

Version 2.1 Revision Date: 25.01.2018 SDS Number: 22595 Date of last issue: 24.02.2017
Date of first issue: 24.02.2017

SECTION 1. IDENTIFICATION

1.1 Product identifier

ACALABRUTINIB

Details of the supplier of the safety data sheet

: ASTRAZENECA
P.O. Box 15437
Wilmington, DE 19850-5437
USA

Phone (24 hr.) Medical :
(800) 236-9933
(24 hr.) Chemical / Spill Emergency:
INFOTRAC - (800) 535-5053

SafetyDataSheets.AlderleyPark@astrazeneca.com

CAS No. : 1420477-60-6

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

Use of the Substance/Mixture : Pharmaceutical active., Treatment of B-cell malignancies

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Specific target organ systemic toxicity - repeated exposure (Oral) : Category 2 (Kidney, Liver, lymphatic system)

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H373 May cause damage to organs (Kidney, Liver, lymphatic system) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

Response:
P314 Get medical advice/ attention if you feel unwell.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Evidence of potential for skin sensitization from consideration of the structure.
See Section 11.

Low Minimum Ignition Energy (MIE) - potential risk of explosion in the presence of ignition source.

Version Revision Date: SDS Number: Date of last issue: 24.02.2017
 2.1 25.01.2018 22595 Date of first issue: 24.02.2017

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Acalabrutinib	1420477-60-6	>= 95 - <= 100

SECTION 4. FIRST AID MEASURES

- If inhaled : Remove patient from exposure, keep warm and at rest.
 Obtain medical attention if ill effects occur.
- In case of skin contact : Take off all contaminated clothing immediately.
 After contact with skin, wash immediately with plenty of water.
 Obtain medical attention if ill effects occur.
- In case of eye contact : Immediately irrigate with eyewash solution or clean water,
 holding the eyelids apart, for at least 10 minutes.
 Obtain medical attention.
- If swallowed : Wash out mouth with water and give 200-300ml of water to
 drink.
 Do NOT induce vomiting as a First-Aid measure.
 Obtain medical attention if ill effects occur.
- Most important symptoms : Refer to sections 2 and 11
 and effects, both acute and May cause damage to organs through prolonged or repeated
 delayed exposure if swallowed.
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.
 Emergency medical treatment advice varies within different
 countries.
 For further information consult the Local National Poisons
 Information Services.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry chemical or CO₂.
- Unsuitable extinguishing : Avoid high pressure media which could cause the formation of
 media a potentially explosible dust-air mixture.
- Specific hazards during fire : If involved in a fire, it may burn and emit noxious and toxic
 fighting fumes.
- Special protective equipment : A self contained breathing apparatus and suitable protective
 for fire-fighters clothing should be worn in fire conditions.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, : Ensure full personal protection (including respiratory

Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2017
2.1	25.01.2018	22595	Date of first issue: 24.02.2017

protective equipment and emergency procedures : protection) during removal of spillages.
See Section 8.
Avoid dispersal of dust in the air.

Environmental precautions : Prevent entry into drains, sewers or watercourses.

Methods and materials for containment and cleaning up : Moisten spillages with water.
Transfer to a container for disposal or recovery.
Wash the spillage area with water.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Avoid contact with skin and eyes.
Avoid inhalation.
Minimize dust generation and accumulation.
The material may form explosible dust-air mixture if dispersed.
Dust clouds are extremely sensitive to ignition by electrostatic discharge or other ignition sources. Ensure good earthing of equipment and personnel.

Conditions for safe storage : Keep tightly closed.

Recommended storage temperature : 59 - 86 °F

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Acalabrutinib	1420477-60-6	TWA	0.01 mg/m ³	COM

Engineering measures : Atmospheric levels should be controlled using the principles of good occupational hygiene practice as specified in the workplace risk assessment.
Prevent entry into drains, sewers or watercourses.

Personal protective equipment

Respiratory protection : As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment.
Consult a qualified safety and health professional for additional guidance, as needed.

Eye protection : Use safety glasses to protect against direct contact with the substance if the risk assessment does not support the selection of other protection.

