



MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Name

GEFITINIB

Alternative Names

Iressa
ZD1839 Pure
ZD1839 Free Base Pure
Zeneca ZD1839
ZD1839

Address / Phone Number: AstraZeneca
PO BOX 15437
Wilmington, Delaware 19850-5437
Phone (24 hr.) Medical : (800) 236-9933
Chemtrec : (800) 424-9300

2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS No.:184475-35-2 Use:signal transduction inhibitor
HAZARDOUS INGREDIENT(S)%CAS No.ZD1839 Free Base 184475-35-2

3. HAZARDS IDENTIFICATION

Form: powderColor: white
Possible risk of impaired fertility. female Risk of serious damage to eyes. Irritating to skin.
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. Harmful to aquatic organisms. Potential explosion risk
in the presence of ignition source (micronised drug substance).

4. FIRST AID MEASURES

Inhalation: Remove patient from exposure, keep warm and at rest. Obtain immediate medical attention. Skin Contact: Remove contaminated clothing. 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 Powder Class: A

Minimum Ignition Temperature: 932 - 1,022 °F

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

Extinguishing Media (suitable): 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. Avoid release to the environment. Obtain special instructions before use.

7. HANDLING AND STORAGE

7.1 HANDLING

Low Minimum Ignition Energy (MIE) of micronised drug substance - potential risk of explosion in the presence of ignition source. Keep away from heat and sources of ignition. Control dust formation. Take precautionary measures against static discharges. 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. Use stainless steel scoops when repacking micronised material. Do not shake bags. Minimise dust dispersion. Store micronised drug substance (>5kg) in conducting polythene liners.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: No ACGIH TLV or OSHA PEL assigned.

Occupational Exposure Limits HAZARDOUS INGREDIENT(S)
TWASTEL/CEILING(C)

ZD1839 0.1 mg/m³ COM

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: white Molecular Weight: 446.90 g/mol Molecular Formula: C₂₂H₂₄ClFN₄O₃ Solubility (Water): practically insoluble Solubility (Other): soluble in: pyridine, sparingly soluble in: tetrahydrofuran, slightly soluble in: methanol, ethanol, ethyl acetate, freely soluble in: acetic acid, DMSO Partition Coefficient: 4.15 Dissociation constant: : 5.42

Dissociation constant: : 7.24

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: It is not a moderate or strong skin sensitiser in animal tests.

Irritating to skin.

Eye Contact: Risk of serious damage to eyes. Ingestion: Harmful if swallowed. Oral Median Lethal Dose (rat) 2,000 mg/kg

approx

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. Studies in animals have shown that low doses produce embryo/foetotoxic effects in the presence of maternal toxicity. (including mortality) The no effect level was 1 mg/kg/day. This effect is unlikely to occur in humans, provided exposure is maintained at or below the

occupational exposure limit.

12. ECOLOGICAL INFORMATION

Environmental Fate and DistributionThe substance has low mobility in soil. The substance has high potential for bioaccumulation.

ToxicityHarmful to aquatic organisms.

No observed effect concentration Daphnia magna 21 d 0.52 mg/l

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 302, 355, 370 and 372): This product does not contain any chemicals subject to the reporting requirements of SARA Section 313. Discarded product is not a hazardous waste under RCRA, 40 CFR 261.

16. OTHER INFORMATION

The following sections contain revisions or new statements :7, 9
This Material Safety Data Sheet was prepared in accordance with ANSI Standard Z400.1 1993, and modified 1998.

GLOSSARY

COM:The company aims to control exposure in its workplace to this limit This is an in-house

standard for the active ingredient handled during manufacture TLV. The company aims to control exposure in its workplace to the ACGIH limit Sk: Can be absorbed through skin
Sen: Capable of causing respiratory sensitisation
The information herein is given in good faith but no warranty, expressed or implied, is made.