Safety Data Sheet (SDS) According to the REACH Regulation (EC) No. 1907/2006

Issuing Date: 2014-03-19 **Revision Date:** 2017-08-28 **Version:** 2

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product No 12961
Product name Axitinib
Reach registration number This substance/mixture contains only ingredients which have been registered, or are exempt from registration, according to Regulation (EC) No. 1907/2006.

Contains

Formula $C_{22}H_{18}N_4OS$
Molecular Weight 386.47
Other means of identification 12961S

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

Identified uses For research use only

1.3. Details of the supplier of the safety data sheet

Importer (Applicable in EU only)
Cell Signaling Technology Europe B.V.
Schuttersveld 2
2316 ZA Leiden
The Netherlands
TEL: +31 (0)71 7200 200
FAX: +31 (0)71 891 0098

Manufacturer
Cell Signaling Technology, Inc.
3 Trask Lane
Danvers, MA 01923
United States
TEL: +1 978 867 2300
FAX: +1 978 867 2400

Website www.cellsignal.com
E-mail Address info@cellsignal.eu

1.4. Emergency telephone number

CHEMTREC 24 hours a day, 7 days a week, 365 days a year
+1 703 527 3887 (INTERNATIONAL) +1 800 424 9300 (NORTH AMERICA)

Europe 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Germ cell mutagenicity	Category 2 - (H341)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity - repeated exposure (STOT RE)	Category 2 - (H373)
Acute aquatic toxicity	Category 1 - (H400)

2.2. Label elements

Signal word
Warning

Hazard statement(s)
H373 - May cause damage to organs through prolonged or repeated exposure
H341 - Suspected of causing genetic defects
H361 - Suspected of damaging fertility or the unborn child
H400 - Very toxic to aquatic life
Precautionary statement(s)
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust
P281 - Use personal protective equipment as required
P273 - Avoid release to the environment
P308 + P313 - IF exposed or concerned: Get medical advice/attention

2.3. Other hazards

None under normal use conditions.

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms Axitinib; Inlyta; AG 013736; Benzamide, N-methyl-2-((3-((1E)-2-(2-pyridinyl)ethenyl)-1H-indazo)-6-yl)thio)-
Formula $C_{22}H_{18}N_4OS$
Chemical nature Monoconstituent substance.

Chemical Name	CAS No	Weight %	EC No	Classification (1272/2008)	REACH Registration Number
N-methyl-2-[3-((E)2-pyridin-2-yl-vinyl)-1H-indazol-6-ylsulfanyl]-benzamide	319460-85-0	100	-	Muta. 2 (H341) Repr. 2 (H361) STOT RE 2 (H373) Aquatic Acute 1 (H400)	no data available

For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice Use first aid treatment according to the nature of the injury. When symptoms persist or in all cases of doubt seek medical advice.
Inhalation Move to fresh air.
Skin contact Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

	Consult a physician.
Ingestion	Clean mouth with water and afterwards drink plenty of water.

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

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

Notes to physician Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media	No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Evacuate personnel to safe areas. Ensure adequate ventilation.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system.

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Use personal protective equipment. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically and collect in suitable container for disposal. Avoid dust formation. Clean contaminated surface thoroughly.

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

Use as a laboratory reagent.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls
Showers, eyewash stations, and ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with side-shields.
Skin protection	
Hand protection	Impervious gloves.
Other	Wear suitable protective clothing.
Respiratory protection	In case of inadequate ventilation wear respiratory protection.

Environmental Exposure Controls
No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline powder
Color	White to off-white
Odor	No information available
Odor Threshold	No information available

Property	Values	Remarks • Method
pH		No information available
Melting point/freezing point	213-224 °C	
Initial boiling point and boiling range		No information available
Flash point		No information available.
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Upper flammability limit		No information available
Lower flammability limit		No information available
Vapor pressure		No information available
Vapor density		No information available
Relative density		No information available
Solubility	Practically insoluble	No information available
Partition coefficient: n-octanol/water		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available.
Viscosity		No information available
Explosive properties		No information available
Oxidizing properties		No information available

9.2. Other information

Softening point	No information available
Molecular Weight	386.47
Solubility in other solvents	No information available
VOC content	No information available
Density	No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization	Hazardous polymerization does not occur.
Hazardous reactions	None under normal processing.

