Safety Data Sheet（SDS）

1. Chemical Product and Company Identification

Chemical product name: TEPICA GEL
Supplier name: KENEI PHARMACEUTICAL CO., LTD.
Address: 5-8, 2 Chome, Fushimimachi, Chuo-ku, Osaka, Japan
Department: Medical Information Department.
Tel: 81-6-6231-5822 Fax: 81-6-6204-0750

2. Summary of Harm and Hazards

GHS Classifications

Physical and chemical hazardousness:

Flammable liquid	Class 2
Pyrophoric liquid	Not classified
Self-heating substance	Not classified
Corrosive to metal	Not classified

Harmfulness for human health:

Acute toxicity (oral)	Not classified
Acute toxicity (dermal)	Cannot Be Classified
Acute toxicity (vapor)	Not classified
Acute toxicity (inhalation: mist)	Not classified
Dermal corrosion/irritation	Not classified
Serious eye damage/irritation	Class 2A-2B
Respiratory sensitization	Cannot Be Classified
Skin sensitization	Cannot Be Classified
Germ cell mutagenicity	Class 1B
Carcinogenicity	Not classified
Reproductive toxicity	Class 1A
Specific target organ systemic toxicity - single exposure	Class 3 (respiratory tract irritability, narcotic)
Specific target organ systemic toxicity - repeated exposure	Class 1 (liver), Class 2 (nerve)
Inhalation respiratory hazard	Cannot Be Classified

Environmental effects:

Acutely hazardous to the aquatic environment	Not classified
Chronically hazardous to the aquatic environment	Not classified

Other harm and/or hazards are not classified.

Pictograms:

Signal Word: Danger

Hazard Statement: Highly flammable liquid and vapor
Strong eye irritability
Possible risk of genetic disease
Possible risk of adverse effect on fertility or fetuses
Possible respiratory irritation
Possible drowsiness or vertigo
Organ (liver) injury after a long-term or repeated exposure
Possible organ (nerve) injury after a long-term or repeated exposure

Precautionary statement:

Do not deal with this substance until you have thoroughly read and understood all the following safety notices.

Do not eat, drink, or smoke while you use this product (No smoking).

Keep this product away from ignition sources such as heat, spark, naked flame, and something with high temperature.

Use explosion-proof electronic products, ventilators, and illuminators.

Prevent ignition from static discharge and/or spark.

Use protective equipment and ventilators to avoid exposure.

Wear protective gloves, goggles, and facemask.

Use this product only outdoors or in a well-ventilated area.

3. Composition/Information on Ingredients

Chemical or Mixture : Mixture

Chemical name: Ethanol

Synonyms: Ethyl alcohol, Methylcarbinol, Ethyl hydroxide, Ethyl hydrate, Spirits of wine

Content: not less than 76.9 %, less than 81.4 ethanol by volume

Hyaluronic acid sodium, glycerin, tocopherol acetate, carboxyvinylpolymer and triethanolamine are contained as additives.

Chemical formula: C_2H_5OH

Molecular mass: 46.07

CAS: ethanol No.64-17-5

Official gazette reference No. (under the Law concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances, and the Law concerning Industrial Safety and Health): (2)-202

Hazardous and harmful ingredients: Not contained

4. First Aid Measures

Inhalation:

Immediately remove affected person into fresh air and keep at rest. Seek immediate medical treatments if affected severely.

Skin contact:

Immediately remove contaminated clothes and wash the affected region with running water. Clean off fully with soap.

Eye contact:

After washing with large amount of water for at least 15 minutes, seek immediate medical treatments by an ophthalmologist.

Take applied contact lenses off if they can be so easily, then consult an ophthalmologist.

Ingestion:

After rinse the mouth with water again and again, give several cups of water to drink for diluting the effect and induce vomiting with fingers inserted into the throat if possible. Seek immediate medical treatments. If unconscious, give nothing orally. Don't try to make him/her vomit. Consult a doctor immediately.

