

# SAFETY DATA SHEETS

According to the UN GHS revision 11

Version: 1.1  
Creation Date: October 19, 2025  
Revision Date: June 26, 2026

## SECTION 1: Identification

### 1.1 GHS Product identifier

Product name Ivacaftor impurity 16

### 1.2 Other means of identification

Product number C4X-296416

Other names -

### 1.3 Recommended use of the chemical and restrictions on use

Identified uses For laboratory and Industrial use only.

Uses advised against no data available

### 1.4 Supplier's details

Company CATO Research Chemicals Inc.

Address 3/F,Building B,No.179 BASIGO, Guangpu Rd East,Huangpu Dist,Guangzhou

Telephone +86-20-81960175

### 1.5 Emergency phone number

Emergency phone number +86-20-81960175

Service hours 'Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

## SECTION 2: Hazard identification

### 2.1 Classification of the substance or mixture

no data available

### 2.2 GHS label elements, including precautionary statements

Pictogram(s) unknown

Signal word no data available

Hazard statement(s) no data available

Precautionary statement(s)

Prevention no data available

Response no data available

Storage no data available

Disposal no data available

### 2.3 Other hazards which do not result in classification

no data available

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

| Chemical name         | Common names and synonyms | CAS number | EC number | Concentration |
|-----------------------|---------------------------|------------|-----------|---------------|
| Ivacaftor impurity 16 | -                         | None       | -         | ≈ 99%         |

## SECTION 4: First-aid measures

### 4.1 Description of necessary first-aid measures

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

**Following ingestion**

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

**4.2 Most important symptoms/effects, acute and delayed**

no data available

**4.3 Indication of immediate medical attention and special treatment needed, if necessary**

no data available

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**SECTION 5: Fire-fighting measures**

**5.1 Suitable extinguishing media**

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

**5.2 Specific hazards arising from the chemical**

no data available

**5.3 Special protective actions for fire-fighters**

Wear self-contained breathing apparatus for firefighting if necessary.

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**SECTION 6: Accidental release measures**

**6.1 Personal precautions, protective equipment and emergency procedures**

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

**6.2 Environmental precautions**

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

**6.3 Methods and materials for containment and cleaning up**

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

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**SECTION 7: Handling and storage**

**7.1 Precautions for safe handling**

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

**7.2 Conditions for safe storage, including any incompatibilities**

Store the container tightly closed in a dry, cool and well-ventilated place. Store apart from foodstuff containers or incompatible materials.

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**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

**Occupational Exposure limit values**

no data available

**Biological limit values**

no data available

**8.2 Appropriate engineering controls**

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

**8.3 Individual protection measures, such as personal protective equipment (PPE)**

**Eye/face protection**

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

**Skin protection**

Wear fire/flammable resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

**Respiratory protection**

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

**Thermal hazards**

no data available

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## SECTION 9: Physical and chemical properties and safety characteristics

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|----------------------------------------------------------|-------------------|
| Physical state                                           | no data available |
| Colour                                                   | no data available |
| Odour                                                    | no data available |
| Melting point/freezing point                             | no data available |
| Boiling point or initial boiling point and boiling range | no data available |
| Flammability                                             | no data available |
| Lower and upper explosion limit/flammability limit       | no data available |
| Flash point                                              | no data available |
| Auto-ignition temperature                                | no data available |
| Decomposition temperature                                | no data available |
| pH                                                       | no data available |
| Kinematic viscosity                                      | no data available |
| Solubility                                               | no data available |
| Partition coefficient n-octanol/water                    | no data available |
| Vapour pressure                                          | no data available |
| Density and/or relative density                          | no data available |
| Relative vapour density                                  | no data available |
| Particle characteristics                                 | no data available |

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

no data available

### 10.2 Chemical stability

no data available

### 10.3 Possibility of hazardous reactions

no data available

### 10.4 Conditions to avoid

no data available

### 10.5 Incompatible materials

no data available

### 10.6 Hazardous decomposition products

no data available

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## SECTION 11: Toxicological information

### Acute toxicity

- Oral: no data available
- Inhalation: no data available
- Dermal: no data available

### Skin corrosion/irritation

no data available

### Serious eye damage/irritation

no data available

### Respiratory or skin sensitization

no data available

### Germ cell mutagenicity

no data available

### Carcinogenicity

no data available

**Reproductive toxicity**

no data available

**STOT-single exposure**

no data available

**STOT-repeated exposure**

no data available

**Aspiration hazard**

no data available

## SECTION 12: Ecological information

### 12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

### 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 Other adverse effects

no data available

## SECTION 13: Disposal considerations

### 13.1 Disposal methods

**Product**

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

**Contaminated packaging**

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

## SECTION 14: Transport information

### 14.1 UN Number

ADR/RID: no data available

IMDG: no data available

IATA: no data available

### 14.2 UN Proper Shipping Name

ADR/RID: no data available

IMDG: no data available

IATA: no data available

### 14.3 Transport hazard class(es)

ADR/RID: no data available

IMDG: no data available

IATA: no data available

### 14.4 Packing group, if applicable

ADR/RID: no data available

IMDG: no data available

IATA: no data available

### 14.5 Environmental hazards

ADR/RID: No

IMDG: No

IATA: No

### 14.6 Special precautions for user

no data available

### 14.7 Transport in bulk according to IMO instruments

no data available

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations specific for the product in question

| Chemical name                                                            | Common names and synonyms | CAS number | EC number   |
|--------------------------------------------------------------------------|---------------------------|------------|-------------|
| -                                                                        | -                         | None       | -           |
| European Inventory of Existing Commercial Chemical Substances (EINECS)   |                           |            | Not Listed. |
| EC Inventory                                                             |                           |            | Not Listed. |
| United States Toxic Substances Control Act (TSCA) Inventory              |                           |            | Not Listed. |
| China Catalog of Hazardous chemicals 2015                                |                           |            | Not Listed. |
| New Zealand Inventory of Chemicals (NZIoC)                               |                           |            | Not Listed. |
| Philippines Inventory of Chemicals and Chemical Substances (PICCS)       |                           |            | Not Listed. |
| Vietnam National Chemical Inventory                                      |                           |            | Not Listed. |
| Chinese Chemical Inventory of Existing Chemical Substances (China IECSC) |                           |            | Not Listed. |
| Korea Existing Chemicals List (KECL)                                     |                           |            | Not Listed. |

## SECTION 16: Other information

### Information on revision

Creation Date                      October 19, 2025

Revision Date                      June 26, 2026

### Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

### References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: [http://www.echemportal.org/echemportal/index?pageID=0&request\\_locale=en](http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en)
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Any questions regarding this SDS, Please send your inquiry to [info@cato-chem.com](mailto:info@cato-chem.com)

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