Safety Data Sheet (SDS)

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1. Product and company identification

Product name: Kenei Vaseline
Company name: Kenei Pharmaceutical Co., Ltd.
Address: 5-8, 2 Chome, Fushimimachi, Chuo-ku, Osaka
Department in charge: Medical Information Department
Phone No.: 81-6-6231-5822
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Contact: Medical Information Department, Kenei Pharmaceutical Co., Ltd.

2. Hazard identification

GHS classification

[Physicochemical hazards]

Explosives: Classification not possible.
Combustible/flammable gases: Not listed.
Combustible/flammable aerosol: Not listed.
Combustion enhancing/oxidizing gases: Not listed.
Gases under pressure: Not listed.
Flammable liquids: Not classified.
Flammable solids: Not listed.
Self-reactive substances: Not listed.
Pyrophoric liquids: Not classified.
Pyrophoric solids: Not listed.
Self-heating substances: Classification not possible.
Substances which, in contact with water, emit flammable gases: Not listed.
Oxidizing liquids: Not listed.
Oxidizing solids: Not listed.
Organic peroxides: Not listed.
Corrosive to metals: Classification not possible.

[Health hazards]

Acute toxicity (oral): Classification not possible.
Acute toxicity (dermal): Classification not possible.
Acute toxicity (inhalation: gases): Classification not possible.
Acute toxicity (inhalation: vapors): Classification not possible.
Acute toxicity (inhalation: dust): Classification not possible.
Acute toxicity (inhalation: mist): Classification not possible.
Skin corrosion/irritation: Not classified.
Serious eye damage/eye irritation: Category 2B
Respiratory sensitization: Classification not possible.
Skin sensitization: Not classified.
Germ cell mutagenicity: Classification not possible.
Carcinogenicity: Classification not possible.
Reproductive toxicity: Classification not possible.
Specific target organ systemic toxicity (single exposure): Classification not possible.
Specific target organ systemic toxicity (repeated exposure): Classification not possible.
Aspiration hazard: Classification not possible.

[Environmental hazards]

Hazardous to the aquatic environment (acute): Classification not possible.
Hazardous to the aquatic environment (chronic): Classification not possible.

GHS label element

[Pictogram or symbol]

None

[Signal word]

Warning

[Hazard statement]

Eye irritation

[Precautionary statement]

[Prevention]

- Thoroughly wash eyes after handling.

[Response]

- If in eyes: Rinse cautiously with water for a few minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- If eye irritation persists: Get medical advice/attention.

[Storage]

- None

[Disposal]

- None

[Other hazards]

- It is not assumed that serious detrimental effect occurs on health when used in accordance with the recommended methods.

3. Composition/Information on ingredients

Classification of the substance or mixture : Substance

Chemical name or common name	: Long-chain saturated hydrocarbon (Petrolatum) 99 to 100% by weight : Semisolid hydrocarbon obtained by dewaxing paraffin-based residual oil. Primarily comprising saturated crystals and liquid hydrocarbon having a carbon number 25 or more.
Alias	: Petrolatum, Petroleum jelly, Mineral grease (petrolatum), Vaseline (white), Vaseline
CAS No.	: 8009-03-8
Reference number in gazetted list in Japan	
Chemical Substance Control Law	: 9-1692 (Lubricant base oil obtained by hydrogenation refining or hydrogenolysis of oil fraction or residual oil)
Industrial Safety and Health Act	: Chemical Substance Control Law applied mutatis mutandis.

4. First aid measures

Inhalation	: Remove the victim to fresh air. If not breathing, if breathing is irregular, or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. For example, loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if any symptoms appear.

Skin contact : Immediately flush affected skin with plenty of water for at least 15 minutes and remove contaminated clothing and work shoes. Wash the clothing and work shoes thoroughly before reusing. Get medical attention if any symptoms appear.

Eye contact : Check for and remove any contact lenses. Flush eyes with plenty of water for at least 15 minutes, occasionally lifting and lowering the upper and lower eyelids. Get medical attention if any symptoms appear.

