Acemetacin

sc-217558

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Acemetacin

STATEMENT OF HAZARDOUS NATURE

NFPA

SUPPLIER
Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, California 95060
800.457.3801 or 831.457.3800

EMERGENCY
ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS
C21-H18-Cl-N-O6, "1H-indole-3-acetic acid, 1-(4-chlorobenzoyl)-5-methoxy-2-methyl-, ", "carboxymethyl ester", acemetacinum, [1-(p-chlorbenzoyl)-5-methoxy-2-methylindol-3-acetoxy]essigsäure, "1-(4-chlorobenzoyl)-5-methoxy-2-methyl-1H-indole-3-acetic acid", "[1-(4-chlorobenzoyl)-5-methoxy-2-methylindol-3-yl)acetoxyl]acetic acid", 2-[2-(1-(p-chlorobenzoyl)-5-methoxy-2-methylindol-3-yl)acetoxyl]acetic acid, Acemix, Aximeixin, K-708, Rantudil, Rheumibis, TV-1322, "NSAID anti-inflammatory/ anti-pyretic"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Body Contact</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Reactivity</td>
<td>1</td>
<td></td>
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</tbody>
</table>

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4
EMERGENCY OVERVIEW
RISK
Possible risk of irreversible effects.
Very toxic by inhalation, in contact with skin and if swallowed.
Very toxic to aquatic organisms.

POTENTIAL HEALTH EFFECTS
ACUTE HEALTH EFFECTS

SWALLOWED
■ Severely toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 5 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
■ There is evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation.
Severe inflammation may be expected with pain.

SKIN
■ Skin contact with the material may produce severely toxic effects; systemic effects may result following absorption and these may be fatal.
■ 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.
■ 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
■ Inhalation of dusts, generated by the material, during the course of normal handling, may produce severely toxic effects; these may be fatal.
■ 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.
■ The material can cause respiratory irritation in some persons.
The body’s response to such irritation can cause further lung damage.

CHRONIC HEALTH EFFECTS
■ Strong evidence exists that this substance may cause irreversible mutations (though not lethal) even following a single exposure.
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).

Reproductive studies in mice and rats, using indomethacin, show evidence of foetotoxicity at or above 4 mg/kg/day. Indomethacin is non-carcinogenic in rats and mice given maximally tolerated oral doses for 110 weeks.

### Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>acemetacin</td>
<td>53164-05-9</td>
<td>&gt;98</td>
</tr>
</tbody>
</table>

### 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 or hair contact occurs
- Immediately flush body and clothes with large amounts of water, using safety shower if available.
- Quickly remove all contaminated clothing, including footwear.
- Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre.
- Transport to hospital, or doctor.

#### 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).

Section 5 - FIRE FIGHTING MEASURES

<table>
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<tr>
<th>Vapour Pressure (mmHG)</th>
<th>Negligible</th>
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</thead>
<tbody>
<tr>
<td>Upper Explosive Limit (%)</td>
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</tr>
<tr>
<td>Specific Gravity (water=1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
<td>Not available</td>
</tr>
</tbody>
</table>

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.
- May be violently or explosively reactive.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 800 metres in all directions.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- 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.
- 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)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people. Combustion products include carbon monoxide (CO), carbon dioxide (CO2), 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 breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.

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.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS
- 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.
- All inner and sole packagings for substances that have been assigned to Packaging Groups I or II on the basis of inhalation toxicity criteria, must be hermetically sealed.

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
- acemetacin CAS53164-05-9

PERSONAL PROTECTION
RESPIRATOR
• Particulate. (AS/NZS 1716 & 1715, EN 1432000 & 1492001, ANSI Z88 or national equivalent)

EYE
- Chemical protective goggles with full seal
- Shielded mask (gas-type)
- 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
- Elbow length PVC gloves
  Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include
  - frequency and duration of contact,
  - chemical resistance of glove material,
  - glove thickness and dexterity
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers. [AS/NZS 2210]

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.).

Unless written procedures, specific to the workplace are available, the following is intended as a guide
• For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets*; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems; Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*.

