



MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Name : ZENECA ZD1839

Address/Phone No. : AstraZeneca

PO Box 15437

Wilmington, Delaware 19850-5437

Phone (24 hr.) Medical : (800) 236-9933

Chemtec : (800) 424-9300

Alternative Names

Iressa

ZD1839 Pure

ZD1839 Free Base Pure

2. COMPOSITION/INFORMATION ON INGREDIENTS

Use : signal transduction inhibitor

HAZARDOUS INGREDIENT(S) CAS No.

ZD1839 Free Base

3. HAZARDS IDENTIFICATION

Form : powder

Color : cream

Caution - Substance not yet fully tested Possible risk of impaired fertility. (female) Risk of serious damage to eyes. Harmful : danger of serious damage to health by prolonged exposure if swallowed. Harmful if swallowed. Studies in animals have shown that repeated doses produce adverse effects on many tissues and organs, including the eye. Some evidence of potential for developmental toxicity but inadequate information is available to assess the teratogenic hazard. May cause skin irritation.

4. FIRST AID MEASURES

- Inhalation : Remove patient from exposure, keep warm and at rest. Obtain immediate medical attention.
- Skin Contact : Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
- Eye Contact : Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. Obtain immediate medical attention. Continue irrigation until medical attention can be obtained.
- Ingestion : Wash out mouth with water and give 200-300 ml of water to drink. Do not induce vomiting. Obtain immediate medical attention.

Note to Physicians

Symptomatic treatment and supportive therapy as indicated.

5. FIRE FIGHTING MEASURES

Flammable Properties

Flammable Powder Class : A

Group A dust. The material can form flammable dust clouds in air.

Extinguishing Media : water spray, foam, dry chemical or CO₂.

Fire Fighting Protective Equipment : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Protect against dust. Ensure suitable personal protection (including respiratory protection) during removal of spillages. Clear up spillages. Transfer to a container for disposal. Wash the spillage area with water.

7. HANDLING AND STORAGE

7.1 HANDLING

Control dust formation. Do not breathe dust. Avoid contact with skin and eyes.

Follow procedures specified in the National Fire Protection Association Codes and Standards for handling combustible dusts. (or explosive dusts)

7.2 STORAGE

Keep container tightly closed. Protect from light. Take precautionary measures against static discharges.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Engineering Controls**

No ACGIH TLV or OSHA PEL assigned.

HAZARDOUS INGREDIENT(S)	TWA		STEL /CEILING (C)	
	ppm	mg/m ³	ppm	mg/m ³
ZD1839	-	0.1	-	-

COM
(Provisional)

This is an in-house standard for the active ingredient during manufacture.

Personal Protective Equipment

Wear suitable protective clothing, gloves and eye/face protection. Wear suitable respiratory protective equipment if exposure to levels above the occupational exposure limit is likely.

Respirators : Use NIOSH respirator approved for dusts with a TLV greater than 0.05 mg/m³.

Protective Clothing : Impervious gloves and apron.

Eye Protection : Chemical tight goggles and full faceshield.

Other Protective Equipment : Eyewash station and safety shower in work area.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form : powder

Color : cream

Solubility (Water) : practically insoluble

Solubility (Other) : sparingly soluble in: polyethylene glycol 400 slightly soluble in: propylene glycol

Partition Coefficient : 4.1

Dissociation constant: 5.28, 7.17 **Minimum Ignition Energy (mJ)** 1-3 (micronised); >3 (milled and unmilled)

10. STABILITY AND REACTIVITY

Hazardous Reactions . None known.

11. TOXICOLOGICAL INFORMATION

- Inhalation : Atmospheric concentrations in excess of the occupational exposure limit may lead to adverse effects as described under long term.
- Skin Contact : May cause skin irritation. It is not a moderate or strong skin sensitizer in animal tests. Inadequate information to assess skin sensitization potential in man.
- Eye Contact : Risk of serious damage to eyes.
- Ingestion : Harmful if swallowed. Oral Median Lethal Dose approx 2000mg/kg (rat). May cause adverse effects as described under long term.
- Long Term Exposure : Harmful : danger of serious damage to health by prolonged exposure if swallowed. Studies in animals have shown that repeated doses produce adverse effects on many tissues and organs, including the eye. Possible risk of impaired fertility. A study in animals has shown that repeated exposures cause adverse effects on fertility. (female). The no effect level was 10 mg/kg/day Some evidence of potential for developmental toxicity but inadequate information is available to assess the teratogenic hazard. None of these effects are likely to occur in humans, provided exposure is maintained at or below the occupational exposure limit.

12. ECOLOGICAL INFORMATION

Toxicity

No information available.

13. DISPOSAL CONSIDERATIONS

Disposal should be in accordance with local, state or national legislation.

Disposal Method : Discarded product is not a hazardous waste under RCRA, 40 CFR 261. However AstraZeneca recommends disposal of waste material via high-temperature incineration.

Container Disposal : Empty container retains product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

Not Classified as Dangerous for Transport.

15. REGULATORY INFORMATION

TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation. CERCLA and SARA Regulations (40 CFR 355, 370 and 372): This product does not contain any chemicals subject to the reporting requirements of SARA Section 313.

16. OTHER INFORMATION

This Material Safety Data Sheet was prepared in accordance with ANSI Standard Z400.1 1993, and

modified 1998.

The following sections contain revisions or new statements: 1,3,11

The information herein is given in good faith but no warranty, expressed or implied, is made.

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