Ingestion : Gargle with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if any symptoms appear.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

5. Fire-fighting measures

Suitable extinguishing media : Use fire-extinguishing powder, fire-extinguishing foam, carbon dioxide, and sand.

Unsuitable extinguishing media : Do not use straight stream.

Specific hazards arising from the chemical: In a fire or if heated, a pressure increase may occur and the container may burst. In case of fire, immediately evacuate all the people to get away from the fire ground. No action shall be taken involving any personal risk or without suitable training.
Carbon dioxide or carbon monoxide is mentioned as harmful combustion by-products.

Specific methods of fire-fighting : Fire-fight from the windward side and use fire-extinguishing methods suited for the surrounding conditions.
Evacuate all the people to safe places except authorized personnel.

Special protective actions for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus covering an entire face operated in positive pressure mode.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
: No action shall be taken involving any personal risk or without suitable training. Evacuate the site of spillage. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through the spilled product. Wear appropriate personal protective equipment (see Section 8 of the present SDS).

Environmental precautions : Avoid diffusion of the spilled product and its outflow to soil, rivers, sewage system and drainage channels. Inform the relevant authorities if the product has caused environmental pollution (sewers, rivers, soil or air).

Methods for collection/neutralization, containment and cleaning up
: In the case of small spillages: Stop the leak if without risks. Move containers from the spill area. Absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
In the case of large spillages: Stop the leak if without risks. Move containers from the spill area. Prevent inflow to sewers, water ways, basement rooms and closed places. Wash away spillages into liquid waste treatment facilities or absorb with non-combustible absorbents, for example, dry sand and soil, vermiculite or diatomaceous earth and collect. And then, place into containers for disposal in conformity to municipal regulations (see Section 13 of the present SDS). Dispose of via a licensed waste disposal contractor.
For waste disposal, see Section 13 of the present SDS.

7. Handling and storage

[Handling]

Engineering measures : Put on appropriate personal protective equipment (gloves, glasses, and mask).

Local ventilation and general ventilation: Handle the product in a well-ventilated area, and use local ventilation and general ventilation as much as possible.

Precautions for safe handling : Put on appropriate personal protective equipment (see Section 8 of the present SDS).
Eating, drinking, and smoking should be prohibited in areas where the product is handled, stored, and processed.

Advice on general occupational hygiene: Workers should wash hands, forearms, and face thoroughly after handling chemical products, before eating, drinking and smoking, and using the restroom, and at the end of the working period. Remove contaminated clothing and protective equipment before entering eating areas. Use appropriate methods to remove invisible contaminants adhering to clothing. Wash contaminated clothing before reusing. Ensure that eye wash stations and safety showers are placed close to the workstation location.

[Storage]

Engineering measures : Abide by the provisions of the Fire Service Act. Store under lock.

Storage conditions : Store at temperatures not exceeding room temperature. Store in accordance with municipal regulations. Store in the original container protected from direct sunlight in a dry, cool and well-ventilated area, away from food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Incompatible substances : Strong oxidants

Container and packaging materials: No information

8. Exposure controls/personal protection

Control exposure limit : Not established.

Permissible exposure limit

Japan Society for Occupational Health (2014): 3 mg/m^3 (as mineral oil mist)

ACGIH (2013) : TWA 5.0 mg/m^3 (as mineral oil mist)

