

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

<b>Catalogue Number</b>	CS-EG-03330
<b>Product Name</b>	Ibuprofen for peak Identification CRS (mixture of impurities A, J and N)
<b>CAS No.</b>	15687-27-1
<b>Category</b>	EP Standards
<b>Synonyms</b>	2-(4-Isobutylphenyl)propionic acid; (4-Isobutylphenyl)- $\alpha$ -methylacetic acid; 4-Isobutyl- $\alpha$ -methylphenylacetic acid
<b>Brand</b>	Clearsynth Labs Ltd.
<b>Identified uses</b>	Laboratory Chemicals
<b>Uses advised against</b>	Not available
<b>Company</b>	Clearsynth Labs Ltd. Mumbai, India
<b>Emergency Phone #</b>	+91-22-245045900
<b>REACH No.</b>	Not available

### SECTION 2: Hazards identification

**Disclaimer:** This is sample MSDS. Please email [sales@clearsynth.com](mailto:sales@clearsynth.com) for more details.

#### 2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Serious eye damage/eye irritation (Category 2)  
Acute toxicity (Category 4)

#### 2.2 Label Elements

**Signal Word:** Warning



#### Hazard Statement(s)

Code	Statement
H302	Harmful if swallowed.
H319	Causes serious eye irritation.

H335	Not available
H361	Not available
H360	Not available
H362	Not available
H371	Not available
H373	Not available
H411	Toxic to aquatic life with long lasting effects.

**Precautionary Statement(s)**

Code	Statement
P203	Not available
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P264+P265	Not available
P270	Not available
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P317	Not available
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present.
P318	Not available
P319	Get medical help if you feel unwell.
P330	Not available
P337+P317	If eye irritation persists: Get medical help.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
P260	Not available
P263	Not available
P273	Not available

P308+P316	Not available
P391	Not available

### SECTION 3: Composition / information on ingredients

#### 3.1 Substance

Component : Ibuprofen for peak Identification CRS (mixture of impurities A, J and N)

CAS Number : 15687-27-1

Molecular Formula : C<sub>13</sub>H<sub>18</sub>O<sub>2</sub>

Molecular Weight : 206.28

Parent Chemical : Ibuprofen

Synonyms : 2-(4-Isobutylphenyl)propionic acid; (4-Isobutylphenyl)- $\alpha$ -methylacetic acid; 4-Isobutyl- $\alpha$ -methylphenylacetic acid

Concentration : Not available

### SECTION 4: First aid measures

#### SECTION 4: First-aid measures

##### 4.1 Description of first aid measures

- General advice: Remove contaminated clothing and shoes. Seek medical attention if symptoms persist or are severe.
- Inhalation: Move person to fresh air. Keep at rest. If breathing is difficult, seek medical attention.
- Skin contact: Wash with plenty of soap and water. Get medical attention if irritation develops.
- Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention if irritation persists.
- Ingestion: Rinse mouth. Do NOT induce vomiting unless directed by medical personnel. Seek medical attention.

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

- Not available.

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

- Treat symptomatically. No data available.

### SECTION 5: Firefighting measures

#### SECTION 5: Fire-fighting measures

##### 5.1 Extinguishing media

- Suitable extinguishing media: Water spray, alcohol-resistant foam, dry chemical, carbon dioxide (CO<sub>2</sub>).
- Unsuitable extinguishing media: Not available.

##### 5.2 Special hazards arising from the substance or mixture

- Hazardous combustion products: Not available.
- Specific hazards: Dust may form explosive mixture with air (general precaution for organic powders); no data available for this product.

##### 5.3 Advice for firefighters

- Wear self-contained breathing apparatus (SCBA) and full protective gear.
- Use water spray to cool unopened containers.
- Avoid inhalation of combustion products.

