

according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 1272/2008

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking

- 1.1 Product Code:** 15141
Product Name: Roflumilast
Synonyms: 3-(cyclopropylmethoxy)-N-(3,5-dichloro-4-pyridinyl)-4-(difluoromethoxy)-benzamide; B 9302-107; BY 217; BYK 20869; Daxas;
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant identified uses: For research use only, not for human or veterinary use.
- 1.3 Details of the Supplier of the Safety Data Sheet:**
- Company Name:** Cayman Chemical Company
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108
- Web site address:** www.caymanchem.com
- Information:** Cayman Chemical Company +1 (734)971-3335
- 1.4 Emergency telephone number:**
- Emergency Contact:** CHEMTREC Within USA and Canada: +1 (800)424-9300
CHEMTREC Outside USA and Canada: +1 (703)527-3887

Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture:**
- 2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]:**
Acute Toxicity: Oral, Category 3
Toxic To Reproduction, Category 2
Toxic To Reproduction, Effects on or via lactation
Target Organ Systemic Toxicity (single exposure), Category 3
Aquatic Toxicity (Chronic), Category 4
- 2.1.2 Classification according to Directive 1999/45/EC:**
T: Toxic
Reproductive Hazard: 3
Risk Phrases: R25, R53, R63, R64, R67
For full text of R- phrases: see SECTION 15.
- 2.2 Label Elements:**
- 2.2.1 Labeling according to Regulation (EC) No 1272/2008 [CLP]:**



GHS Signal Word: **Danger**

GHS Hazard Phrases:

- H301: Toxic if swallowed.
H361: Suspected of damaging fertility or the unborn child.
H362: May cause harm to breast-fed children.
H335: May cause respiratory irritation.
H413: May cause long lasting harmful effects to aquatic life.

GHS Precaution Phrases:

- P264: Wash {hands} thoroughly after handling.
- P201: Obtain special instructions before use.
- P202: Do not handle until all safety precautions have been read and understood.
- P281: Use personal protective equipment as required.
- P263: Avoid contact during pregnancy/while nursing.
- P260: Do not breathe {dust/fume/gas/mist/vapours/spray}.
- P261: Avoid breathing {dust/fume/gas/mist/vapours/spray}.
- P273: Avoid release to the environment.

GHS Response Phrases:

- P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- P330: Rinse mouth.
- P308+313: IF exposed or concerned: Get medical attention/advice.
- P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P312: Call a {POISON CENTER/doctor/...} if you feel unwell.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.2.2 Labeling according to Directive 1999/45/EC:



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Reproductive Hazard: 3

- 2.3 Adverse Human Health** Material may be irritating to the mucous membranes and upper respiratory tract.
- Effects and Symptoms:**
- May be harmful by inhalation or skin absorption.
 - May cause eye, skin, or respiratory system irritation.
 - May cause harm to breast-fed children.
 - May cause respiratory irritation.
 - May cause long lasting harmful effects to aquatic life.
 - Suspected of damaging fertility or the unborn child.
 - Toxic if swallowed.
 - To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	Risk Phrases/ GHS Classification
162401-32-3 NA	Roflumilast	100.0 %	NA NA	T; Rp:3, R25-53-63-64-67 Acute Tox.(O) 3: H301 TOST (SE) 3: H335 H336 Toxic Repro. 2: H361 Toxic Lactate: H362 Aquatic (C) 4: H413

Section 4. First Aid Measures

- 4.1 Description of First Aid Measures:** No data available.
- In Case of Inhalation:** Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
- In Case of Skin Contact:** 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.
- In Case of Eye Contact:** Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
- In Case of 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.

Section 5. Fire Fighting Measures

- 5.1 Suitable Extinguishing Media:** Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.
- Unsuitable Extinguishing Media:** A solid water stream may be inefficient.
- 5.2 Flammable Properties and Hazards:** No data available.
- Flash Pt:** No data.
- Explosive Limits:** LEL: No data. UEL: No data.
- Autoignition Pt:** No data.
- 5.3 Fire Fighting Instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

- 6.1 Protective Precautions, Protective Equipment and Emergency Procedures:** Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
- 6.2 Environmental Precautions:** Take steps to avoid release into the environment, if safe to do so.
- 6.3 Methods and Material For Containment and Cleaning Up:** Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7. Handling and Storage

- 7.1 Precautions To Be Taken in Handling:** Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.
- 7.2 Precautions To Be Taken in Storing:** Keep container tightly closed. Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

CAS #	Partial Chemical Name	Britain EH40	France VL	Europe
162401-32-3	Roflumilast	No data.	No data.	No data.