Engineering measures : Recommended monitoring procedures: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be prepared in line with appropriate monitoring standards. Reference to official compendiums for methods for the determination of hazardous substances will also be required.
Engineering controls: There are no special requirements for ventilation equipment. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, closed type manufacturing lines, local ventilation or other engineering controls shall be provided in order to keep worker exposure to the state falling below the recommended or statutory threshold values.
Environmental exposure controls: Emissions from ventilation or effluent treatment equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, engineering modifications to the fume scrubbers, filters or effluent treatment equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Respiratory protection	: A tightly fitting protective mask, air-purifying respirator or supplied-air respirator approved and complying with an approved standard should be used if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
Hand and foot protection	: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Wear rubber gloves, long rubber boots, and rubber aprons.
Eye protection	: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, or dusts. If contact is possible, the protective goggles with side shield should be worn, unless the assessment indicates a higher degree of protection.
Skin and body protection	: Personal protective equipment and protective clothing for the body should be selected based on the task being actually performed and the risks involved, and should be approved by a specialist before handling this product.
Hygiene measures	: Wash hands thoroughly after handling the product. Do not eat, drink, or smoke when using this product.

9. Physical and chemical properties

Physical state, appearance, color, etc.	: Colorless to white liquid or waxy solid
Odor	: Hydrocarbon smell
pH (25°C, 50 g/L)	: Not applicable
Melting point (°C)	: 38 to 60°C
Boiling point, initial boiling point, and boiling range	: >230°C
Flash point	: 182 to 221°C (59.6 to 429.8°F/closed cup test method) >200°C (92°F/Cleveland open cup test method)
Explosive limits	: No specific data
Vapor pressure	: <0.0013 kPa (<0.00975 mmHg/room temperature)
Vapor density (air = 1)	: No specific data
Specific gravity (density)	: 0.75 to 0.87 g/cm^3 (100°C)
Solubility	: Insoluble to cold water and warm water.
Octanol/water partition coefficient	: log P > 6
Auto-ignition temperature	: >290°C (>554°F)
Decomposition temperature	: No specific data
Odor threshold	: No specific data
Evaporation rate (butyl acetate = 1)	: No specific data
Viscosity	: 5 to 30 mm^2/s (100°C) (ASTM D445)

10. Stability and reactivity

Stability	: Stable under normal handling conditions.
Possibility of hazardous reactions	: No hazardous reaction occurs in the storage and the use under normal conditions.
Conditions to avoid	: Avoid direct sunlight, high heat, flame, sparks, or other ignition sources.
Incompatible substances	: Avoid contact with strong oxidants.
Hazardous decomposition products	: Combustion generates carbon monoxide, carbon dioxide, or trace amounts of carbon compounds, and soot.

11. Toxicological information

Acute toxicity

Oral	: Rat LD_{50} > 5000 mg/kg
Dermal	: Rabbit LD_{50} > 2000 mg/kg
Inhalation	: No specific data
Irritations (skin, eye)	: No known significant effects or critical hazards.
Respiratory or skin sensitization	: No information

Germ cell mutagenicity : No specific data

Carcinogenisity : EU R-phrase: R45 (Carcinogenisity category 2: May cause cancer). However, the grounds of classification are not known. Animal test: No carcinogenisity is recognized (IARC, 1984; ACGIH: 2006). IARC classification (1984): Mineral oils, highly-refined ... "Group 3" (Classification not possible).
GHS classification: IARC classification is adopted and "Classification not possible".

Toxicity for reproduction : Two-year dietary study in rats by orally administering dietary admixture: No effect was observed on reproductive organs even at a high dose (US HPVIS, 2011).

Specific target organ systemic toxicity

Single exposure : No known significant effects or critical hazards in ingestion.

Repeated exposure : Two-year dietary study in rats by orally administering dietary admixture: In the 50,000 ppm group, no effect on indicators of blood tests and clinical chemical tests and no histopathological alteration were observed. The repeated dose toxicity of petrolatum is extremely low, with NOAEL of 1,000 mg/kg/day or more (US HPVIS, 2011).
GHS classification: "Classification not possible" because harmfulness in exposure routes other than oral is unknown.

Aspiration hazards : Inhalation of petrolatum may generate lipid pneumonia or lipid granuloma (IARC, 1984).
GHS classification: "Classification not possible" because no information is obtained to ensure that the product clearly meets or does not meet the judgment standard.

