2Z)-3, 5-dimethyl thiazol-2(3H)-ylidene]-4-hydroxy-2-methyl-2H-1, 2-benzothiazine-3-carboxamide 1, 1-dioxide</li><li>N-[(2Z)-3-ethyl-5-methylthiazol-2(3H)-ylidene]-4-hydroxy-2-methyl-2H-1, 2-benzothiazine-3-carboxamide 1, 1-dioxide</li></ul>
Concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels.	0.3%
Cut-off level for reproductive toxicity, carcinogenicity and category 1 mutagenicity is <sup>3</sup> 0.1%	Not Applicable

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Cut-off level for all other hazard classes is <sup>3</sup> 1%	Information not available.
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### 4) First-Aid-Measures

Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact and ingestion.	<p><b>Eye Contact:</b> Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.</p> <p><b>Skin Contact:</b> Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.</p> <p><b>Serious Skin Contact:</b> Not available.</p> <p><b>Inhalation:</b> Remove to fresh air. If not breathing, give artificial respiration, give oxygen by trained personnel. Get immediate medical attention.</p> <p><b>Serious Inhalation:</b> Not available.</p> <p><b>Ingestion:</b> Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. DO NOT induce vomiting unless directed to do so by medical personnel.</p> <p><b>Serious Ingestion:</b> Not available</p>
Most important symptoms /Effects/, Acute and Delayed.	Not available.
Indication of immediate medical attention and special treatment needed, if necessary	<p><b>Eye Contact:</b> Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.</p> <p><b>Skin Contact:</b> Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.</p> <p><b>Serious Skin Contact:</b> Not available.</p> <p><b>Inhalation:</b> Remove to fresh air. If not breathing, give</p>

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artificial respiration, give oxygen by trained personnel. Get immediate medical attention.

**Serious Inhalation:** Not available.

### Ingestion:

Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. DO NOT induce vomiting unless directed to do so by medical personnel.

**Serious Ingestion:** Not available

## 5) Fire Fighting Measures

Suitable and unsuitable extinguishing media.

**Flammability of the Product:** May be combustible at high temperature.

**Auto-Ignition Temperature:** Not available.

**Flash Points:** Not available.

**Flammable Limits:** Not available.

**Products of Combustion:** Carbon monoxide; Carbon dioxide; Nitrogen oxides; Sulfur oxides.

**Fire Hazards in Presence of Various Substances:** During heating or in case of fire poisonous gases are produced.

**Suitable Extinguishing media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray mist or foam

**Unsuitable Extinguishing media:** Not Known

Specific hazardous arising from the chemical

Take care as it may decompose upon combustion or in high temperatures to generate poisonous fume.

Special Protective Equipment and precautions for fire-fights

Wear suitable protective equipment.

Fire-fighting equipment / instructions

Fire-extinguishing work is done from the windward and the suitable fire-extinguishing method according to the surrounding situation is used. Uninvolved persons should evacuate to a safe place. In case of fire in the surroundings: Remove movable containers if safe to do so.

Specific methods

Use standard fire fighting procedures and consider the hazards of other involved materials.

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### 6) Accidental Release Measures

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. Avoid breathing dust.
Environmental Precautions. Methods and materials for containment and cleaning up.	Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/surface or ground water.
Methods and material for containment for and cleaning up.	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

### 7) Handling & Storage

Precautions for safe handling	Avoid all contact and inhalation of dust, mists, and/or vapours associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.
Conditions for safe storage, including any incompatibilities	Store in well-closed, light resistant container. This material should be handled and stored per label instructions to ensure product integrity.

### 8) Exposure Controls/Personal Protection

National Exposure Standards	No exposure standard has been allocated for this mixture or any significant ingredient within this mixture.
Biological Limit Values	No biological limit has been allocated for this mixture
Appropriate engineering controls	<b>Engineering Controls:</b> Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust

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because it can control the Contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust generating procedures.

### Individual Protection measures, Such as personal protective equipment

**Eye/face protection:** Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

#### Skin protection

**Hand protection:** Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic no latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Other:** For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Respiratory protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place.

