

[Precautionary statements]

Keep out of reach of children and store in the dry and dark place at room temperature.
 Carefully read instructions before use and do not use for other purposes.
 Wear personal protective equipment if necessary.
 Do not inhale reagents.
 Wash contaminated clothing.
 Wash hands thoroughly before and after handling.
 Avoid release to the environment.

3. Composition/ information on ingredients

Discrimination of single substance or mixture: Mixture

Reagent name	K-1 reagent		K-2 reagent	
Chemical name	Other (not regulated)	Ethanol	Water	Other (not regulated)
Content	100%	50 – 59 %	40 – 49 %	1 – 4.9 %
Chemical formula	-	C ₂ H ₅ OH	H ₂ O	-
METI No. (reference number under CSCL in Japan)	-	(2)-202	-	-
CAS No.	-	64-17-5	7732-18-5	-

Reagent name	K-3 reagent	
Chemical name	Other (not regulated)	Polyethylene
Content	5 – 9.9 %	90 – 99 %
Chemical formula	-	(C ₂ H ₄) _n
METI No. (reference number under CSCL in Japan)	-	(6)-1
CAS No.	-	9002-88-4

4. First-aid measures

If reagents or developed sample;

Enter in eyes: Immediately rinse eyes with water thoroughly.
 Contact with skin: Immediately wash out contaminated site with plenty of water.
 Enter into mouth: Immediately rinse mouth with plenty of water.

If ingested or in case any symptoms appear after above measures, immediately get medical advice or treatment.
 Especially in case ingested reagents or test solutions, drink plenty of water or milk and immediately get medical advice or treatment.

5. Fire-fighting measures

Extinguishing methods: Cut off ignition sources and extinct by a suitable media.
 Suitable extinguishing media: Water (mist), powder, carbon dioxide, dry sand.

6. Accidental release measures

In case of outdoor use: Avoid spill of reagents and waste solutions.
 In case of indoor use: If spilled on a table or floor, wipe off immediately spilled reagents and dispose of them.

7. Handling and storage

Handling: Avoid contact of the reagents with eyes and skin. Do not ingest or inhale the reagents.
Especially for outdoor use, ensure to bring back reagents, waste solutions after the measurement and used containers.

Storage: Avoid direct sunlight and store in a well-ventilated, dry and dark place at temperature.

8. Exposure controls and personal protection

Administrative control level

Working environment standard: Not established

Occupational exposure limits

Japan Society for Occupational health: Not established

ACGIH (TLVs): TWA 1000 ppm

OSHA (PEL): 8H air TWA 1000 ppm (only for Ethanol)

Protective equipment: Recommend to wear protective glasses and gloves

9. Physical and chemical properties

Physical state: K-1: powder reagent 0.05 g x 40 tubes in a poly bag
K-2: liquid reagent 12 mL x 1 poly-bottle in a poly bag
K-3: tube containing powder reagent 1.1 g x 40 tubes/kit
(5 tubes per one aluminum laminated packaging)

Color: K-1: white (powder), K-2: light-brown(liquid)
K-3: orange (powder), semi-transparent (polyethylene tube)

Odor: K-1,K-3: no odor, K-2: irritating odor

pH: 7 (K-1 and K-2 reagents), 9(K-3 reagent and final measurement solution)

Melting point, boiling point, flash point, ignition point, lower explosion limit, vapor pressure, density, specific gravity, solubility, Pow, kinetic viscosity: not available as a mixture

Note that ethanol has a flash point of 13 °C and a boiling point of 78.5 °C and is classified as flammable liquid Category 2 (Danger, Highly flammable liquid and vapor) by NITE. This product is classified as flammable liquid Category 3 (Warning, flammable liquid and vapor) because more than 10% of ethanol is contained in this product and 0.04% Phenolphthalein ethanol solution (40) manufactured by Wako Pure Chemical Industries Ltd., which has a similar composition to K-2 reagent, is classified as Category 3 in MSDS "No. JW162060 (revised 2010.07.08)".

10. Stability and reactivity

Avoid leaving in a place where high temperature, humid or under direct sunlight.

No data on flash point, ignition point, explosion limits and dangerous/hazardous decomposition product is available. Although ethanol vapor generates explosive mixed gas with air, stable under normal handling conditions and no dangerous reaction is expected to occur under specific conditions.

11. Toxicological information

No data on mixture is available. Data on each ingredient in K-2, K-3 reagents is shown below.

K-2 reagent

Ethanol (no data on solution)

Acute toxicity (oral):

Not classified based on the following data: Rat-oral LD₅₀ = 6200-15000mg/kg bw (DFGOT Vol.12 (1999)), 13700mg/kg, 17800mg/kg, 11500mg/kg (Patty (5th, 2005)), 9.8-11.6 ml/kg bw(7938-9396 mg/kg), 15010 mg/kg bw, 7000-11000 mg/kg bw, 14.6 ml/kg bw(11826 mg/kg), 7800 mg/kg bw, 11500 mg/kg bw, 11170-16710 mg/kg bw, 7060 mg/kg bw, 8300 mg/kg bw (SIDS(J)(2009)).