### SECTION 6: Accidental release measures

#### SECTION 6: Accidental release measures

##### 6.1 Personal precautions, protective equipment and emergency procedures

- Avoid breathing dust. Avoid contact with skin and eyes.
- Use appropriate personal protective equipment (see Section 8).
- Ensure adequate ventilation.

##### 6.2 Environmental precautions

- Prevent further leakage or spillage if safe to do so.
- Avoid release to the environment. Do not allow to enter drains/surface waters/groundwater.

##### 6.3 Methods and material for containment and cleaning up

- Avoid dust formation.
- Collect spilled material using non-sparking tools and place in a suitable, closed container for disposal.
- Clean contaminated area with water and detergent as appropriate.

##### 6.4 Reference to other sections

- See Section 8 for personal protective equipment and Section 13 for disposal considerations.

### SECTION-7: Handling and storage

#### SECTION 7: Handling and storage

##### 7.1 Precautions for safe handling

- Handle in accordance with good industrial hygiene and safety practice.
- Avoid formation of dust and aerosols.
- Avoid contact with skin, eyes, and clothing.
- Use with adequate ventilation.
- Wash hands thoroughly after handling.

##### 7.2 Conditions for safe storage, including any incompatibilities

- Store in a tightly closed container.
- Store in a cool, dry, well-ventilated place.
- Protect from moisture.
- Incompatible materials: Not available.

##### 7.3 Specific end use(s)

- Laboratory/research standard (EP/CRS reference material). No other specific uses identified.

### SECTION 8: Exposure controls / personal protection

#### SECTION 8: Exposure controls/personal protection

##### 8.1 Control parameters

- Occupational exposure limits: Not available.

- Biological limit values: Not available.

### 8.2 Exposure controls

- Appropriate engineering controls: Use local exhaust ventilation or general ventilation to minimize dust exposure.

### Personal protective equipment (PPE)

- Eye/face protection: Safety glasses with side shields or chemical splash goggles.

- Skin protection: Protective gloves (material selection dependent on use conditions; no data available).

- Body protection: Lab coat or suitable protective clothing.

- Respiratory protection: If ventilation is inadequate or dust is generated, use a suitable particulate respirator per applicable standards.

### Hygiene measures

- Do not eat, drink, or smoke when using this product. Wash hands after handling.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	2.7
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available

Property	Value
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available
q) Oxidizing Properties	No data available

### SECTION 10: Stability and reactivity

#### SECTION 10: Stability and reactivity

##### 10.1 Reactivity

- No data available.

##### 10.2 Chemical stability

- Stable under recommended storage conditions.

##### 10.3 Possibility of hazardous reactions

- No data available.

##### 10.4 Conditions to avoid

- Excessive heat. Dust generation. Moisture (as a general precaution).

##### 10.5 Incompatible materials

- Not available.

##### 10.6 Hazardous decomposition products

- Not available.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

- Acute toxicity: Signs and Symptoms of Overdose Ibuprofen's toxic potential is derived from its inhibition of the cyclooxygenase pathway and the subsequent effects on various cellular processes and multiple organ systems. Prostaglandins and thromboxanes help maintain the gastric mucosal layer and renal blood flow; ibuprofen is associated with a mildly elevated risk of adverse gastrointestinal and renal events, even at therapeutic levels. Ibuprofen is the most common NSAID involved in overdose cases; 29% of overdoses are the result of ibuprofen ingestion alone. Patients can also overdose by ingesting ibuprofen combined with other analgesics. One study created a risk score for improving the risk-benefit ratio of NSAID administration; this score was accurate in categorizing the one-year risk of significant toxicity among NSAID users. Reye syndrome is an increasingly rare presentation, primarily due to international efforts to curb aspirin usage since the 1980s. Restricted aspirin administration to children in the United Kingdom reduced the incidence of Reye syndrome from 100 cases in 1984 to 3 cases in 2000. NSAIDs damage the mitochondria in hepatocytes, precipitating Reye syndrome. Furthermore, the mechanism of NSAID-induced liver damage remains largely unknown. Due to the increasing use of ibuprofen in children, the possibility of increased rates of drug-induced liver damage and Reye syndrome should be considered.