CAS #	Partial Chemical Name	OSHA TWA	ACGIH TWA	Other Limits
162401-32-3	Roflumilast	No data.	No data.	No data.

8.2 Exposure Controls:

8.2.1 Engineering Controls Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne (Ventilation etc.): levels below recommended exposure limits.

8.2.2 Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves

Other Protective Clothing: Lab coat

Respiratory Equipment NIOSH approved respirator, as conditions warrant.

(Specify Type):

Work/Hygienic/Maintenance Practices: Do not take internally.

Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.

Wash thoroughly after handling.

No data available.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Physical States: [] Gas [] Liquid [X] Solid

Appearance and Odor: A crystalline solid

Melting Point: No data.

Boiling Point: No data.

Flash Pt: No data.

Evaporation Rate: No data.

Explosive Limits: LEL: No data. UEL: No data.

Vapor Pressure (vs. Air or mm Hg): No data.

Hg):

Vapor Density (vs. Air = 1): No data.

Specific Gravity (Water = 1): No data.

Solubility in Water: No data.

Solubility Notes: ~0.25 mg/ml in 1:3 DMF:PBS (pH 7.2); ~10 mg/ml in EtOH; ~20 mg/ml in DMSO; ~30 mg/ml in DMF;

Autoignition Pt: No data.

9.2 Other Information

Percent Volatile: No data.

Molecular Formula & Weight: C₁₇H₁₄Cl₂F₂N₂O₃ 403.2

Section 10. Stability and Reactivity

10.1 Reactivity: No data available.

10.2 Stability: Unstable [] Stable [X]

10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.

Polymerization: Will occur [] Will not occur [X]

10.4 Conditions To Avoid: No data available.

10.5 Incompatibility - Materials To Avoid: strong oxidizing agents

10.6 Hazardous Decomposition Or carbon dioxide

carbon monoxide

nitrogen oxides

Byproducts:

Section 11. Toxicological Information

11.1 Information on Toxicological Effects: The toxicological effects of this product have not been thoroughly studied.
Roflumilast - Toxicity Data: Oral TDLO (rat): 1089 µg/kg; Subcutaneous TDLO (mouse): 30 mg/kg; Oral TDLO (rat): 0.24 mg/kg;

Chronic Toxicological Effects: Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.
Roflumilast RTECS Number: CV3325600

Carcinogenicity: NTP? No IARC Monographs? No OSHA Regulated? No

Section 12. Ecological Information

12.1 Toxicity: Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.

12.2 Persistence and Degradability: No data available.

12.3 Bioaccumulative Potential: No data available.

12.4 Mobility in Soil: No data available.

12.5 Results of PBT and vPvB assessment: No data available.

Section 13. Disposal Considerations

13.1 Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

Section 14. Transport Information

14.1 LAND TRANSPORT (US DOT):

DOT Proper Shipping Name: Not dangerous goods.
DOT Hazard Class:
UN/NA Number:

14.1 LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Not dangerous goods.
UN Number:
Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods.

Additional Transport Information: Transport in accordance with local, state, and federal regulations.

Section 15. Regulatory Information

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

CAS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
162401-32-3	Roflumilast	No	No	No

CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists
162401-32-3	Roflumilast	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No

European Community Hazard Symbol codes:



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Reproductive Hazard: 3

European Community Risk and Safety Phrases:

R25	Toxic if swallowed.
R53	May cause long-term adverse effects in the aquatic environment.
R63	Possible risk of harm to the unborn child.
R64	May cause harm to breastfed babies.
R67	Vapours may cause drowsiness and dizziness
S24/25	Avoid contact with skin and eyes.
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label whenever possible.)

Regulatory Information Statement: This SDS was prepared in accordance with 29 CFR 1910.1200, Regulation (EC) No.1272/2008, and European Directive 67/548/EEC as amended.

Section 16. Other Information

Revision Date: 11/26/2014

Additional Information About No data available.

This Product:

Company Policy or Disclaimer: DISCLAIMER: This information 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.