**Thermal hazards:** Not available.

**General hygiene considerations:** Handle in accordance with good industrial hygiene and safety practices.

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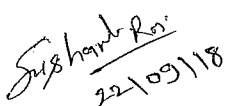
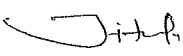
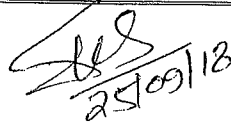
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### 9) Physical and Chemical Properties

Appearance (Physical state, colour, etc.)	Pale yellow powder
Odour	Not available
Taste	Not available
Molecular Weight	351.4
pH(1% soln./water)	5-7
Boiling Point	Not available
Melting Point	469.4 - 507.2 °F (243 - 264 °C) (decomposes)
Critical Temperature	Not available
Specific Gravity	Not available
Vapour Pressure	< 0.0000001 pKa at 25 °C
Vapour Density	Not available
Volatility	Not available
Odour Threshold	Not available
Water/Oil Dist. Coif.	Not available
Ionicity (in Water)	Not available
Dispersion Properties	Not available
Solubility	Practically insoluble in water
Solubility (other)	Soluble in dimethylformamide; slightly soluble in acetone; very slightly soluble in ethanol and in methanol.

### 10) Stability & Reactivity Data

Chemical Stability	Stable at normal condition.
Possibility of Hazardous Reactions	No reactivity hazards known.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Heat
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition	SO <sub>x</sub> , NO <sub>x</sub> . Irritating and/or toxic fumes or gases. Emits toxic fumes x under fire conditions.

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### 11) Toxicological Information

Symptoms related to the physical, chemical, and toxicological characteristics	For non-steroidal anti-inflammatory drugs (NSAIDs): Nausea. Vomiting. Diarrhoea. Constipation. Heartburn. Stomach pain. Black or tarry stools. Bleeding or bruising. Swelling. Sores, ulcers, or white spots on lips or mouth. Sweating. Bluish-colored skin. Insomnia. Mood, mental or behavioural changes. Confusion. Dizziness. Drowsiness. Headache. Itching. Rash. Weight gain. C Vision, speech, or walking problems. Ringing in ears. Tremors. Trouble breathing. Fast heartbeat or palpitations.
Delayed and immediate effects of exposure	For non-steroidal anti-inflammatory drugs (NSAIDs): Gastrointestinal ulceration or bleeding. Hypertension. Kidney impairment. Blood disorders. Cardiovascular thrombotic events. Stroke. Central nervous system effects. Coma.
Medical conditions aggravated by exposure	Persons sensitive to any of the non-steroidal anti-inflammatory drugs, including aspirin, may be sensitive to this material also. This material may cause bronchoconstriction Or anaphylaxis in aspirin-sensitive asthmatics, especially those with aspirin-induced nasal polyps, allergies, and asthma. Special Remarks on other Toxic Effects on Humans: Not available. Dehydration. For non-steroidal anti-inflammatory drugs (NSAIDs): Asthma. Aspirin allergy. Active alcoholism. Anaemia. Impaired kidney or liver function. Cardiovascular disorders. Bleeding disorders. Peptic ulcer or gastrointestinal bleeding. Hypertension. Steatitis
Acute toxicity	Toxic if swallowed.
LD50 (oral-mouse)	470mg/kg
LD50 (oral-rat)	83.5mg/kg
Dermal LD50	No data available
Inhalation LC50	No data available
Local effects	Eye irritancy: Result: Non-irritant, Species: Rabbit Skin irritancy: Result: Non-irritant, Species: Rabbit Skin sensitization test: Result: Non-sensitizing, Species: Guinea pig

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Mutagenicity	<p>Ames test :Result: Negative</p> <p>Chromosomal aberration assay in human lymphocytes: Result: Negative.</p> <p>Mouse bone marrow micronucleus test: Result: Negative</p>
Carcinogenicity	<p>0.8mg/kg/day Long-term carcinogenicity study, administered orally:</p> <ul style="list-style-type: none"> <li>• Result: Not carcinogenic, Species: Rat, Test Duration: 104 weeks</li> </ul> <p>8mg/kg/day Long-term carcinogenicity study, administered orally:</p> <ul style="list-style-type: none"> <li>• Result: Not carcinogenic, Species: Mouse, Test Duration: 99 weeks</li> </ul>
Reproductive toxicity	<p>Suspected of damaging fertility or the unborn child. Therapeutic use of non-steroidal anti-inflammatory agents (NSAIDs) during the second half of pregnancy is associated with adverse effects in the fetus such as premature closure of the ducts arteries, which may lead to persistent pulmonary hypertension in the newborn. Animal studies have shown that NSAIDs administered during late pregnancy can cause prolonged gestation, difficult labour, delayed birth, and decreased pup survival rates.</p>
Reproductively	<p>4mg/kg/day Reproductively and development study, administered orally during Organogenesis.</p> <ul style="list-style-type: none"> <li>• Result: No teratogenicity observed, Species: Rat</li> </ul> <p>5 - 9 mg/kg/day Fertility study, administered orally.</p> <ul style="list-style-type: none"> <li>• Result: No impairment of fertility noted, Species: Rat</li> </ul> <p>60mg/kg/day Reproductively and development study, administered orally during organogenesis.</p> <ul style="list-style-type: none"> <li>• Result: Increased incidence of heart defects, Species: Rabbit</li> </ul> <p>&gt; 1mg/kg/day Reproductively and development study, administered orally prior to and during early gestation.</p> <ul style="list-style-type: none"> <li>• Result: Embryo lethality, Species: Rat</li> </ul> <p>&gt;= 5mg/kg/day Reproductively and development study, administered orally during organogenesis.</p> <ul style="list-style-type: none"> <li>• Result: Embryo lethality, Species: Rabbit</li> </ul> <p>Specific target organ toxicity repeated exposure: Causes damage to organs (cardiovascular system, gastrointestinal tract) through prolonged or repeated exposure</p>