10.4. Conditions to avoid

None known based on information supplied.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

None under normal use conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

This material should only be handled by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxicological and physiological properties of this compound is not well defined.

Information on likely routes of exposure

Inhalation	There is no data available for this product.
Eye contact	There is no data available for this product.
Skin contact	There is no data available for this product.
Ingestion	Target Organ Effects. Reproductive Toxicity.

Symptoms	No information available.
Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Sensitization	No information available.
Mutagenic effects	Genotoxic in the i*n vivo* mouse bone marrow micronucleus assay.
Carcinogenic effects	No information available.
Reproductive toxicity	This material is classified as a Pregnancy Category D: Positive evidence of risk.
Developmental toxicity	May cause birth defects.
STOT - single exposure	No information available.
STOT - repeated exposure	Subjects who received starting doses of 10 mg twice daily or 20 mg twice daily experienced adverse reactions which included hypertension, seizures associated with hypertension, and fatal hemoptysis. Toxicities in bone and teeth were observed in immature mice and dogs administered oral axitinib twice daily for 1 month or longer.
Target Organ Effects	Reproductive system, Respiratory system, Heart, Skeletal system, Teeth.
Aspiration Hazard	No information available.
Other information	NOAEL Oral = 2000 mg/kg (Mouse).

SECTION 12: Ecological information

12.1. Toxicity

No information available.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
N-methyl-2-[3-((E)2-pyridin-2-yl-vinyl)-1H-indazol-6-ylsulfanyl]-benzamide	EC50 0.9 mg/L (Pseudokirchneriella subcapitata) 72 h	LC50 >0.055 mg/L (Cyprinodon variegatus) 96 h	-

12.2. Persistence and degradability

OECD 21 Day(s) NOEC = 0.088 mg/L (Daphnia magna)
OECD 32 Day(s) NOEC = 0.0035 mg/L (Pimephales promelas).

12.3. Bioaccumulative potential

Bioaccumulation No information available.
Bioconcentration factor (BCF) No information available.

Chemical Name	Octanol-Water Partition Coefficient
N-methyl-2-[3-((E)2-pyridin-2-yl-vinyl)-1H-indazol-6-ylsulfanyl]-benzamide	3.5

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

Bacterial Inhibition: OECD EC50 > 1000 mg/L (Activated sludge)

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.
Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.
Other information Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

IMDG/IMO

14.1 UN number UN3077
14.2 UN proper shipping name (Axitinib)
14.3 Transport hazard class(es) 9
14.4 Packing group III
14.5 Environmental hazards Yes
14.6 Special precautions for user None
EmS No. F-A, S-F
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not regulated

ADR/RID

14.1 UN number	UN3077
14.2 UN proper shipping name	(Axitinib)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	None
Classification Code	M7
Tunnel Restriction Code	(E)

IATA

14.1 UN number	UN3077
14.2 UN proper shipping name	(Axitinib)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	None
Special provisions	A158, A179, A97

SECTION 15: Regulatory information

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

Candidate List of Substances of Very High Concern for Authorization Information

This product does not contain Substances of Very High Concern (SVHC).

SEVESO Directive Information

This product does not contain substances identified in the SEVESO Directive.

International inventories

TSCA 8(b)	-
DSL/NDSL	-
EINECS/ELINCS	-
ENCS	-
IECSC	-
KECL	-
PICCS	-
AICS	-

International inventories legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out

SECTION 16: Other information

Full text of H-Statements referred to under Sections 2 and 3

H341 - Suspected of causing genetic defects
H361 - Suspected of damaging fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure
H400 - Very toxic to aquatic life

Classification procedure: Expert judgment and weight of evidence determination.
Issuing Date: 2014-03-19
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Disclaimer

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