Skin and body protection : Use impervious clothing to protect against direct contact with the substance if the risk assessment does not support the

Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2017
2.1	25.01.2018	22595	Date of first issue: 24.02.2017

selection of other protection. Use impervious protective gloves to protect against direct contact with the substance. If the substance is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: solid
Color	: white to yellow, to, light brown
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Self-ignition	: 1,112 - 1,247 °F
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
Solubility(ies)	
Water solubility	: insoluble

SAFETY DATA SHEET



Version 2.1 Revision Date: 25.01.2018 SDS Number: 22595 Date of last issue: 24.02.2017
Date of first issue: 24.02.2017

pH: > 6

soluble
pH: < 3

Solubility in other solvents : soluble in: dichloromethane, Dimethylformamide, dimethyl sulfoxide, slightly soluble in: Acetone, Ethanol, tetrahydrofuran, methanol

Partition coefficient: n-octanol/water : log Pow: 2.03

Autoignition temperature : 1,112 - 1,247 °F

Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : No data available

 Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

Molecular weight : 465.5 g/mol

Minimum ignition energy : 3 - 10 mJ

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : None known.

Conditions to avoid : No conditions producing hazardous situations known.

Incompatible materials : None known.

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Acute toxicity

Not classified based on available information.

Ingredients:

Acalabrutinib:

Acute oral toxicity : Oral minimum lethal dose (Rat): > 2,000 mg/kg

Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2017
2.1	25.01.2018	22595	Date of first issue: 24.02.2017

Acute inhalation toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute dermal toxicity : Remarks: No data available

11.2 Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Acalabrutinib:

Remarks: No data available

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

Acalabrutinib:

Remarks: No information available.

11.4 Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

11.5 Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Acalabrutinib:

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

11.6 Carcinogenicity

Not classified based on available information.

Ingredients:

Acalabrutinib:

Carcinogenicity - Assessment : No information available.

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No ingredient of this product present at levels greater than or

Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2017
2.1	25.01.2018	22595	Date of first issue: 24.02.2017

equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

11.7 Reproductive toxicity

Not classified based on available information.

Ingredients:

Acalabrutinib:

Reproductive toxicity - Assessment : No effects on development have been reported from developmental toxicology studies in rats and rabbits., No toxicity to reproduction

11.8 STOT-single exposure

Not classified based on available information.

Ingredients:

Acalabrutinib:

Routes of exposure: Oral

Remarks: May cause effects as described under repeated exposure.(STOT)

11.9 STOT-repeated exposure

May cause damage to organs (Kidney, Liver, lymphatic system) through prolonged or repeated exposure if swallowed.

Ingredients:

Acalabrutinib:

Routes of exposure: Oral

Target Organs: Kidney, Liver, lymphatic system

Assessment: May cause damage to organs through prolonged or repeated exposure.

Remarks: May cause gastrointestinal discomfort, drowsiness, itchiness, increased tendency to bruise, feeling cold, headache and musculoskeletal pain.

Based on human experience.

11.10 Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Acalabrutinib:

Toxicity to fish : Remarks: No information available.

Persistence and degradability

Ingredients:

Acalabrutinib:

SAFETY DATA SHEET



Version 2.1 Revision Date: 25.01.2018 SDS Number: 22595 Date of last issue: 24.02.2017
Date of first issue: 24.02.2017

Biodegradability : Remarks: No degradation data available. The substance is assumed not to be rapidly degradable.

Bioaccumulative potential

Ingredients:

Acalabrutinib:

Bioaccumulation : Remarks: No data available

Mobility in soil

Ingredients:

Acalabrutinib:

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Disposal should be in accordance with local, state or national legislation.
Waste, even small quantities, should never be poured down drains, sewers or water courses.
Dispose of contents/ container to an approved incineration plant.

Contaminated packaging : Empty container will retain residue. Observe all hazard precautions.

SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2017
2.1	25.01.2018	22595	Date of first issue: 24.02.2017

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Ingredients	CAS-No.	Component TPQ (lbs)
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SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Acalabrutinib 1420477-60-6

New Jersey Right To Know

Acalabrutinib 1420477-60-6

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2017
2.1	25.01.2018	22595	Date of first issue: 24.02.2017

The ingredients of this product are reported in the following inventories:

REACH	:	Not listed
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Acalabrutinib
AICS	:	Not listed
ENCS	:	Not listed
ISHL	:	Not listed
IECSC	:	Not listed
TCSI	:	Not listed
TSCA	:	Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

AGW – Arbeitsplatzgrenzwert (Germany TRGS 900); AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2017
2.1	25.01.2018	22595	Date of first issue: 24.02.2017

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; Sen - Capable of causing respiratory sensitization; Sk - Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV - Threshold Limit Value (ACGIH); TLV-C - Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA - Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Minor changes:

2
3
11
15
16

Revision Date : 25.01.2018

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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