

# Safety Data Sheet



## 1. Identification of the Substance/Mixture and the Supplier

Supplier : National Institute of Advanced Industrial Science and Technology (AIST)

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Identity of Substance/Mixture : Certified reference material: NMIJ CRM 6211-a  
4-Hydroxy-clomifene Standard Solution

Recommended Use of the Chemical and Restriction on Use : This CRM is intended for use in the calibration of instruments and validation of analytical methods.  
Do not use this CRM for other purposes than testing/research.

## 2. Hazards Identification

GHS Classification :

Flammable liquid	:	Hazard Category 2
Acute Toxicity (oral)	:	Hazard Category 4
Serious Eye Damage/ Eye Irritation	:	Hazard Category 2
Reproductive toxicity	:	Hazard Category 1B
Specific Target Organ Toxicity/Systemic Toxicity (Single Exposure)	:	Hazard Category 1 (central nervous system, visual organ, systemic Toxicity)
Specific Target Organ Toxicity/Systemic Toxicity (Repeated Exposure)	:	Hazard Category 3 (anesthetic action, respiratory tract irritation) Hazard Category 1 (central nervous system, visual organ)

GHS Label Element:



Signal Word : Danger

Hazards Statement: Flammable liquid and vapor  
May be harmful if swallowed.  
Eye irritation  
May cause adverse effects on fertility or the unborn child.

Causes damage to organs (visual organ and nerve system)  
Systemic Toxicity  
May cause respiratory irritation  
May cause drowsiness or dizziness  
Causes damage to organs (visual organ and nerve system) through prolonged or repeated exposure

Precautionary Statement : [Safety Precaution]  
Get the instruction manual before use.  
Do not handle until all safety precautions have been read and understood.  
Use personal protective equipment if necessary.  
Do not eat, drink or smoke when using this reference material.  
Keep away from heat/sparks/open flames/hot surfaces. No smoking.  
Wash hands thoroughly after handling.  
Keep container tightly closed after using this reference material.  
Use explosion-proof electrical/ventilating/lighting equipment.  
Use only non-sparking tools.  
Ground and bond container and receiving equipment.  
Take precautions against electrostatic discharge.  
Avoid breathing dust/fume/gas/mist/vapors/spray.  
Use only outdoors or in a well-ventilated area.  
[First-Aid Measures]  
If exposed or concerned: Get medical advice/attention.  
If you feel unwell: Get medical advice/attention.  
If in eyes: Rinse cautiously with clean water for several minutes.  
Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.  
If on skin or hair: Remove/Take off all contaminated clothing and adhered materials. Rinse skin or hair with running water.  
In case of fire: Use powder, CO<sub>2</sub> or foam fire extinguisher.  
[Storage]  
Store this reference material in a light-shielded clean environment at temperatures of -30 °C to -15 °C.  
[Disposal]  
Dispose of this reference material in accordance with applicable legislation and local government ordinance.  
Entrust disposal of this reference material to a professional waste disposal company licensed by prefectural governor.

The other hazards than the above do not result in classification or are not classifiable.

### 3. Composition/Information on Ingredients

Substance/Mixture : Mixture  
Chemical name : 4-Hydroxy-clomifene Standard Solution

Ingredient 1	:	Methanol (Methyl alcohol)
Synonym	:	Methyl alcohol, Wood alcohol
Chemical Formula or Structural Formula	:	CH <sub>3</sub> OH
Molecular Weight	:	32.04
CAS Number	:	67-56-1
Content	:	Ca. 99 %
Reference Number in Gazetted List in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : (2)-201 Industrial Safety and Health Act : Published
Ingredient 2	:	4-hydroxy-clomiphene
Synonym	:	4-[2-Chloro-1-[4-[2-(diethylamino)ethoxy]phenyl]-2-phenylethenyl]phenol
Chemical Formula or Structural Formula	:	C <sub>26</sub> H <sub>28</sub> ClNO <sub>2</sub>
Molecular Weight	:	421.97
CAS Number	:	79838-51-0
Content	:	254 µg/g, 200 µg/mL
Reference Number in Gazetted List in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. :- Industrial Safety and Health Act :-
Hazardous Ingredient	:	Methanol

4-hydroxy-clomiphene is a mixture of the following two chemical components :