Acute toxicity (inhalation: vapor):

Not classified based on the following rat-inhalation LC₅₀ data: One corresponded to Category 4 (3837ppmV(SIDS(2009))), and other four corresponded to outside of classification (63000ppmV

(4h)(DFGOT Vol.12(1999)), 20661ppmV(4h), 66181ppmV(4h), 22627ppmV(4h)(SIDS (2009)). It used the gaseous standard value because the concentration of the test substance was lower than 90% (70,223ppmV (132.4 mg/L)) of the saturated vapor pressure, 78,026ppmV(147.1 mg/L).

Skin corrosion/ irritation:

Not classified based on the following data: In the exposure test to rabbit for 4h (OECD TG 404), the average scores of the erythema for 1 and 24h after adhibition were 1.0, and those of the erythema and edema for other time after were 0.0, hence no irritating properties were evaluated (SIDS (2009)).

Serious eye damage/ eye irritation:

Classified as Category 2B based on the following data: Ethanol is evaluated as moderate irritating in Draize tests (OECD TG405) with rabbit (SIDS (2009), DFGOT Vol.12 (1999)). It caused cloudy cornea, iris inflammation, conjunctival redness, and conjunctival chemosis within 1-3 days. MMAS (Modified Maximum Average Score: correspond to AOI) indicated 24.0. Moreover the symptoms were almost recovered improvement within 7 days.

Respiratory or skin sensitization:

Respiratory sensitization:

Classification is not possible because data is not conclusive. Following findings were reported: Increment of bronchial asthmatic symptom caused by alcohol seemed to be concerned with increment of blood-aldehyde concentration (DFGOT (1996)). Two asthmatic patients of mild degree were affected with massive bronchoconstriction on inhalation challenge test with Ethanol, but the results did not indicate from allergies (DFGOT (1996)).

Skin sensitization:

Classification is not possible because data is not conclusive. Following findings were reported: "Contact dermatitis in human epidemiological studies which relate to allergic reaction against alcohols." (DFGOT(1996)). "Although cross-reactions with primary and secondary alcohols are observed, no sufficient data is available to conclude Ethanol is a skin sensitizer."(ACGIH (2001), DFGOT (1996) and IUCLID (2000)).

Germ cell mutagenicity:

Classified as Category 1B because of positive results in dominant lethal tests (*in vivo* heritable mutagenicity assays to germ cell) of oral administration in rats and mice (intraperitoneal administration in mice, further) (SIDS (2009), IARC (1988)). All Ames tests as *in vivo* heritable mutagenicity assays indicated negative results (DFGOT Vol.12 (1999), SIDS (2009), NTP DB (2009)). All chromosome aberration analyses indicated negative results, except one positive result with CHO cell (SIDS (2009)).

Carcinogenicity:

Classification is not possible at this point, evaluated depending on the following data: ACGIH classified Ethanol as A3 (ACGIH (2009)), corresponding to Category 2. The data was obtained from tests of lifetime oral administration in male and female rats through drinking water, conducted at high level (10% of concentration) simulated alcohol drinking by human. Other oral administration tests in male and female rats through liquid feed at lower levels (1% or 3%) for 2 years did not indicate clear carcinogenic (ACGIH (2009)). Furthermore, a proviso was added that the data is not based on epidemiological studies in human work exposure, but on animal experiments, so effects on human were not clear. IARC classified alcoholic beverages as Group 1, based on many epidemiological studies to human taking it habitually (IARC Vol. 44 (1987)). On a re-evaluating in 2007, IARC classified again alcoholic beverages and Ethanol in them as Group 1 (IARC vol. 96 summary (Access on Oct., 2009)). The data was based on experiments of human feeding preferably and habitually (IARC vol. 96 was not released). EU has not been classified Ethanol about Carcinogenicity.

Reproductive toxicity:

Classified as Category 1A based on the following data, indicated clear reproductive toxicity to human: Large number of epidemiological information about Ethanol were reported. Previous prospective studies and case-control studies reported that alcohol drinking over a certain amount increased risk of miscarriage and developmental infection (IARC vol.44 (1987)). Some studies reported that habitually alcohol drinking caused growth inhibition, microcephalus, characteristic facies and mental disorder etc. (IARC vol.44 (1987), SIDS (2009), DFGOT Vol.12 (1999)). Other abnormality caused by prenatal intake of Ethanol was reported, such as cleft palate, abnormal palmar crease, defect of the interventricular septum and defect of ustachian. Another reports suggested strongly that high Ethanol intake by a pregnant woman caused teratogenesis and embryotoxicity (SIDS (2009)). Animal experiments indicated that untoward effects was not found on lifetime tests in rats or mice (SIDS (2009)), and decrement of surviving littermate on two generation tests in mice (SIDS (2009)). Some oral study in rats through pregnancy reported deformations such as polydactylism and polysyndactyly (IARC vol.44 (1987)).

