INDOLINONE

GHS Safety Data Sheet

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
INDOLINONE

OTHER NAMES
C14-H9-Cl2-N-O, "1-(2, 6-dichlorophenyl)-1, 3-dihydro-2H-indol-2-one", "1-(2, 6-dichlorophenyl)oxoindole", "N-(2, 6-dichlorophenyl)-2-indolinone", "N-(2, 6-dichlorophenyl)indolin-2-one", "diclofenac impurity A CRS", "diclofenac related compound A", "NSAID analgesic/ antipyretic/ anti-inflammatory"

PROPER SHIPPING NAME
MEDICINE, SOLID, TOXIC, N.O.S.(contains diclofenac amide)

PRODUCT USE
A potential prodrug of diclofenac and possible impurity during its commercial synthesis
Diclofenac is an analgesic, anti-pyretic and anti-inflammatory; inhibitor of prostaglandin synthetase (cyclo-oxygenase). Used for the relief of pain and inflammation in conditions such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout. .

SUPPLIER
Company: S D FINE- CHEM LIMITED
Address:
315- 317, T.V.Ind.Estate,
248, Worli Road,
Mumbai- 400030, India
www.sdfine.com
Telephone: 91- 22 24959898/99
Fax: 91- 22 2493 7232
Email: technical@sdfine.com

Section 2 - HAZARDS IDENTIFICATION

GHS Classification
Acute Toxicity Category 5
Acute Toxicity Category 5
Chronic Aquatic Hazard Category 2

EMERGENCY OVERVIEW

HAZARD
WARNING

Determined by using GHS criteria

H303	May be harmful if swallowed
H333	May be harmful if inhaled
H411	Toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS
Prevention

Code	**Phrase**
P273	Avoid release to the environment.

Response

continued...

Code	**Phrase**
P304+P312	IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P391	Collect spillage.

Disposal

Code	**Phrase**
P501	Dispose of contents/container to ...

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
indolinone	15362-40-0	>98

Section 4 - FIRST AID MEASURES

SWALLOWED
- Give a slurry of activated charcoal in water to drink. NEVER GIVE AN UNCONSCIOUS PATIENT WATER TO DRINK.
- At least 3 tablespoons in a glass of water should be given.
- Although induction of vomiting may be recommended (IN CONSCIOUS PERSONS ONLY), such a first aid measure is dissuaded due to the risk of aspiration of stomach contents. (i) It is better to take the patient to a doctor who can decide on the necessity and method of emptying the stomach. (ii) Special circumstances may however exist; these include non- availability of charcoal and the ready availability of the doctor.

NOTE: If vomiting is induced, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

EYE
■ If this product comes in contact with the eyes:
- Immediately hold eyelids apart and flush the eye continuously with running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.

SKIN
■ If skin contact occurs:
- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED
- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.

NOTES TO PHYSICIAN
■ Treat symptomatically.
for non-steroidal anti-inflammatories (NSAIDs)
- Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression, and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
- Patients should be managed by symptomatic and supportive care following a NSAIDs overdose.
- There are no specific antidotes.
- Emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 g/kg in children), and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose).

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Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA
• Foam.
• Dry chemical powder.
• BCF (where regulations permit).
• Carbon dioxide.

FIRE FIGHTING
• Alert Fire Brigade and tell them location and nature of hazard.
• Wear full body protective clothing with breathing apparatus.
• Prevent, by any means available, spillage from entering drains or water course.
• Use fire fighting procedures suitable for surrounding area.

FIRE/EXPLOSION HAZARD
• Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
• Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).
• Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
• In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC).

Combustion products include: carbon monoxide (CO), carbon dioxide (CO_2), hydrogen chloride, phosgene, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.

FIRE INCOMPATIBILITY
• Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS
• Clean up waste regularly and abnormal spills immediately.
• Avoid breathing dust and contact with skin and eyes.
• Wear protective clothing, gloves, safety glasses and dust respirator.
• Use dry clean up procedures and avoid generating dust.