Name	CAS Number	Content
( <i>E</i> )- 4-hydroxy-clomiphene	104575-08-8	176 µg/g
( <i>Z</i> )- 4-hydroxy-clomiphene	104575-09-9	78 µg/g

#### 4. First-aid Measures

If inhaled	:	Remove victim to fresh air and keep at rest and warm. Get medical advice/attention.
If on Skin	:	Rinse away thoroughly with clean water. Take off/Remove contaminated clothing, shoes, etc. If skin irritation or rash occurs get medical advice/attention.
If in Eyes	:	Rinse away thoroughly with clean water. Get medical advice/attention.
If swallowed	:	Rinse mouth thoroughly with water. Get medical advice/attention immediately.
Protection for first aid provider	:	Use appropriate protective equipment to avoid inhalation.

#### 5. Fire-fighting Measures

Extinguishing Media	:	Powder, foam, carbon dioxide, dry sand, water spray
Fire-Specific Hazard	:	In case of fire: May emit irritating or toxic fume (or gas).
Specific Fire-Fighting	:	Eliminate ignition sources at the origin of a fire and put out

Method : fire by using extinguishing media. Remove movable containers promptly to a safe place. If containers are immovable, cool their surroundings with water spray.

Protection of Fire-Fighters : Fight fire upwind to avoid breathing hazardous gas. Use personal protective equipment such as fire-resistant clothing, self-contained compressed air breathing apparatus, closed circuit breathing apparatus, rubber gloves, and rubber boots.

## 6. Accidental Release Measures

Personal Precaution : Remove ignition sources in the vicinity immediately. Make fire extinguishing media/equipment available to prepare for potential ignition.

Personal Protective Equipment and Emergency Procedure : Ventilate the affected areas thoroughly, if it is in an indoor environment, until the clean-up operation is completed. Use appropriate personal protective equipment during the operation to avoid skin contact of splash, etc. and inhalation of dust and gas.

Environmental Precaution : Take precautions to prevent spillage from draining into rivers etc. to adversely impact the environment. Make it sure to appropriately treat contaminated wastewater in order to prevent untreated wastewater from being released into the surrounding environment.

Recovery and Neutralization : Adsorb spillage with waste clothes, wiping clothes, or dry sand, and collect in empty containers. Rinse away the remains with plenty of water.

Prevention of Secondary Disaster : Mark the restricted area with rope, etc. to keep out unauthorized people. Carry out the clean-up operation from the windward and make people on the leeward side evacuate.

## 7. Handling and Storage

Handling

Engineering Precaution : Strict ban on fire.  
Keep away from hot surfaces and sparks. Do not allow contact with strong oxidizers.

Local and General Ventilation : If vapor or mist is emitted: Seal the source. Provide local exhaust ventilation or general ventilation.

Precautions for Safe Handling : Avoid rough handling such as turning over, dropping, giving a shock to and dragging containers.  
Prevent this reference material from leaking, overflowing, and splashing. Do not allow vapor to be emitted.  
Keep container tightly closed after use.  
Wash hands, face, etc. thoroughly and gargle after handling this reference material.  
Restrict drinking, eating and smoking to a designated area.  
Do not bring gloves and other contaminated personal protective

equipment into staff room.

Make a place handling this reference material a restricted area to keep out unauthorized people.

Use appropriate personal protective equipment to avoid inhalation and contact with eyes, skin and clothing.

Use local ventilation system in indoor handling area.

#### Storage

- Appropriate Storage : Store at temperatures of  $-30\text{ }^{\circ}\text{C}$  to  $-15\text{ }^{\circ}\text{C}$  in a clean place and  
Condition : protect from light.  
Safe Container : Glass  
Packaging Material

※Refer to the reference material certificate for the precaution statement regarding the appropriate condition of the storage and usage of the reference material.

## 8. Exposure Controls/Personal Protection (Methanol)

#### Threshold Limit Value

Not specified

#### Permissible Concentration

- ACGIH TLV-TWA : 200 ppm (260 mg/m<sup>3</sup>)
- Value recommended by Japan Society for Occupational Health : 200 ppm (260 mg/m<sup>3</sup>)
- OSHA PEL TWA : 200 ppm

#### Engineering Controls

- Ventilation/Exhaust : Local ventilation system or General ventilation system  
Safety Control/  
Gas Detection : Measuring equipment, Detecting tube  
Storage Precaution : Ventilate along floor surface. Seal. Keep away from flammable substances, reducing agents and strong oxidizers.

