

## SAFETY DATA SHEET

NERATINIB

Page: 1

Compilation date: 20/06/2013

Revision date: 09/09/2014

Revision No: 2

### Section 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Product name:** NERATINIB

**CAS number:** 698387-09-6

**Product code:** BIFK0031

**Synonyms:** HKI-272

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.3. Details of the supplier of the safety data sheet

**Company name:** Apollo Scientific Ltd

Units 3 & 4

Parkway

Denton

Manchester

M34 3SG

UK

**Tel:** 0161 337 9971

**Fax:** 0161 336 6932

**Email:** david.tideswell@apolloscientific.co.uk

#### 1.4. Emergency telephone number

### Section 2: Hazards identification

#### 2.1. Classification of the substance or mixture

**Classification under CHIP:** Xn: R63

**Classification under CLP:** Repr. 2: H361d

**Most important adverse effects:** Possible risk of harm to the unborn child.

#### 2.2. Label elements

**Label elements under CLP:**

**Hazard statements:** H361d: Suspected of damaging the unborn child.

**Signal words:** Warning

**Hazard pictograms:** GHS08: Health hazard



**Precautionary statements:** P261: Avoid breathing dust.

# SAFETY DATA SHEET

NERATINIB

Page: 2

P280: Wear protective gloves/protective clothing/eye protection.

P308+313: IF exposed or concerned: Get medical advice/attention.

## Label elements under CHIP:

**Hazard symbols:** Harmful.



**Risk phrases:** R63: Possible risk of harm to the unborn child.

**Safety phrases:** S22: Do not breathe dust.

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37/39: Wear suitable protective clothing, gloves and eye / face protection.

## 2.3. Other hazards

**PBT:** This substance is not identified as a PBT substance.

## Section 3: Composition/information on ingredients

### 3.1. Substances

**Chemical identity:** NERATINIB

**CAS number:** 698387-09-6

## Section 4: First aid measures

### 4.1. Description of first aid measures

**Skin contact:** Remove all contaminated clothes and footwear immediately unless stuck to skin. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Consult a doctor.

**Eye contact:** Bathe the eye with running water for 15 minutes. Consult a doctor.

**Ingestion:** Wash out mouth with water. Do not induce vomiting. Consult a doctor.

**Inhalation:** Remove casualty from exposure ensuring one's own safety whilst doing so. Consult a doctor.

### 4.2. Most important symptoms and effects, both acute and delayed

**Skin contact:** There may be irritation and redness at the site of contact.

**Eye contact:** There may be irritation and redness. The eyes may water profusely.

**Ingestion:** There may be soreness and redness of the mouth and throat. Nausea and stomach pain may occur. There may be vomiting.

**Inhalation:** There may be irritation of the throat with a feeling of tightness in the chest.

**Delayed / immediate effects:** Immediate effects can be expected after short-term exposure.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Immediate / special treatment:** Not applicable.

[cont...]

# SAFETY DATA SHEET

NERATINIB

Page: 3

## Section 5: Fire-fighting measures

### 5.1. Extinguishing media

**Extinguishing media:** Carbon dioxide, dry chemical powder, foam. Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

### 5.2. Special hazards arising from the substance or mixture

**Exposure hazards:** In combustion emits toxic fumes of carbon dioxide / carbon monoxide. Nitrogen oxides (NO<sub>x</sub>). Hydrogen chloride (HCl).

### 5.3. Advice for fire-fighters

**Advice for fire-fighters:** Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

## Section 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions:** Refer to section 8 of SDS for personal protection details. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Do not create dust.

### 6.2. Environmental precautions

**Environmental precautions:** Do not discharge into drains or rivers.

### 6.3. Methods and material for containment and cleaning up

**Clean-up procedures:** Clean-up should be dealt with only by qualified personnel familiar with the specific substance. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

### 6.4. Reference to other sections

**Reference to other sections:** Refer to section 8 of SDS.

## Section 7: Handling and storage

### 7.1. Precautions for safe handling

**Handling requirements:** Avoid direct contact with the substance. Ensure there is sufficient ventilation of the area. Do not handle in a confined space. Avoid the formation or spread of dust in the air. Only use in fume hood.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage conditions:** Keep container tightly closed. Store at -20 °C

**Suitable packaging:** Must only be kept in original packaging.

[cont...]

# SAFETY DATA SHEET

NERATINIB

Page: 4

## 7.3. Specific end use(s)

**Specific end use(s):** No data available.

## Section 8: Exposure controls/personal protection

### 8.1. Control parameters

**Workplace exposure limits:** No data available.

**DNEL / PNEC** No data available.

### 8.2. Exposure controls

**Engineering measures:** Ensure there is sufficient ventilation of the area.

**Respiratory protection:** Self-contained breathing apparatus must be available in case of emergency. Respiratory protective device with particle filter.

