

SAFETY DATA SHEETS

This SDS packet was issued with item:

078838601

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078838593

MATERIAL SAFETY DATA SHEET

Selon Norme AFNOR T01 – 102 et Arrêté du 5/1/93

1. CHEMICAL PRODUCT AND FIRM IDENTIFICATION:

PRODUCT NAME: KINAVET-CA1

FIRM NAME: AB Science

ADDRESS: 3 Avenue George V, 75008 Paris -FRANCE

TELEPHONE: +33 (0) 1 47 20 23 11

TELEFAX: +33 (0)1 47 20 24 11

EMERGENCY TELEPHONE CALLS: ----

2. COMPOSITION / INFORMATION ON INGREDIENTS:

COMPOSITION: Tablets contain 50, or 150 mg masitinib as masitinib mesylate (AB1010).

Inactive ingredients: cellulose, povidone, crospovidone, pig liver powder, magnesium stearate, Opadry

CHEMICAL FORMULA: API: C₂₉H₃₄N₆O₄S₂

CAS NUMBER: API : 790299-79-5

3. PHYSICAL AND CHEMICAL CHARACTERISTICS:

SOLUBILITY: API freely soluble in acidified water pH2, soluble in water, slightly soluble to practically insoluble in organic solvents

Tablets disintegrate in liquids and masitinib is solubilised according to its solubility hereabove

APPEARANCE: Round coated tablets embossed with a logo C on one side and the strength (50 or 150) on the other side.

COLOR: Light orange

ODOR: Not specific

pH: Not available

FLASH POINT: Not available

EXPLOSIVE PROPERTIES: Not available

MELTING POINT: Not available

RELATIVE DENSITY: > 1

VAPOR PRESSURE: Not available

VAPOR DENSITY: Not available

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Edition 3	Masitinib 50 & 150 mg coated tablets	
4. FIRE FIGHTING MEASURES:		
FLASH POINT	Not determined	
AUTOIGNITION TEMPERATURE:	Not determined	
COMBUSTIBILITY OF DUSTS:	Not determined	
EXTINGUISHING MEDIA:	In case of fire, flood the fire with water, dry chemical CO2 or "alcohol" foam	
FIREFIGHTING INSTRUCTIONS:	Firefighters should wear self contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Cool containers with water from a maximum distance. Avoid skin contact, inhalation and ingestion. If materials contacts protective clothing or equipment, decontaminate prior to reuse	
HAZARDOUS COMBUSTION PRODUCTS:	Not determined	
5. REACTIVITY DATA:		
STABILITY:	Stable at room temperature	
HAZARDOUS DECOMPOSITION PRODUCTS:	Unknown	
6. HEALTH / HAZARD DATA:		
EFFECTS ON HEALTH:	Antineoplastic agent in dog Drug substance under development in human, for tyrosine-kinase inhibition properties leading to potential cytostatic properties. LOEL = 0.7mg/kg/day; Maximum tolerated dose= 15mg/kg/day	
ROUTES OF ENTRY:	♦Inhalation : Under normal conditions, this product is contained within double bags and inhalation would not be expected to occur. If bags break or spill, vapors of this material may be inhaled, if material is aerolised, there may be potential for inhalation of AB 1010. The extent of absorption after inhalation is unknown ♦Skin contact : Under normal conditions, this product is contained within double bags and skin contact would not be expected to occur. Exposure to AB 1010 may occur via skin contact if bagss break or spill and if gloves and protective clothing are not worn. The extent of systemic absorption after skin contact is unknown ♦ Eye contact : Irritant ♦Ingestion : Under normal conditions, this product is contained within double bags and ingestion would not be expected to occur. Ingestion of a trace amount of the material might occur if materials contact hands and if hands are not washed prior to eating, drinking or smoking. The extent of systemic absorption of AB1010 by oral route is not yet determined, but oral absorption is good.	
EMERGENCY AND FIRST AID MEASURES:		
INHALATION:	Remove exposed person to fresh air	
SKIN CONTACT:	Remove contaminated clothing. Flush with water for 10 minutes at least. If irritation (redness, itching, swelling) develops, seek medical attention.	
EYES CONTACT:	Flush with running water for at least 15 minutes. Seek medical attention if pain, redness or trouble occurs.	
INGESTION:	Call a physician or Poison Center. Only induce vomiting at the instructions of a physician. Never give anything by mouth to an unconscious person.	