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

• The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated. Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated. When handling Quantities of up to 25 grams, an approved respirator with HEPA filters or cartridges should be considered; Quantities of 25 grams to 1 kilogram, a half-face negative pressure, full negative pressure, or powered helmet-type air purifying respirator should be considered. Quantities in excess of 1 kilogram, a full face negative pressure, helmet-type air purifying, or supplied air respirator should be considered.

Written procedures, specific to a particular work-place, may replace these recommendations

* For Class II Biological Safety Cabinets, Types B2 or B3 should be considered.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.
Does not mix with water.

<table>
<thead>
<tr>
<th>State</th>
<th>Divided solid</th>
<th>Molecular Weight</th>
<th>415.82</th>
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<tbody>
<tr>
<td>Melting Range (°F)</td>
<td>302-307</td>
<td>Viscosity</td>
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<tr>
<td>Boiling Range (°F)</td>
<td>Not available</td>
<td>Solubility in water (g/L)</td>
<td>Partly miscible</td>
</tr>
<tr>
<td>Flash Point (°F)</td>
<td>Not available</td>
<td>pH (1% solution)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition Temp (°F)</td>
<td>Not Available</td>
<td>pH (as supplied)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition Temp (°F)</td>
<td>Not available</td>
<td>Vapour Pressure (mmHG)</td>
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<td>Upper Explosive Limit (%)</td>
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<td>Specific Gravity (water=1)</td>
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<tr>
<td>Lower Explosive Limit (%)</td>
<td>Not available</td>
<td>Relative Vapour Density (air=1)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Volatile Component (%vol)</td>
<td>Negligible</td>
<td>Evaporation Rate</td>
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</tr>
</tbody>
</table>

APPEARANCE

Very fine crystalline solid; does not mix well with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

• Presence of incompatible materials.
• Product is considered stable.
• Hazardous polymerisation will not occur.

STORAGE INCOMPATIBILITY

• Avoid reaction with oxidising agents

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

Section 11 - TOXICOLOGICAL INFORMATION

acemetacin

TOXICITY AND IRRITATION

• unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.
The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. The material may produce respiratory tract irritation, and result in damage to the lung including reduced lung function.

Section 12 - ECOLOGICAL INFORMATION

Very toxic to aquatic organisms.
This material and its container must be disposed of as hazardous waste.
Avoid release to the environment.
Refer to special instructions/ safety data sheets.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions
All waste must be handled in accordance with local, state and federal regulations.
- 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. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate:
- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)
This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.
- 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
DOT:
Symbols: None
Identification Numbers: UN3249
Label Codes: 6.1
Packaging: Exceptions: 153
Quantity Limitations: Cargo aircraft only: 5 kg
Vessel stowage: Other: 40
Hazardous materials descriptions and proper shipping names:
Medicine, solid, toxic, n.o.s.

Air Transport IATA:
ICAO/IATA Class: 6.1
UN/ID Number: 3249
Special provisions: A3
Cargo Only
Packaging Instructions: 676
Passenger and Cargo
Packaging Instructions: 669
Passenger and Cargo
Limited Quantity
Packaging Instructions: Y644
Maximum Qty/Pack:
Passenger and Cargo
100 kg
25 kg
Limited Quantity
1 kg

Maritime Transport IMDG:
IMDG Class: 6.1
UN Number: 3249
EMS Number: F-A,S-A
Limited Quantities: 500 g
Shipping name:MEDICINE, SOLID, TOXIC, N.O.S.(contains acemetacin)

Section 15 - REGULATORY INFORMATION
acemetacin (CAS: 53164-05-9) is found on the following regulatory lists;
"US FDA Maximum Recommended Therapeutic Dose (MRTD) Database"

Section 16 - OTHER INFORMATION
LIMITED EVIDENCE
■ Cumulative effects may result following exposure*.
■ May produce discomfort of the eyes and respiratory tract*.
* (limited evidence).
### Denmark Advisory list for selfclassification of dangerous substances

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS</th>
<th>Suggested codes</th>
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<tr>
<td>acemetacin</td>
<td>53164-05-9</td>
<td>Mut3; R68 Tx, R28 N; R50</td>
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- 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. A list of reference resources used to assist the committee may be found at: www.chemwatch.net/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.

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