5. Fire Fighting Measures

Extinguishing media:

Water, dry chemical, alcohol-resistant foam and carbon dioxide.

The digestive which you must not use:

Stick flooding

Fire fighting ways:

In the initial stage of fire, extinguish the fire with large amount of water injection, or with fire extinguishers using dry chemical, carbon dioxide, etc. In case of big fire, interrupt from the air by foam (alcohol-resistant foam).

Protection for fire fighters:

Wear an appropriate respirator and chemical protective clothing during fire fighting.

6. Accidental Release Measures

Personal Precautions, Protective Equipment, and Emergency Measures:

Let only authorized people enter.

For avoiding physical contact with high concentration of material, put on appropriate protection such as protective glasses, gas mask and hose mask.

Environmental Precautions:

Prevent this product from being released into the river that may affect on the environment.

When this product is diluted with a large amount of water, prevent contaminated wastes from being released into the environment without appropriate treatment.

Measures and Equipment for Containment and Cleaning:

In case of small amount, wash away the leaky area immediately with plenty of water.

In case of large amount, collect leaking and spilling liquid in empty sealable containers as much as possible. Wash away remainder with plenty of water.

Preventive Measures against Secondary Disaster:

Immediately remove adjacent ignition sources because this has permeability and volatility.

7. Handling and Storage

Handling

Technical Measures:

Take engineering measures and wear protective equipment specified under “8. Exposure Controls/Personal Protection.”

Local and General Ventilation:

Take engineering measures specified under “8. Exposure Controls/ Personal Protection” for good ventilation.

Precautions:

Avoid contact with or pouring into flammable or other possible fire sources. Do not vaporize or heat up it.

Don’t lay, drop, impact, or drag containers.

Make the whole electrical equipment in facilities for handling and storing with explosion-proof constructions. In places where possibly causes static electricity by alcohol flowage or others, set up equipment for effectively removing it.

Always keep facilities for handling in order and do not lay flammable or oxidative materials in or near the facilities.

Safe Handling Advice: See “10. Stability and Reactivity.”

Storage

Storage Conditions:

Store in a storage facility under the Fire Service Law. Keep the place well ventilated to prevent the vapor from retention. Also the materials less than designated volume should be kept away from ignition sources and other dangerous areas, stored in cool and dark places well ventilated, at appropriate temperature and humidity, and shielded from light.

Do not store the material mixed with hazardous materials designated as Category 1 and Category 6 under the Fire Service Law. In principle, do not store it mixed with nonhazardous materials but in case of storing with flammable solids or flammable liquid other than hazardous materials, by way of exception, store each of them in a mass and place the masses at intervals of one meter or more each other.

Container and Packaging Materials:

Use containers specified under the Fire Service Law and UN legislation covering transportation.

Incompatible Materials : See 10. Stability and reactivity.

8. Exposure Controls, Personal Protection

Facility measures:

It is important to use a closed system. Use explosion-proof lighting. Handling should be made in places with no ignition sources and well ventilated.

Occupational exposure limits: ACGIH (1996): TWA 1000 ppm (1880 mg/m^3)

Protective equipment:

Put on rubber gloves, rubber apron and protective footwear in ordinary circumstances. In places with high concentration of material, put on rubber gloves, rubber apron, protective footwear, protective glasses and gas mask.

Working clothes: Put on antistatic clothes.

9. Physical and Chemical Properties (as ethanol 100%)

Physical state: Liquid, Color: Transparent and colorless, Odor: Characteristic redolence,
Sapor: Stimulating taste, pH: Not applicable, Boiling point: 78.32°C (101.325 kPa),
Melting point: -114.5°C, Flash point: 13°C, Ignition temperature: 439°C
Explosive limits: From lower point of 3.3 vol% to upper point of 19.0 vol% (in the air),
Vapor pressure: 5.878 kPa (at 20°C), Relative vapor density (air = 1): 1.59,
Density: 0.78493 g/cm^3 (at 25°C), Solubility in solvents: Well dissolves in water and ether.,
Octanol/water partition coefficient: -0.30 (logPow), Decomposition temperature: No data

10. Stability and Reactivity (as ethanol 100%)

Stability:

Stable, not generate hazardous or harmful decomposition product in ordinary handling conditions.