MAJOR SPILLS
• Clear area of personnel and move upwind.
• Alert Fire Brigade and tell them location and nature of hazard.
• Wear full body protective clothing with breathing apparatus.
• Prevent, by any means available, spillage from entering drains or water course.

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

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR 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.
• Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)
• Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.

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• Establish good housekeeping practices.
• Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.

SUITABLE CONTAINER
• Glass container is suitable for laboratory quantities.
• Lined metal can, lined metal pail/ can.
• Plastic pail.
• Polyliner drum.
• Packing as recommended by manufacturer.
For low viscosity materials
• Drums and jerricans must be of the non-removable head type.
• Where a can is to be used as an inner package, the can must have a screwed enclosure. <</>.

STORAGE INCOMPATIBILITY
• Avoid strong acids, acid chlorides, acid anhydrides and chloroformates.
• Avoid reaction with oxidising agents.
Avoid exposure to light and air.

STORAGE REQUIREMENTS
• Store in original containers.
• Keep containers securely sealed.
• Store in a cool, dry, well-ventilated area.
• Store away from incompatible materials and foodstuff containers.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS
The following materials had no OELs on our records
• diclofenac amide: CAS:15362- 40- 0

MATERIAL DATA
DICLOFENAC AMIDE:
■ Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

PERSONAL PROTECTION




RESPIRATOR
•Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

EYE
■ For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
• Chemical goggles
• Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
• Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens 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].

HANDS/FEET
■ The selection of the suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.
Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:.

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- Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Change gloves frequently and when contaminated, punctured or torn.

OTHER
- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

ENGINEERING CONTROLS
■ For potent pharmacological agents:
Powders
To prevent contamination and overexposure, no open handling of powder should be allowed.
- Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
- In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
- Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
- An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).

Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg

When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE
Off-white to light-brown crystalline powder; does not mix well with water.Soluble in toluene, chloroform

PHYSICAL PROPERTIES

State	Divided Solid	Molecular Weight	278.14
Melting Range (°C)	115- 119	Viscosity	Not Applicable
Boiling Range (°C)	Not Applicable	Solubility in water (g/L)	Partly Miscible
Flash Point (°C)	>150	pH (1% solution)	8.1 (0.1 g/l H2O)
Decomposition Temp (°C)	Not Available	pH (as supplied)	Not Applicable
Autoignition Temp (°C)	Not Available	Vapour Pressure (kPa)	Negligible
Upper Explosive Limit (%)	Not Available	Specific Gravity (water=1)	Not Available
Lower Explosive Limit (%)	Not Available	Relative Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY
- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

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Section 11 - TOXICOLOGICAL INFORMATION

Health hazard summary table:

Acute toxicity	Acute Tox. (inhal) 5 Acute Tox. (oral) 5
Skin corrosion/irritation	Not applicable
Serious eye damage/irritation	Not applicable
Respiratory or skin sensitization	Not applicable
Germ cell mutagenicity	Not applicable
Carcinogenicity	Not applicable
Reproductive toxicity	Not applicable
STOT- single exposure	Not applicable
STOT- repeated exposure	Not applicable
Aspiration hazard	Not applicable

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED
■ Toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual.
■ Non-steroidal anti-inflammatory drug (NSAID) overdose may produce nausea, vomiting, indigestion and upper abdominal pain. Other effects may include drowsiness, dizziness, confusion, disorientation, lethargy, "pins and needles", intense headache, blurred vision, ringing in the ears, muscle twitching, convulsions, stupor and coma.

EYE
■ Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn).
Slight abrasive damage may also result.

SKIN
■ The material is not thought to be a skin irritant (as classified by EC Directives using animal models).
Abrasive damage however, may result from prolonged exposures.
■ Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
■ 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.

INHALED
■ The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models).
Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
■ Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.
If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result□□in excessive exposures.