#### Personal Protective Equipment (PPE)

- Respiratory System : Protective gas mask for organic vapors, Self-contained compressed air breathing apparatus as required.  
Hands : Protective gloves  
Eyes : Eye protector (Goggle type as necessary)  
Skin and Body : Protective clothing, Protective face mask

#### Hygiene Controls

Handle this reference material in accordance with industrial health and safety standards.

## 9. Physical and Chemical Properties

- Appearance, etc. : Liquid  
Color : Clear and colorless  
Odor : Characteristic odor  
pH : No data  
Melting point :  $-98\text{ }^{\circ}\text{C}$  (methanol)  
Boiling point :  $64\text{ }^{\circ}\text{C}$  (methanol)

Flashing point	: 11 °C (methanol)
Explosive range	: From 6.0 v/v% to 36.5 v/v% (methanol)
Vapor pressure	: 12.3 kPa (methanol)
Relative vapor density (Air=1)	: 1.1 (methanol)
Specific gravity or bulk specific gravity	: 0.791 to 0.793 (methanol)
Solubility	: Easily soluble in water, diethyl ether and ethanol.
<i>n</i> -Octanol/water partition coefficient (Log Po/w)	: -0.74 (methanol)
Auto-ignition temperature	: 464 °C (methanol)
Decomposition temperature	: No data available
Flammability	: No data available

## 10. Stability and Reactivity

Stability	: Stable under recommended storage conditions
Reactivity	: Contact with strong oxidizer may cause fire or explosion.
Conditions to Avoid	: Direct sunlight, heat, open flame, high temperature material, spark, static electrical charge, and other fire sources. Contact with oxidizers.
Incompatible materials	: Contact with strong oxidizer.
Hazardous	: Carbon monoxide, carbon dioxide
Decomposition	
Products	

## 11. Toxicological Information (Methanol)

Acute Toxicity	Oral: Rat LD <sub>50</sub> =6200 mg/kg Dermal: Rabbit LD <sub>50</sub> =15800 mg/kg
Serious Eye Damage/Eye Irritation	In the Draize test using rabbits, the mean score for conjunctivitis after 24, 48, and 72 hours was 2.1 (greater than 2.0), and conjunctive edema was observed for 4 hours (score 2.00), but it was noticeably improved after 72 hours (score 0.50). However, it is unknown whether the symptoms recovered within 7 days.
Carcinogenicity	Not classifiable
Reproductive Toxicity	In a test of pregnant mice exposed through inhalation during the period of organogenesis, fetal resorption and exencephaly were observed. In separate inhalation and oral exposure tests, similar results were obtained, including cleft palate. As for the effect of methanol on reproduction, there is sufficient evidence to provide a strong presumption on the basis of sound scientific judgment that exposure to methanol may result in health impairment. Although the available data on humans are limited, there is clear evidence for effects on animals, and it is concluded that prolonged human exposure to methanol may result in adverse effects on development of human fetus. It is

	accordingly assumed that it causes developmental toxicity to humans.
Specific Target Organ/Systemic Toxicity (Single Exposure)	Symptoms of acute intoxication in humans include central nervous system depression and metabolic acidosis resulting from formic acid accumulation in blood. Symptoms such as vision disorders, blindness, headache, dizziness, nausea, vomiting, tachypnea, and coma can occur, in addition to death. Disorders in the central nervous system, specifically tremor and extrapyramidal paralysis, as well as cerebral white matter necrosis, have been reported. The visual organs are the primary target organs; eye disorders are distinctive clinical features of metabolic acidosis, in addition to headache, nausea, vomiting, tachypnea, and coma. Anesthesia was produced by inhalation exposure in mice, rats, and humans as a result of central nervous system depression.
Specific Target Organ/Systemic Toxicity (Repeated Exposure)	In humans, prolonged exposure to low-concentration methanol caused eye damage; blindness is a toxic effect of chronic occupational methanol exposure. Chronic toxic symptoms caused by repeated exposure to methanol vapor including headache, dizziness, insomnia, and stomach disorders have been reported. Although changes in liver weight and hepatocyte hypertrophy have been reported in rats following oral administration, such changes are considered to be adaptive changes to methanol exposure.
Other	–

\* Section “Toxicological Information” is prepared based on the information on the raw materials because no information on the mixture is available.