Possible Hazardous Reactions:

The substance violently reacts with strong oxidants such as nitric acid, silver nitrate, mercury nitrate, and magnesium perchlorate, causing fire and explosion hazard.

The product erodes certain plastics, rubbers, and film forming agents.

Conditions to Avoid: Exposure to a high temperature

Incompatible Materials : Strong oxidants, calcium hypochlorite, and ammonia

Hazardous Decomposition Products: Carbon monoxide

11. Toxicological Information (as ethanol 100%)

Acute toxicity

Oral, in humans: LDL_0: 1400 mg/kg, affects behaviors and gastrointestinal systems (causes nausea).

Oral, in rats: LD_{50}: 7060 mg/kg, affects respiratory systems.

Inhalation, in rats: LC_{50} 20000 ppm/10h, toxicity unassessed.

Oral, in humans (male): TDL_0: 700 mg/kg, affects behaviors (psychophysiologically)

Injection, in rats: LD_{50}: 1440 mg/kg, affects respiratory systems.

Injection, in dogs: LDL_0: 1600 mg/kg, causes ataxia and affects respiratory systems.

Intra-abdominal, in mammals: LD_{50}: 4300 mg/kg, causes ataxia

Mutagenicity

Micronucleus, in mice (abdominal cavity): 1240 mg/kg/48 hours.

Dermal corrosion/irritation

Skin, in rabbits: 400 mg, open, causes mild irritation.

Skin, in rabbits: 500 mg/24 hours, causes severe irritation.

Carcinogenicity

IARC classifies the product as Group 1 due to it is “carcinogenic as an alcoholic drink in human.” This is because IARC considers the causal relationship between alcoholic drink and esophageal system and liver carcinomas based on various epidemiological surveys on people habitually taking alcoholic drink. On the other hand, ACGIH classifies ethanol as A4 (substance that cannot be classified as human carcinogen) as a hazardous factor mainly in a working environment.

Oral, in mice: TDL_0: 320 mg/kg/50 weeks, toxicity unassessed.

Serious eye damage/irritation

This product is classified as “moderate” based on a study according to OECD TG405 and Draize test.

Human corneal epithelium injury and conjunctival injection will be reversed in 1 or 2 days.

Eyes, in rabbits: 100 mg/24 hours, causes moderate irritation.

Respiratory sensitization

No information

Skin sensitization

No significant skin sensitization has been observed in animal studies.

Germ cell mutagenicity

Dominant lethal in rats and mice and heteroploidy in mouse germ cells have been reported.

Reproductive toxicity

There have been many reports that habitual intake of a large amount of alcohol may cause malformation and other adverse effects in human fetuses.

Inhalation, in rats: TCL_0: 20000 ppm/7 hours, causes poor development on day 1 to 22 of gestation.

Oral, in rats: TDL_0: 44 g/kg, causes poor development on day 7 to 17 of gestation.

Specific target organ systemic toxicity - single exposure

In human, oral intake of ethanol may cause adverse effect on the central nervous system and headache, fatigue, less concentration, and, in case of acute intoxication, death.

In human, inhalation at 5000 ppm (9.4 mg/L) may cause respiratory tract irritation, stupor, abnormal sleep.

Specific target organ systemic toxicity - repeated exposure

In human, intake of a large amount of alcohol can cause injury in almost all organs, of which the liver is a target organ that might be adversely effected most. Fatty degeneration may occur first, leading to necrosis, fibrosis, and eventually cirrhosis.

Withdrawal symptoms in patients with alcohol intoxication (tremor, epilepsy, confusion)

Inhalation respiratory hazard

No information

12. Ecological Information

Degradability

Calculated oxygen demand (ThOD): 2.10

BOD_5 44 to 80%ThOD

COD 90 to 100%ThOD

Inhibition of bacterial nitrification: Inhibits 50% of ammonia oxidation by Nitrosomonas in 4100mg/L.

