

SAFETY DATA SHEET Ivacaftor

Page: 1 of 6

Revision: 11/26/2014

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: 15145
Product Name: Ivacaftor

Synonyms: N-[2,4-bis(1,1-dimethylethyl)-5-hydroxyphenyl]-1,4-dihydro-4-oxo-3-quinolinecarboxamide;

Kalydeco; VX 770;

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]:
- 2.1.2 Classification according to Directive 1999/45/EC:

Risk Phrases:

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:

GHS Hazard Phrases:

Based on evaluation of currently available data this substance or mixture is not classifiable according to GHS.

GHS Precaution Phrases:

No phrases apply.

GHS Response Phrases:

No phrases apply.

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:

Page: 2 of 6



SAFETY DATA SHEET

Ivacaftor

Revision: 11/26/2014

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, ingestion, or skin absorption.

May cause eye, skin, or respiratory system irritation.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	Risk Phrases/ GHS Classification
873054-44-5 NA	Ivacaftor	100.0 %	No phrases apply. No data available.

Section 4. First Aid Measures

4.1 Description of First Aid No data available.

Measures:

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 Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.

Media: Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing A solid water stream may be inefficient.

Media:

5.2 Flammable Properties and No data available.

Hazards:

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, Avoid raising and breathing dust, and provide adequate ventilation.

Protective Equipment and As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator,

Emergency Procedures: and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Take steps to avoid release into the environment, if safe to do so.

Precautions:

6.3 Methods and Material For Contain spill and collect, as appropriate.

Containment and Cleaning Transfer to a chemical waste container for disposal in accordance with local regulations.

Up:



SAFETY DATA SHEET Ivacaftor

Page: 3 of 6

Revision: 11/26/2014

Section 7. Handling and Storage

7.1 Precautions To Be Taken Avoid breathing dust/fume/gas/mist/vapours/spray.

in Handling: Avoid prolonged or repeated exposure.

7.2 Precautions To Be Taken Keep container tightly closed.

in Storing: 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
873054-44-5	Ivacaftor	No data.	No data.	No data.
0.4.0. //			A COULTINA	
CAS#	Partial Chemical Name	OSHA TWA	ACGIH TWA	Other Limits

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/Maintenan Do not take internally.

ce Practices: 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		Informa	ation or	Basic Ph	ysical and	Chemical	Properties
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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 No data.

Hg):

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

Specific Gravity (Water = 1): No data.

Solubility in Water: No data.

Solubility Notes: ~0.1 mg/ml in EtOH; ~25 mg/ml in DMSO & DMF;

Autoignition Pt: No data.

SAFETY DATA SHEET
Page: 4 of 6

Ivacaftor

Cayman

Revision: 11/26/2014

9.2 Other Information

Percent Volatile: No data.

Molecular Formula & Weight: C24H28N2O3 392.5

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 strong oxidizing agents

To Avoid:

10.6 Hazardous No data available.

Decomposition Or

Byproducts:

Section 11. Toxicological Information

11.1 Information on The toxicological effects of this product have not been thoroughly studied.

Toxicological Effects:

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 No data available.

Degradability:

12.3 Bioaccumulative No data available.

Potential:

12.4 Mobility in Soil: No data available.

12.5 Results of PBT and vPvB No data available.

assessment:

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:



SAFETY DATA SHEET Ivacaftor

Page: 5 of 6

Revision: 11/26/2014

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods.

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

Information:

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)
873054-44-5	Ivacaftor	No	No	No

CAS#	Hazardous Components (Chemical Name)	Other US EPA or State Lists
873054-44-5	Ivacaftor	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No

European Community Hazard Symbol codes:

European Community Risk and Safety Phrases:

S24/25 Avoid contact with skin and eyes.

S37/39 Wear suitable gloves and eye/face protection.

Regulatory Information This SDS was prepared in accordance with 29 CFR 1910.1200, Regulation (EC) No.1272/2008,

Statement: 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.