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### 12) Ecological Information

Eco toxicity (aquatic and terrestrial, where available).	EC50/48h: 50mg/l (dolphin) IC50/72h: 13mg/l (Algae) LC50/96h: 50mg/l (fish)
BOD5 and COD	Not available
Products of Biodegradation	Not readily biodegradable.
Toxicity of the Products of Biodegradation	Not available
Special Remarks on the Products of Biodegradation	Not available

### 13) Disposal Consideration

Description of waste residues and information on their safe handling and methods of disposal, including any contaminated packing.	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. 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.
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### 14) Transport Information

UN Number DOT, ADR, IMDG, IATA	2811
UN Proper Shipping Name DOT, ADR, IMDG, IATA	Toxic Solid Organic N.O.S. (Meloxicam)
Transport Hazard Class: DOT, ADR, IMDG, IATA	6.1 Toxic substances
Packing Group: DOT, ADR, IMDG, IATA	III
Environmental hazards: Marine pollutant:	No
Additional Transport Information	Transport in accordance with local, State and Federal regulations

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### 15) Other Regulatory Information

Safety, Health and environmental regulations specific for the product on question.

#### Section 355 (extremely hazardous substances):

Substance is not listed.

#### Section 313 (Specific toxic chemical listings):

Substance is not listed.

#### TSCA (Toxic Substances Control Act):

Substance is not listed.

· Proposition 65

· Chemicals known to cause cancer: Substance is not listed.

· Chemicals known to cause reproductive toxicity for females: Substance is not listed.

· Chemicals known to cause reproductive toxicity for males: Substance is not listed.

· Chemicals known to cause developmental toxicity: Substance is not listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency) Substance is not listed.

· TLV (Threshold Limit Value established by ACGIH) Substance is not listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.

· GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

#### · PICTOGRAM



**GHS06**



**GHS07**

Signal word Danger

Hazard statements

H301 Toxic if swallowed.

H315 Causes skin irritation.

Safety, Health and environmental regulations specific for the product on question.

Activity	Prepared By	Checked By	Approved By
Sign & Date	<i>Sushant Rai</i> 22/09/18	<i>Jitendra</i> 24/09/18	<i>S.K. Srivastava</i> 25/09/18
Name & Designation	Mr. Sushant Rai Officer-EHS	Mr. Jitendra Varma Project & MNT - Head	Mr. S. K. Srivastava Corporate Head QA & QC

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# SWATI SPENTOSE PVT. UNIT-I

Manufacturing Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India

## Safety Data Sheet

Document No.: FP/SDS/005/02	Revision No.: 02
Effective Date: 25/09/2018	Supersede No.: 01
Product Name: Meloxicam	Page 13 of 13

**H319** Causes serious eye irritation.

**H335** May cause respiratory irritation.

### Precautionary statements

**P261** Avoid breathing dust/fume/gas/mist/vapours/spray

**P264** Wash thoroughly after handling.

**P280** Wear protective gloves/protective clothing/eye protection/face protection.

**P301+P310 IF SWALLOWED:** Immediately call a POISON CENTRE/ doctor.

**P305+P351+P338 IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

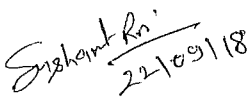
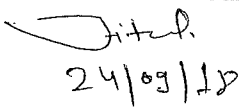
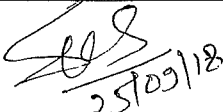
**Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16) Other Information

Other information including information on preparation and revision of SDS

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall **Swati Spentose Pvt. Ltd. Unit-I**. Be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if **Swati Spentose Pvt. Ltd. Unit-I**. Has been advised of the possibility of such damages.

-----\* End of Document \*-----

Activity	Prepared By	Checked By	Approved By
Sign & Date	 22/09/18	 24/09/18	 25/09/18
Name & Designation	Mr. Sushant Rai Officer-EHS	Mr. Jitendra Varma Project & MNT - Head	Mr. S. K. Srivastava Corporate Head QA & QC

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