The maximum recommended daily dose of ibuprofen is 3200 mg. Overdosing on ibuprofen can cause severe toxicity, particularly in children ingesting 400 mg/kg or more. Complications of overdose include seizures, apnea, hypertension, and potential renal and hepatic dysfunction. Chronic administration of high-dose ibuprofen is also associated with increased risks of myocardial infarction. Management of Overdose There is no available antidote for ibuprofen. The toxicity resolves with time and supportive care. The management of severe ibuprofen toxicity typically involves supportive care and interventions like continuous renal replacement therapy (CRRT) or hemodialysis (HD). Despite ibuprofen's large molecule size and high protein binding, which typically limits dialysis clearance, CRRT can stabilize metabolic balance and support hemodynamics. In patients with significant metabolic acidosis and hemodynamic instability, CRRT may be initiated to facilitate the gradual elimination of ibuprofen and restore homeostasis, even though it does not acutely remove the drug. Selective Plasma Adsorption (SPAD) has demonstrated potential as a treatment for severe ibuprofen overdose. This process uses albumin dialysate to eliminate highly protein-bound toxins, improving outcomes for patients with multi-organ failure and shock. Rates of serum aminotransferase elevations during low dose, chronic ibuprofen therapy are comparable to those that occur with placebo controls (0.4%). However, higher rates of ALT elevations occur with high, full doses of 2,400 to 3,200 mg daily (up to 16%). Generally, ALT elevations are mild and rarely above 100 U/L. Rare instances of drug fever arise within 1 to 4 weeks of starting ibuprofen which can be accompanied by serum aminotransferase elevations. If ibuprofen is continued in these situations, more severe liver injury and jaundice may arise. These outcomes may account for a rare case of hepatocellular injury attributed to conventional doses of ibuprofen. Ibuprofen overdose (>5-10 grams) is characterized by onset of agitation, nausea and vomiting, and stupor 3 to 6 hours after ingestion and with higher dose, followed by coma, respiratory depression, renal dysfunction, and lactic acidosis which can be fatal. While many cases of ibuprofen overdose have not been accompanied by prominent liver injury or jaundice, recently, clear cut cases of acute liver injury resembling the acute hepatic necrosis that occurs with ischemia or acetaminophen overdose have been reported after intentional and unintentional overdoses. The injury arises 2 to 4 days after the overdose and is characterized by a rapid rise in serum aminotransferase levels (typically AST greater than ALT) accompanied by elevations in INR, and delayed increase in bilirubin levels. Serum aminotransferase levels fall rapidly thereafter and are usually normal or near normal within 2 to 4 weeks. Deaths have been reported but generally as a result of medical complications. The liver injury associated with ibuprofen overdose is probably a direct toxicity but its etiology has not been clearly defined. Idiosyncratic, clinically apparent liver injury due to ibuprofen is very rare (estimated to occur at a rate of 1.0-1.6 cases per 100,000 prescriptions and in 1 per 10,000 new users). However, many convincing reports have been published of acute liver injury attributed to ibuprofen, usually after presentation with an immunoallergic-like reaction within days of starting (Cases 1 and 2). Some instances are associated with severe hypersensitivity reactions, such as DRESS syndrome, Stevens Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) typically with a mixed or cholestatic pattern of liver injury. The time to onset is within a few days to 3 weeks of starting, occasional cases arising after 3 to 6 weeks. Immunoallergic features are prominent (fever, rash, eosinophilia, facial edema, lymphadenopathy). Most cases are mild-to-moderate in severity and rapidly reversible on stopping ibuprofen. Rare instances of cholestatic liver injury due to ibuprofen are followed by severe, protracted cholestasis, vanishing bile duct syndrome, and chronic liver failure (Case 3). Idiosyncratic liver injury due to ibuprofen is typically seen in patients taking rather high daily doses and can occur abruptly in patients who restart ibuprofen have tolerated therapy in the past. The appearance of clinically apparent liver injury during long term or intermittent, low dose ibuprofen therapy has not been convincingly demonstrated. Some instances of liver injury from ibuprofen have arisen in patients on long-term, low-dose or intermittent therapy who increase the dose to high levels (at least 1,200 mg daily). However, ibuprofen is a commonly used analgesic and acute liver injury of unclear cause can be falsely attributed to low dose or intermittent use of ibuprofen which is sometimes started at the onset of the incidental illness such as herpes zoster or viral or bacterial pharyngitis. Likelihood score: A (well defined but very rare cause of clinically apparent liver injury).