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Edition 3	Masitinib 50 & 150 mg coated tablets	
7. PRECAUTIONS FOR SAFE HANDLING AND USE:		
STEPS TO BE TAKEN IN CASE MATERIEL IS RELEASED OR SPILLED:	Not to throw away in the drain or in the natural environment. Wipe up with absorbent towels or other absorbent material as appropriate; place collected materials into a suitable waterproof container for disposal. Wash twice with detergent and water. Then flush with water to process sewer, if allowable under national, federal, state, or local permits or regulations. Destroy waste according to national, federal, state, or local regulations.	
WASTE DISPOSAL METHOD:	Incineration according to the national, federal, state and local regulations.	
PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING:	Masitinib is presented as coated tablets which prevent contact with or dissemination of it. Each time, the coating is damaged, tablets or derivatives must be handled as masitinib i.e. as an HAZARDOUS PRODUCT as defined by NIOSH.	
HANDLING PRECAUTIONS:	Avoid ingestion, inhalation, skin or eye contact with this material	
PERSONAL EXPOSURE PRECAUTIONS:	Wear suitable protective clothing and gloves.	
FIRE AND EXPLOSION PREVENTION:	Do not expose to heat source.	
STORAGE CONDITIONS:	Recommended storage is between 15°C and 30°C, into the original container.	
8. CONTROL MEASURES:		
PERSONAL PROTECTION:	Grinding of the tablets and handling of pulverized tablets should be performed in biologic safety cabinet (class I BSC, vertical flow hood)	
RESPIRATORY PROTECTION:	Mask highly recommended when handling pulverized tablets	
HAND PROTECTION:	Gloves recommended when handling tablets or solutions.	
EYE PROTECTION:	Safety goggles highly recommended when handling pulverized tablets or solutions.	
SKIN PROTECTION:	One use working clothes when handling pulverized tablets.	
HYGIEN:	Wash hands thoroughly after handling tablets or tablets derivatives and before eating smoking, using lavatory and at the end of the day	
CROSSCONTAMINATION	Grinding of the tablets and handling of pulverized tablets should be performed in biologic safety cabinet (class I BSC, vertical flow hood)	
9. TOXICOLOGICAL INFORMATION:		
ACUTE TOXICITY:	Rat, oral route: LD50 > 1600 mg/kg	
REPEATED DOSE TOXICITY:	Rat, IV: LD0 > 80 mg/kg	
	Rat , 14 days, oral route: NOAEL 15 mg/kg/day .	
	Dog, 13 weeks, oral route: NOAEL 15 mg/kg/day.	
	Reversible haematological changes (non regenerative anemia, increase in activated partial thromboplastin time and fibrinogen level, decrease in leucocyte and neutrophile counts), blood biochemicals changes (increase in chloride level and alkaline phosphatase activity, decrease in albumin level) and hepatocellular hypertrophy	

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9. <u>TOXICOLOGICAL INFORMATION:</u> (end) <div> <div><u>CARCINOGENICITY:</u></div> <div>In rat, dose dependant increase of frequency of adeno carcinomas of uterus at the highest doses (tested 75-60 mg/Kg/day) was observed after 2 years exposure.</div> </div> <div> <div><u>MUTAGENICITY:</u></div> <div>AB 1010 was negative in <i>in vitro</i> tests [chromosome aberrations test (human lymphocyte) and thymidine kinase locus mutation test (mouse lymphoma)] and in <i>in vivo</i> micronuclei test.</div> </div> <div> <div><u>TERATOGENICITY:</u></div> <div>Segment 2: embryo foetal development: No effect in rabbits, developmental toxicity in rats at doses above 30 mg/Kg/day</div> </div> <div> <div><u>REPRODUCTIVE EFFECTS:</u></div> <div>Segment 1 in rats showed that the fertility of females given 100 mg/kg was affected..</div> </div>		
10. <u>ECOLOGICAL INFORMATION:</u> <div>Not available.</div>		
11. <u>DISPOSAL CONSIDERATIONS:</u>		
Incineration according to the federal, state and local regulations		
14. <u>TRANSPORT INFORMATION:</u> <div> <div><u>UN NUMBER:</u></div> <div></div> </div> <div> <div><u>PLACARD REQUIREMENTS:</u></div> <div>Toxic</div> </div> <div> <div><u>LABEL REQUIREMENTS:</u></div> <div>Toxic</div> </div> <div> <div><u>PROPER SHIPPING NAME:</u></div> <div>Coated tablets</div> </div>		
15. <u>REGULATORY INFORMATION:</u>		
Masitinib 50mg and 150mg tablets are veterinarian drug products, registered by FDA under trade mark Kinavet-CA1 (NADA 141-308) and registered in Europe under trade mark Masivet		
16. <u>OTHER INFORMATION:</u> <p>This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities. The data given here is based on current knowledge and experience. Investigational drug products are intended for use under direction of a physician, according to national, state or local regulations. As a general precaution, personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.</p>		