This reference material is stable under normal condition, and there is no risk of noxious additive ingredient elusion. In case of handling this reference material under special conditions, such as high temperatures, however, it is recommended to take sufficient safety precautions for appropriate use.

## 11. Toxicological Information

Acute toxicity	: No data available
Skin corrosivity/ irritation	: No data available
Serious eye damage/ Eye irritation	: No data available
Respiratory sensitization	: No data available
Skin sensitization	: No data available
Germ cell mutagenicity	: No data available
Carcinogenicity	: Evaluated as Group 3 (cannot be classified as carcinogenic to humans) by IARC.

- Reproductive toxicity : No data available
- Specific organ toxicity (single exposure) : No data available
- Specific organ toxicity (repeated exposure) : Rats were fed 2% polystyrene in 5% diet and had no effect.
- Aspiration hazard : No data available

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This reference material is stable under normal condition, and there is no risk of noxious additive ingredient elusion. In case of handling this reference material under special conditions, such as high temperatures, however, it is recommended to take sufficient safety precautions for appropriate use.

## 12. Ecological Information

- Ecotoxicity : No data available
- Persistence and Degradability : Easily degradable by microorganisms.
- Bioaccumulative Potential : No data available
- Mobility in soil : No data available
- Influence to the ozone layer : No data available

## 13. Disposal Considerations

- Residual Waste : Incineration method  
Incinerate in an incinerator equipped with scrubber.  
Dispose in accordance with applicable legislation and local government ordinance.  
When the above-mentioned treatments are not possible, entrust disposal of this reference material to a professional waste disposal company licensed by local or national authority.
- Contaminated Container and Package : Dispose of containers after thoroughly removing their contents.

## 14. Transport Information

- UN Number : 1230
- UN Classification : Class 3
- Shipping Name : METHANOL
- Packing Group : PG III
- ICAO/IATA : Class 8, grade II
- Marine Pollutant : Hazardous Liquid Substance (Class Y Substance)
- Precaution : Transport this reference material carefully while keeping it away from direct sunlight and fire and preventing accidental release due to



falling, being knocked over, etc.

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## 15. Regulatory Information

- ◇ Fire Service Act
  - Hazardous materials Category IV Alcohols Hazard Class II Water soluble
- ◇ Industrial Safety and Health Act
  - Article 57 (Enforcement Order: Article 18) Hazardous substance whose name, etc. must be labeled.
  - Article 57-2 (Enforcement Order: Article 18-2) Hazardous substance whose name, etc. must be notified No. 560
  - Type 2 Organic Solvents (Order of Enforcement Appended Table 6-2 Ordinance on Prevention of Organic Solvent Poisoning Article 1 Section 1 Paragraph 4
  - Dangerous goods and flammable substances (Order of Enforcement Appended Table 1 Paragraph 4)
  - Criteria for assessment of the working environment (Article 65-2, Paragraph 1 of the Act)
- ◇ Regulations for the Carriage and Storage of Dangerous Goods in Ships
  - Flammable liquid (Dangerous Goods Regulations Article 3 Notification of Dangerous Goods Appended Table 1)
- ◇ Civil Aeronautics Act
  - Flammable liquid (Regulations for Enforcement Article 194 Notification of Dangerous Goods Appended Table 1)
- ◇ Act for the Prevention of Marine Pollution and Maritime Disasters
  - Order for Enforcement Appended Table 1 Noxious Liquid Substances Category Y Substance
- ◎ **This SDS was originally prepared for the use of the reference material in Japan, and therefore Section 15 “Regulatory Information” covers only those laws and regulations which are enacted and enforced in Japan. In case of using this reference material outside of Japan, it is necessary to refer to and apply relevant laws and regulations of the country in which it is used.**

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## 16. Other Information

Others

The information in this document is not intended to be exhaustive and is based on currently available information and data. The measures given in this document are applicable only to normal handling conditions. When handling this reference material under special conditions etc., it is recommended to take safety measures appropriate to each specific application and context of use. This document is intended to provide information and not intended to guarantee anything in handling this reference material.

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