- Skin corrosion/irritation: No data available.

- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: No data available.
- Carcinogenicity: No data available.
- Reproductive toxicity: No data available.
- STOT-single exposure: No data available.
- STOT-repeated exposure: Signs and Symptoms of Overdose Ibuprofen's toxic potential is derived from its inhibition of the cyclooxygenase pathway and the subsequent effects on various cellular processes and multiple organ systems. Prostaglandins and thromboxanes help maintain the gastric mucosal layer and renal blood flow; ibuprofen is associated with a mildly elevated risk of adverse gastrointestinal and renal events, even at therapeutic levels. Ibuprofen is the most common NSAID involved in overdose cases; 29% of overdoses are the result of ibuprofen ingestion alone. Patients can also overdose by ingesting ibuprofen combined with other analgesics. One study created a risk score for improving the risk-benefit ratio of NSAID administration; this score was accurate in categorizing the one-year risk of significant toxicity among NSAID users. Reye syndrome is an increasingly rare presentation, primarily due to international efforts to curb aspirin usage since the 1980s. Restricted aspirin administration to children in the United Kingdom reduced the incidence of Reye syndrome from 100 cases in 1984 to 3 cases in 2000. NSAIDs damage the mitochondria in hepatocytes, precipitating Reye syndrome. Furthermore, the mechanism of NSAID-induced liver damage remains largely unknown. Due to the increasing use of ibuprofen in children, the possibility of increased rates of drug-induced liver damage and Reye syndrome should be considered. The maximum recommended daily dose of ibuprofen is 3200 mg. Overdosing on ibuprofen can cause severe toxicity, particularly in children ingesting 400 mg/kg or more. Complications of overdose include seizures, apnea, hypertension, and potential renal and hepatic dysfunction. Chronic administration of high-dose ibuprofen is also associated with increased risks of myocardial infarction. Management of Overdose There is no available antidote for ibuprofen. The toxicity resolves with time and supportive care. The management of severe ibuprofen toxicity typically involves supportive care and interventions like continuous renal replacement therapy (CRRT) or hemodialysis (HD). Despite ibuprofen's large molecule size and high protein binding, which typically limits dialysis clearance, CRRT can stabilize metabolic balance and support hemodynamics. In patients with significant metabolic acidosis and hemodynamic instability, CRRT may be initiated to facilitate the gradual elimination of ibuprofen and restore homeostasis, even though it does not acutely remove the drug. Selective Plasma Adsorption (SPAD) has demonstrated potential as a treatment for severe ibuprofen overdose. This process uses albumin dialysate to eliminate highly protein-bound toxins, improving outcomes for patients with multi-organ failure and shock. Rates of serum aminotransferase elevations during low dose, chronic ibuprofen therapy are comparable to those that occur with placebo controls (0.4%). However, higher rates of ALT elevations occur with high, full doses of 2,400 to 3,200 mg daily (up to 16%). Generally, ALT elevations are mild and rarely above 100 U/L. Rare instances of drug fever arise within 1 to 4 weeks of starting ibuprofen which can be accompanied by serum aminotransferase elevations. If ibuprofen is continued in these situations, more severe liver injury and jaundice may arise. These outcomes may account for a rare case of hepatocellular injury attributed to conventional doses of ibuprofen. Ibuprofen overdose (>5-10 grams) is characterized by onset of agitation, nausea and vomiting, and stupor 3 to 6 hours after ingestion and with higher dose, followed by coma, respiratory depression, renal dysfunction, and lactic acidosis which can be fatal. While many cases of ibuprofen overdose have not been accompanied by prominent liver injury or jaundice, recently, clear cut cases of acute liver injury resembling the acute hepatic necrosis that occurs with ischemia or acetaminophen overdose have been reported after intentional and unintentional overdoses. The injury arises 2 to 4 days after the overdose and is characterized by a rapid rise in serum aminotransferase levels (typically AST greater than ALT) accompanied by elevations in INR, and delayed increase in bilirubin levels. Serum aminotransferase levels fall rapidly thereafter and are usually normal or near normal within 2 to 4 weeks. Deaths have been reported but generally as a result of medical complications. The liver injury associated with ibuprofen overdose is probably a

