

Imatinib Methanesulphonate Salt Apollo Scientific

Part Number: BIFK0026 Version No: 1.2 Safety Data Sheet

Chemwatch Hazard Alert Code: 2

Issue Date: **25/05/2023**Print Date: **25/05/2023**S.GHS.GB-NIR.EN

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

Product Identifier

Product name	Imatinib Methanesulphonate Salt
Chemical Name	imatinib
Synonyms	Not Available
Chemical formula	C30H35N7O4S
Other means of identification	Not Available
CAS number	220127-57-1*

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

Relevant identified uses Not Available

Details of the manufacturer or supplier of the safety data sheet

Registered company name	Apollo Scientific	Apollo Scientific Itd	
Address	Whitefield Road, Bredbury SK62QR United Kingdom	Whitefield Road Not Available SK6 2QR United Kingdom (NI)	
Telephone	01614060505	+44(0) 161 406 0505	
Fax	0161 406 0506	Not Available	
Website	http://www.apolloscientific.co.uk/	apolloscientific.co.uk	
Email sales@apolloscientific.co.uk sales@apolloscientific.co.uk		sales@apolloscientific.co.uk	

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1]	H302 - Acute Toxicity (Oral) Category 4, H361fd - Reproductive Toxicity Category 2, H341 - Germ Cell Mutagenicity Category 2, H351 - Carcinogenicity Category 2
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

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Label elements

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Hazard pictogram(s)





Signal word

Warning

Hazard statement(s)

H302	Harmful if swallowed.		
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.		
H341	Suspected of causing genetic defects.		
H351	Suspected of causing cancer.		

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.	
P280	Vear protective gloves and protective clothing.	
P264	Wash all exposed external body areas thoroughly after handling.	
P270	Do not eat, drink or smoke when using this product.	

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/ attention.	
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.	
P330	Rinse mouth.	

Precautionary statement(s) Storage

P405 Store locked up.

Precautionary statement(s) Disposal

P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3 Composition / information on ingredients

Substances

CAS No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor
Not Available	100	Imatinib Methanesulphonate Salt	Acute Toxicity (Oral) Category 4, Reproductive Toxicity Category 2, Germ Cell Mutagenicity Category 2, Carcinogenicity Category 2; H302, H361fd, H341, H351 [1]	Not Available

Legend:

1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

Mixtures

See section above for composition of Substances

SECTION 4 First aid measures

Description of first aid measures

Description of first and measures		
Eye Contact	If this product comes in contact with eyes: • Wash out immediately with water. • If irritation continues, seek medical attention. • Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.	
Skin Contact	If skin or hair contact occurs: Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.	

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Inhalation

Inhalation

Infermation

Ingestion

Ingestion

Ingestion

In fumes, aerosols or combustion products are inhaled remove from contaminated area.

Inhalation

Indestion

Ingestion

Ingestio

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

Extinguishing media

- ▶ There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.		
Advice for firefighters			
Fire Fighting	 Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use. 		
Fire/Explosion Hazard	 Non combustible. Not considered a significant fire risk, however containers may burn. May emit poisonous fumes. 		

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	 Clean up all spills immediately. Avoid breathing vapours/ aerosols/ or dusts and avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Place in a suitable, labelled container for waste disposal.
Major Spills	 Minor hazard. Clear area of personnel. Alert Fire Brigade and tell them location and nature of hazard. Control personal contact with the substance, by using protective equipment as required. Prevent spillage from entering drains or water ways. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal. Wash area and prevent runoff into drains or waterways. If contamination of drains or waterways occurs, advise emergency services.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

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Precautions for safe handling

- ▶ Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- ▶ DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- ▶ When handling, **DO NOT** eat, drink or smoke.
- ▶ Keep containers securely sealed when not in use.
- Avoid physical damage to containers
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

Other information

Safe handling

Conditions for safe storage, including any incompatibilities

Suitable container Polyethylene or polypropylene container. Packing as recommended by manufacturer. Check all containers are clearly labelled and free from leaks. None known Storage incompatibility None known Store at-20°c Store under argon

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
Imatinib Methanesulphonate Salt	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Imatinib Methanesulphonate Salt	Not Available	Not Available

Exposure controls

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.

Appropriate engineering controls

General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:		Air Speed:
solvent, va	oours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)

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aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, 0.5-1 m/s (100-200 welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation) f/min.) direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge 1-2.5 m/s (200-500 (active generation into zone of rapid air motion) f/min) 2.5-10 m/s grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion). (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood - local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Individual protection measures, such as personal protective equipment











Eye and face protection

Safety glasses with side shields

Chemical goggles.