Ecological toxicity

Orange fin: LC_{50}: 11.2 g/L/24 hours

A kind of carp: LC_{50}: 18 to 13.4 g/L/96 hours

Creek-chub: LC_{50}: 7 g/L/24 hours

Guppy: LC_{50}: 11 g/L/7 days

13. Disposal Considerations

Remaining wastes shall be burned up in an incinerator by means of spraying.

Discard the product according to relevant legislation as well as standards in local governments.

Consign disposal to industrial waste disposal services or local public body certified by prefectural governors or the like. Waste disposal should be consigned to waste disposal services after they were fully informed of risks and hazards.

- Recycle containers after cleaning or dispose them according to relevant legislation as well as standards in local governments.

When discarding used containers or pipes, etc., they shall be rinsed with water in advance.

Disposal shall be in accordance with descriptions in the column of “Precautions to be taken during handling and storing”, and with other general cautions to flammable liquids.

14. Transport Information

UN Hazard Class: Class 3 (Flammable liquid)

UN No.: 1170 ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

Fire Service Law: Article 2, Category 4 flammable liquid, 3 A kind of spirits in Attached Table 1 (designated volume: 400 L)

Civil Aeronautics Law: Article 194 in Regulation 3 flammable liquid (flash point: not more than 60 °C)

Civil Aeronautics Law: Notice of establishing criteria for transportation of explosive substances by air in Attached Table 1 Substances permitted to be transported

Port Regulations Law: Article 12 in Regulation 5 in Attached Table 2 on Notification of Hazardous Materials

Regulations on Transport by Ocean and Storage of Dangerous Goods:
Article 2, No.1 “ハ” (1) Flammable liquid

Notice of establishing criteria for transportation of explosive substances by ocean
Article 2, No.3 Flammable liquids in Attached Table 1

Law relating to the Prevention of Marine Pollution and Maritime Disaster:
Ordinance of Law Class Z material of 3-“イ”-21 in Attached Table 1

In addition to the above 7. Handling and Storage, mixed loading with hazardous materials designated as Category 1 and Category 6 is placed under a ban according to the Fire Service Law.

Guideline No. for emergency first aid measures: 127 (a yellow card should be retained during transfer)

15. Regulatory Information

Fire Service Law: Under Article 2, Category 4 flammable liquid, 3. A kind of spirits in Attached Table 1 (designated volume: 400L)

Alcohol Business Act: Article 2, 90 vol-% or more alcohol

Industrial Safety and Health Law: Ordinance, Hazardous substances 4. Flammable substances in Attached Table 1 Hazardous Materials.

Ordinance, Reportable Harmful Material to notify the name, etc. 61 in Attached Table 9.

Food Sanitation Law: This product is contained in No.56, Appendix 3 “The list of items that are used as additives that are generally served as food” of “Labeling of food additives according to the Food Sanitation Law” as of May 23, 1996.

Note) This product is not applicable to "Law concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management" (PRTR).

16. Other Information

Reference

Japan Bioindustry Association (a juridical foundation): Alcohol Handbook 9th Edition (1997)

The Chemical Society of Japan: Handbook of Chemical 4th Revised Edition, Maruzen (1993)

The Chemical Daily Co., Ltd.: 13700 Chemical Products

The Chemical Daily Co., Ltd.: International Chemical Safety Cards (ICSC) Japanese Version 3rd Series (1997)

Ministry of International Trade and Industry: Official Gazette (December 28, 1993)

Verschueren, K.: Handbook of Environmental Data on Organic Chemicals 4th ed.,(2001)

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Although this datasheet is prepared based on currently available materials, information, and data, the content, physical and chemical properties, and harm and hazards of this product might be revised according to new findings or tests. These precautions are applicable to ordinary handling. Safety measures appropriate for the usage should be taken for a special handling.

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