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- Aspiration hazard: No data available.

#### Likely routes of exposure

- Signs and Symptoms of Overdose Ibuprofen's toxic potential is derived from its inhibition of the cyclooxygenase pathway and the subsequent effects on various cellular processes and multiple organ systems. Prostaglandins and thromboxanes help maintain the gastric mucosal layer and renal blood flow; ibuprofen is associated with a mildly elevated risk of adverse gastrointestinal and renal events, even at therapeutic levels. Ibuprofen is the most common NSAID involved in overdose cases; 29% of overdoses are the result of ibuprofen ingestion alone. Patients can also overdose by ingesting ibuprofen combined with other analgesics. One study created a risk score for improving the risk-benefit ratio of NSAID administration; this score was accurate in categorizing the one-year risk of significant toxicity among NSAID users. Reye syndrome is an increasingly rare presentation, primarily due to international efforts to curb aspirin usage since the 1980s. Restricted aspirin administration to children in the United Kingdom reduced the incidence of Reye syndrome from 100 cases in 1984 to 3 cases in 2000. NSAIDs damage the mitochondria in hepatocytes, precipitating Reye syndrome. Furthermore, the mechanism of NSAID-induced liver damage remains largely unknown. Due to the increasing use of ibuprofen in children, the possibility of increased rates of drug-induced liver damage and Reye syndrome should be considered. The maximum recommended daily dose of ibuprofen is 3200 mg. Overdosing on ibuprofen can cause severe toxicity, particularly in children ingesting 400 mg/kg or more. Complications of overdose include seizures, apnea, hypertension, and potential renal and hepatic dysfunction. Chronic administration of high-dose ibuprofen is also associated with increased risks of myocardial infarction. Management of Overdose There is no available antidote for ibuprofen. The toxicity resolves with time and supportive care. The management of severe ibuprofen toxicity typically involves supportive care and interventions like continuous renal replacement therapy (CRRT) or hemodialysis (HD). Despite ibuprofen's large molecule size and high protein binding, which typically limits dialysis clearance, CRRT can stabilize metabolic balance and support hemodynamics. In patients with significant metabolic acidosis and hemodynamic instability, CRRT may be initiated to facilitate the gradual elimination of ibuprofen and restore homeostasis, even though it does not acutely remove the drug. Selective Plasma Adsorption (SPAD) has demonstrated potential as a treatment for severe ibuprofen overdose. This process uses albumin dialysate to eliminate highly protein-bound toxins, improving outcomes for patients with multi-organ failure and shock.