CHRONIC HEALTH EFFECTS
■ Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.
Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray.
Prolonged use of non-steroidal analgesics damages the lining of the gastrointestinal tract, causing ulcers and bleeding. There may be diarrhoea or constipation, perforations causing serious infection, and blood in the vomit or stools. Kidney damage can result in blood or pus in the urine, changes in urine chemistry, change in the frequency of urination, insufficiency of kidney function, destruction of the kidney lining and kidney inflammation. Occasionally, the liver may be affected, causing inflammation (hepatitis) and jaundice. There may be changes in blood cell distribution, and disturbance in platelet function. Sensitivity to light may occur. Anaphylactic-like syndrome is characterised by rash with redness, spots and blisters, itching, and fainting. The eyes, ears and urinary tract can all be affected. Asthma and anaemia may be exacerbated. These drugs can cause circulatory defects in the foetus and newborn. Once the kidney has been damaged, there is an increased likelihood that cancers could develop there.
Exposure to small quantities may induce hypersensitivity reactions characterised by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic oedema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur. An individual may be predisposed to such anti-body mediated reaction if other chemical agents have caused prior sensitisation (cross-sensitivity).
Abnormalities of liver-function tests, impairment of renal function, agranulocytosis and thrombocytopenia are longer term

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manifestations of diclofenac exposure. Haemolytic and aplastic anaemia, neutropenia and decreases in haemoglobin and haematocrit may also occur.

TOXICITY AND IRRITATION
No data for this material.

Section 12 - ECOLOGICAL INFORMATION

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
This material and its container must be disposed of as hazardous waste.
Avoid release to the environment.
Refer to special instructions/ safety data sheets.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
diclofenac amide	HIGH	No Data Available	LOW	MED

Section 13 - DISPOSAL CONSIDERATIONS

• Containers may still present a chemical hazard/ danger when empty.
• Return to supplier for reuse/ recycling if possible.
Otherwise:
• If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
• Where possible retain label warnings and MSDS and observe all notices pertaining to the product.
Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.
A Hierarchy of Controls seems to be common - the user should investigate:
• Reduction.
• DO NOT allow wash water from cleaning or process equipment to enter drains.
• It may be necessary to collect all wash water for treatment before disposal.
• In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
• Where in doubt contact the responsible authority.
• Recycle wherever possible.
• Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
• Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
• Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

Labels Required: TOXIC

HAZCHEM:
2X

Land Transport UNDG:

Class or division:	6.1	Subsidiary risk:	None
UN No.:	3249	UN packing group:	III

Shipping Name:MEDICINE, SOLID, TOXIC, N.O.S. (contains diclofenac amide)

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Air Transport IATA:

ICAO/IATA Class:	6.1	ICAO/IATA Subrisk:	None
UN/ID Number:	3249	Packing Group:	III
Special provisions:	A3		

Shipping name:MEDICINE, SOLID, TOXIC, N.O.S.(contains diclofenac amide)

Maritime Transport IMDG:

IMDG Class:	6.1	IMDG Subrisk:	None
UN Number:	3249	Packing Group:	III
EMS Number:	F- A, S- A	Special provisions:	221 223
Limited Quantities:	5 kg	Marine Pollutant:	Yes

Shipping name:MEDICINE, SOLID, TOXIC, N.O.S.(contains diclofenac amide)

Section 15 - REGULATORY INFORMATION

REGULATIONS

No data for indolinone (CAS: , 15362-40-0)

Section 16 - OTHER INFORMATION

Denmark Advisory list for selfclassification of dangerous substances

Substance	CAS	Suggested codes
indolinone	15362-40-0	Mut3;R68N; R50/53

■ Classification of the preparation and its individual components has drawn on official and authoritative sources using available literature references.

■ The (M)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.

The above information is believed to be accurate and represent the best information currently available to us, but does not represent any warranty expressed or implied of the properties of the product. User should make their own investigation to determine the suitability of the information for their particular purpose.

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