Contact lenses may pose a special hazard: soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

Skin protection Hands/feet protection **Body protection** Overalls.

See Hand protection below

- ▶ Wear chemical protective gloves, e.g. PVC.
- ▶ Wear safety footwear or safety gumboots, e.g. Rubber

See Other protection below

Other protection

- P.V.C apron.
- ▶ Barrier cream.
- Skin cleansing cream.
- ▶ Eye wash unit.

Respiratory protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

^{* -} Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

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SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Not Available		
Physical state	Powder	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	203-224	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

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Еуе	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).		
Chronic	Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility.		
Legend:	Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances		
Acute Toxicity	~	Carcinogenicity	~
Skin Irritation/Corrosion	×	Reproductivity	~
Serious Eye Damage/Irritation	×	STOT - Single Exposure	×
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	✓	Aspiration Hazard	×

Legend: ★ - Data either not available or does not fill the criteria for classification

✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal

- ▶ Recycle wherever possible or consult manufacturer for recycling options.
- ► Consult State Land Waste Management Authority for disposal.
- ▶ Bury residue in an authorised landfill.
- Recycle containers if possible, or dispose of in an authorised landfill.

SECTION 14 Transport information

Labels Required

Marine Pollutant NO

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Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
Imatinib Methanesulphonate Salt	Not Available

Transport in bulk in accordance with the IGC Code

Product name	Ship Type
Imatinib Methanesulphonate Salt	Not Available

SECTION 15 Regulatory information

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

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (Imatinib Methanesulphonate Salt)
Canada - DSL	No (Imatinib Methanesulphonate Salt)
Canada - NDSL	No (Imatinib Methanesulphonate Salt)
China - IECSC	No (Imatinib Methanesulphonate Salt)
Europe - EINEC / ELINCS / NLP	No (Imatinib Methanesulphonate Salt)
Japan - ENCS	No (Imatinib Methanesulphonate Salt)
Korea - KECI	No (Imatinib Methanesulphonate Salt)
New Zealand - NZIoC	No (Imatinib Methanesulphonate Salt)
Philippines - PICCS	No (Imatinib Methanesulphonate Salt)
USA - TSCA	No (Imatinib Methanesulphonate Salt)
Taiwan - TCSI	Yes
Mexico - INSQ	No (Imatinib Methanesulphonate Salt)
Vietnam - NCI	Yes
Russia - FBEPH	No (Imatinib Methanesulphonate Salt)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	25/05/2023
Initial Date	26/05/2023

SDS Version Summary

Version	Date of Update	Sections Updated
0.2	25/05/2023	Toxicological information - Acute Health (eye), Toxicological information - Acute Health (inhaled), CAS Number, Toxicological information - Chronic Health, Hazards identification - Classification, Disposal considerations - Disposal, Exposure controls / personal protection - Engineering Control, Exposure controls / personal protection - Exposure Standard, Composition / information on ingredients - Ingredients, Stability and reactivity - Instability Condition, Exposure controls / personal protection - Personal Protection (Respirator), Exposure controls /

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Date of Version **Sections Updated** Update personal protection - Personal Protection (hands/feet), Accidental release measures - Spills (major), Accidental release measures - Spills (minor), Handling and storage - Storage (storage requirement), Handling and storage -Storage (suitable container), Identification of the substance / mixture and of the company / undertaking - Supplier

Information, Identification of the substance / mixture and of the company / undertaking - Synonyms

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Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eve-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

Definitions and abbreviations

PC-TWA: Permissible Concentration-Time Weighted Average

PC-STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit。

IDLH: Immediately Dangerous to Life or Health Concentrations

ES: Exposure Standard OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors BEI: Biological Exposure Index

AIIC: Australian Inventory of Industrial Chemicals

DSL: Domestic Substances List NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

NLP: No-Longer Polymers

ENCS: Existing and New Chemical Substances Inventory

KECI: Korea Existing Chemicals Inventory NZIoC: New Zealand Inventory of Chemicals

PICCS: Philippine Inventory of Chemicals and Chemical Substances

TSCA: Toxic Substances Control Act TCSI: Taiwan Chemical Substance Inventory INSQ: Inventario Nacional de Sustancias Químicas

NCI: National Chemical Inventory

FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure
Acute Toxicity (Oral) Category 4, H302	Expert judgement
Reproductive Toxicity Category 2, H361fd	Expert judgement
Germ Cell Mutagenicity Category 2, H341	Expert judgement

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Classification according to regulation (EC) No
1272/2008 [CLP] and amendments

Carcinogenicity Category 2, H351

Expert judgement

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