**Hand protection:** Protective gloves.

**Eye protection:** Safety glasses. Ensure eye bath is to hand.

**Skin protection:** Protective clothing.

## Section 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**State:** Solid

**Colour:** off-white to pale yellow.

**Odour:** Odourless

**Melting point/range °C:** 139-158

### 9.2. Other information

**Other information:** No data available.

## Section 10: Stability and reactivity

### 10.1. Reactivity

**Reactivity:** Stable under recommended transport or storage conditions.

### 10.2. Chemical stability

**Chemical stability:** Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

**Hazardous reactions:** Hazardous reactions will not occur under normal transport or storage conditions.

### 10.4. Conditions to avoid

**Conditions to avoid:** Heat.

### 10.5. Incompatible materials

**Materials to avoid:** Strong oxidising agents. Strong acids.

[cont...]

# SAFETY DATA SHEET

NERATINIB

Page: 5

## 10.6. Hazardous decomposition products

**Haz. decomp. products:** In combustion emits toxic fumes of carbon dioxide / carbon monoxide. Nitrogen oxides (NO<sub>x</sub>). Hydrogen chloride (HCl).

## Section 11: Toxicological information

### 11.1. Information on toxicological effects

#### Relevant hazards for substance:

| Hazard                | Route | Basis              |
|-----------------------|-------|--------------------|
| Reproductive toxicity | --    | Based on test data |

### Symptoms / routes of exposure

**Skin contact:** There may be irritation and redness at the site of contact.

**Eye contact:** There may be irritation and redness. The eyes may water profusely.

**Ingestion:** There may be soreness and redness of the mouth and throat. Nausea and stomach pain may occur. There may be vomiting.

**Inhalation:** There may be irritation of the throat with a feeling of tightness in the chest.

**Delayed / immediate effects:** Immediate effects can be expected after short-term exposure.

## Section 12: Ecological information

### 12.1. Toxicity

**Ecotoxicity values:** No data available.

### 12.2. Persistence and degradability

**Persistence and degradability:** No data available.

### 12.3. Bioaccumulative potential

**Bioaccumulative potential:** No data available.

### 12.4. Mobility in soil

**Mobility:** No data available.

### 12.5. Results of PBT and vPvB assessment

**PBT identification:** This substance is not identified as a PBT substance.

### 12.6. Other adverse effects

**Other adverse effects:** No data available.

## Section 13: Disposal considerations

### 13.1. Waste treatment methods

**Disposal operations:** MATERIAL SHOULD BE DISPOSED OF IN ACCORDANCE WITH LOCAL, STATE AND FEDERAL REGULATIONS

**Disposal of packaging:** Dispose of as special waste in compliance with local and national regulations Observe all federal, state and local environmental regulations.

[cont...]

# SAFETY DATA SHEET

NERATINIB

Page: 6

**NB:** The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

## Section 14: Transport information

### 14.1. UN number

**UN number:** UNnone

### 14.2. UN proper shipping name

**Shipping name:** NOT CLASSIFIED AS DANGEROUS IN THE MEANING OF TRANSPORT REGULATIONS.

### 14.3. Transport hazard class(es)

### 14.4. Packing group

### 14.5. Environmental hazards

**Environmentally hazardous:** No

**Marine pollutant:** No

### 14.6. Special precautions for user

**Special precautions:** No special precautions.

## Section 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

### 15.2. Chemical Safety Assessment

**Chemical safety assessment:** A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

## Section 16: Other information

### Other information

**Other information:** This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

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\* Data predicted using computational software. Toxtree - Toxic Hazard Estimation by decision tree approach. <http://ecb.jrc.ec.europa.eu/qsar/qsar-tools/index.php?c=TOXTREE>

~ Data predicted using computational software ACD/ToxSuite v 2.95.1 Copyright 1994-2009 ACD/labs, Copyright 2001-2009 Pharma Algorithms, Inc, Advanced Chemistry Development, Inc (ACD/Labs). [http://www.acdlabs.com/products/pc\\_admet/tox/tox/](http://www.acdlabs.com/products/pc_admet/tox/tox/)

**Phrases used in s.2 and 3:** H361d: Suspected of damaging the unborn child.

R63: Possible risk of harm to the unborn child.

**Legal disclaimer:** The material is intended for research purposes only and should be handled exclusively by those who have been fully trained in safety, laboratory and chemical handling procedures. The above information is believed to be correct to the best of our knowledge. The above information is believed to be correct to the best of our knowledge.

[cont...]

## **SAFETY DATA SHEET**

NERATINIB

**Page: 7**

at the date of its publication, but should not be considered to be all inclusive. It should be used only as a guide for safe handling, storage, transportation and disposal. We cannot guarantee that the hazards detailed in this document are the only hazards that exist for this product. This is not a warranty and Apollo Scientific Ltd shall not be held liable for any damage resulting from handling or from contact with the above product.