#### Symptoms related to the physical, chemical and toxicological characteristics

- Signs and Symptoms of Overdose Ibuprofen's toxic potential is derived from its inhibition of the cyclooxygenase pathway and the subsequent effects on various cellular processes and multiple organ systems. Prostaglandins and thromboxanes help maintain the gastric mucosal layer and renal blood flow; ibuprofen is associated with a mildly elevated risk of adverse gastrointestinal and renal events, even at therapeutic levels. Ibuprofen is the most common NSAID involved in overdose cases; 29% of overdoses are the result of ibuprofen ingestion alone. Patients can also overdose by ingesting ibuprofen combined with other analgesics. One study created a risk score for improving the risk-benefit ratio of NSAID administration; this score was accurate in categorizing the one-year risk of significant toxicity among NSAID users. Reye syndrome is an increasingly rare presentation, primarily due to international efforts to curb aspirin usage since the 1980s. Restricted aspirin administration to children in the United Kingdom reduced the incidence of Reye syndrome from 100 cases in 1984 to 3 cases in 2000. NSAIDs damage the mitochondria in hepatocytes, precipitating Reye syndrome. Furthermore, the mechanism of NSAID-induced liver damage remains largely unknown. Due to the increasing use of ibuprofen in children, the possibility of increased rates of drug-induced liver damage and Reye syndrome should be considered. The maximum recommended daily dose of ibuprofen is 3200 mg. Overdosing on ibuprofen can cause severe toxicity, particularly in children ingesting 400 mg/kg or more. Complications of overdose include seizures, apnea, hypertension, and potential renal and hepatic dysfunction. Chronic administration of high-dose ibuprofen is also associated with increased risks of myocardial infarction. Management of Overdose There is no available antidote for ibuprofen. The toxicity resolves with time and supportive care. The management of severe ibuprofen toxicity typically involves supportive care and interventions like continuous renal replacement therapy (CRRT) or hemodialysis (HD). Despite ibuprofen's large molecule size and high protein binding, which typically limits dialysis clearance, CRRT can stabilize metabolic balance and support hemodynamics. In patients with significant metabolic acidosis and hemodynamic instability, CRRT may be initiated to facilitate the gradual elimination of ibuprofen and restore homeostasis, even though it does not acutely remove the drug. Selective Plasma Adsorption (SPAD) has demonstrated potential as a treatment for severe ibuprofen overdose. This process uses albumin dialysate to eliminate highly protein-bound toxins, improving outcomes for patients with multi-organ failure and shock.

## SECTION 12: Ecological information

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#### 12.1 Toxicity

- No data available.

#### 12.2 Persistence and degradability

- No data available.

#### 12.3 Bioaccumulative potential

- No data available.

#### 12.4 Mobility in soil

- No data available.

#### 12.5 Results of PBT and vPvB assessment

- Not available.

#### 12.6 Endocrine disrupting properties

- No data available.

#### 12.7 Other adverse effects

- No data available.

### SECTION 13: Disposal considerations

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- Dispose of contents/container in accordance with local/regional/national/international regulations.
- Do not discharge to drains.
- Recommended disposal method: Incineration or disposal via a licensed chemical waste contractor, as appropriate.
- Contaminated packaging: Dispose of as unused product in accordance with regulations.

### SECTION 14: Transport information

SECTION 14: Transport information

- UN number: Not available.
- UN proper shipping name: Not available.
- Transport hazard class(es): Not available.
- Packing group: Not available.
- Environmental hazards: Not available.
- Special precautions for user: Not available.

Transport in bulk according to IMO instruments

- Not available.

### SECTION 15: Regulatory information

SECTION 15: Regulatory information

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

- Not available.

15.2 Chemical safety assessment

- No data available.

### SECTION 16: Other information

SECTION 16: Other information

- Product name: Ibuprofen for peak Identification CRS (mixture of impurities A, J and N)
- Catalog No.: CS-EG-03330
- CAS No.: 15687-27-1
- Supplier: Clearsynth Labs Ltd., Mumbai, India
- Emergency phone: +91-22-245045900

Disclaimer

- The information provided is based on available product identification details and is intended for SDS-format guidance. No warranty is expressed or implied. Users are responsible for determining suitability and for compliance with applicable regulations.

Revision date

- 2026-03-18

### DISCLAIMER

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