12. Ecological information

Biotoxicity, Acute harmfulness : No specific data. Since petrolatum primarily comprises alkanes having a carbon number exceeding 20, the product is assumed not to have acute toxicity to aquatic invertebrate (IUCLID, 2000) and is designated as Not Listed, on the basis of NITE materials.

Biotoxicity, Chronic harmfulness : No specific data.
GHS classification: No specific data for fish, crustacean, and algae but the product is assumed to be bioaccumulative from its physical properties. Therefore, "Category 4" is designated for each organism species. "Category 4" is also designated as overall chronic aquatic toxicity.

Persistence and degradability : Not readily degradable (US HPVIS (2011))

Bioaccumulative potential : Estimated Log P: > 6 (IUCLID, 2000)

Mobility in soil : No information

13. Disposal considerations

Residual wastes : Dispose of in conformity to laws and regulations of the government and municipalities. Avoid and minimize generation of wastes as much as possible. Always meet requirements of environmental protection and wastes disposal laws and all the regulations of municipalities for disposal of the present product, its solution, and all the by-products. Entrust disposal of the product which remains and is unable to be reused to licensed waste disposal contractors. Do not discharge wastes in an untreated state to any sewage system, with the exception that the wastes completely comply with requirements of all the government offices and organizations in the jurisdiction. Avoid diffusion of the spilled product and its outflow to soil, rivers, sewage system and drainage channels.

Contaminated containers and packages: Clean and recycle containers or dispose of properly in conformity to related laws and regulations as well as standards of municipalities.
When empty containers are disposed of, completely remove the

content.
When disposal is entrusted, entrust disposal to professional waste disposal contractors licensed by the governor. In such event, thoroughly notify the professional waste disposal contractors of hazards and harmfulness of the product.

14. Transport information

International regulations

Maritime transport regulatory information : Not applicable

Air transport regulatory information : Not applicable

Domestic regulations

Land transport regulatory information : Fire Service Act: Non-hazardous material (designated combustibles)

Maritime transport regulatory information : Not applicable

Air transport regulatory information : Not applicable

Special safety measures : Load cargo with care to prevent leakage, and definitely take measures to prevent cargo collapse.

15. Regulatory information

Industry Safety and Health Act : Designated combustibles, Combustible solids

Pollutant Release and Transfer Register Law (PRTR Law): Not applicable

Fire Service Act : Non-hazardous material
(Designated combustibles, Combustible solids (Act Article 9-4, Ordinance on the Control of Dangerous Substances Article 1-12, Appended Table No. 4))

Poisonous and Deleterious Substances Control Act: Not applicable

Marine Pollution Prevention Act : Hydrocarbon oil (excluding those extracted from coal) and that other than mixtures obtained by blending chemically single organic compounds and two or more relevant organic compounds (Act Article 3, Paragraph 2 and Enforcement regulations Article 2)

Water Pollution Control Act : Permissible limit for mineral oils content: 5 mg/L
(Normal-hexane extract content: Enforcement ordinance Article 3-4)

Sewage Service Act : Mineral oils content: 5 mg/L or less
(Normal-hexane extract content: Enforcement ordinance Article 9 and Article 9-5)

Wastes Disposal and Public Cleansing Act: Industrial waste regulations (Enforcement ordinance Article 6, etc.)

16. Other information

References:

SONNEBORN: SDS (2015/05/29)
Japan Society for Occupational Health, Journal of Occupational Health: Recommendations on Permissible Exposure Concentration (2014)
NITE CHRIP (Chemical Risk Information Platform)
US HPVIS (2011)
Patty (5th, 2001)
IUCLID (2000)
IARC (1984)
ACGIH (2013)

Disclaimer

The described contents are created on the basis of materials and data available at the present moment and may be subject to revision as new findings become available. The precautions contained in this document are for ordinary handling. For special handling, it is the obligation of each user of the product to provide safety measures suitable for the applications and use. The described contents are intended for providing information and not intended for providing any warranty.