Specific target organ toxicity (single exposure):

Classified as Category 3 (narcotic effect) based on the following data: Inhalational exposure

tests in human indicated somnolentia and mild degree of paralysis (ACGIH (2001)). Acutely toxic effect from Ethanol intake was described as disorder of the central nervous system (DFGOT Vol.12 (1999)). On severe poisoning, symptoms such as muscular deconditioning, blurred vision, stupor, hypothermia, feeling of sickness, emesis and twitch were observed. Furthermore, high-dose Ethanol intake caused death as a result of respiratory or cardiovascular failure, or else aspiration of gastric contents in cases of lack of faucial reflex (Patty (5th, 2001)). Inhalational exposure tests in rats, mice and guinea pig reported symptoms such as freezing, somnolentia and ataxia, in addition to the above symptoms in human (SIDS (2009), DFGOT Vol.12 (1999)).

Meanwhile, Ethanol was also classified as Category 3 (respiratory irritation) based on the following data: Inhalational exposure in human caused irritation of eye and upper airway even at low level (ACGIH (2001)). Inhalational exposure caused cough and pain in eye and nasal cavity (Patty (5th, 2001)). Inhalational exposure tests in non-resistant human subject reported nasal stinging (Patty (5th, 2001)).

Specific target organ toxicity (repeated exposure):

Classified as Category 1 (liver system) based on the following date: High-dose and long-term intake of Ethanol in human caused adverse effects on almost all organs. Especially, the strongest impact was affected to liver. The damage was initiated by fatty degeneration, through a stage of necrosis and fibrosing, developed cirrhosis (DFGOT (1996)).

Meanwhile, Ethanol was also classified as Category 2 (nervous system) based on the following data: Patients with heavy physical alcoholism experienced withdrawal symptoms of thrill, twitch and subdelirium, often with feeling of sickness, weakness, insecurity and sweating. Intentional behavior to take alcohol and clear hyperreflexia were also observed (HSDB (2003)). Incidentally, animal experiments indicated that onset of adverse effects was not very aggressive. Oral exposure tests in rats or mice across 90 days reported fatty degeneration as effects on liver at high-dose level much higher than the value of guidance (SIDS (2009)).

Other data: Not available

Water: Acute toxicity: Oral-rat: LD₅₀ >90 mL/kg

Other data: Not available

K-3 reagent

Polyethylene:

Acute toxicity: Oral-rat: LD₅₀ > 7,950 mg/kg

Carcinogenicity: IARC Group 3 (not classifiable as to carcinogenicity to humans).

Other data: Not available

GHS classifications as a mixture of each K-1, K-2 and K-3 reagent are shown below.

[Serious eye damage/ eye irritation]

K-2 reagent: Classified as Category 2B (Warning, Causes eye irritation.) because it contains more than or equal to 10% of ethanol.

Classification is not possible for other reagents because of data lack.

[Germ cell mutagenicity]

K-2 reagent: Classified as Category 1 (Danger, May cause genetic defects.) because it contains more than or equal to 0.1% of ethanol.

Classification is not possible for other reagents because of data lack.

[Reproductive toxicity]

K-2 reagent: Classified as Category 1 (Danger, May damage fertility or the unborn child.) because it contains more than or equal to 0.3% of ethanol.

Classification is not possible for other reagents because of data lack.

[Specific target organ toxicity (single exposure)]

K-2 reagent: Classified as Category 3 (Warning, May cause respiratory irritation, May cause drowsiness or dizziness.) because it contains more than or equal to 20% of ethanol.

Classification is not possible for other reagents because of data lack.

[Specific target organ toxicity (repeated exposure)]

K-2 reagent: Classified as Category 1 (Danger, Causes damage to liver through prolonged or repeated exposure.) and Category 2 (Warning, May cause damage to nervous system through prolonged or repeated exposure.) because it contains more than or equal to 10% of ethanol.

Classification is not possible for other reagents because of data lack.

[Acute toxicity (oral)], [Skin corrosion/ irritation], [Respiratory or skin sensitization], [Carcinogenicity],

[Aspiration hazard]

Not classified or classifications are not possible because of data lack.

12. Ecological information

No data on mixture is available. Data on each ingredient in K-2, K-3 reagents is shown below.

K-2 reagent

Ethanol:

Hazardous to the aquatic environment, short-term (acute):

Not classified because of the following data:

Fish (*Pimephales promelas*): 96h LC₅₀ > 100 mg/L (SIDS, 2005)

Crustacea (*Ceriodaphnia quadrangular*): 48h LC₅₀ = 5012 mg/L (SIDS, 2005)

Algae (chlorella): 96h EC₅₀ = 1000 mg/L (SIDS, 2005)

Hazardous to the aquatic environment, long-term (chronic):

Not classified based on Ethanol is not classified as the acute toxicity, and it does not indicate poor water solubility (aqueous solubility = 1000000 mg/L (SIDS, 2005)).

Harmful effects on the ozone layer:

Classification is not possible because the substance is not described in Annex to Montreal Protocol.

K-3 reagent

Polyethylene: No eco-toxicological information available.

GHS classifications as a mixture of each K-1, K-2 and K-3 reagent are shown below.

[Hazardous to the aquatic environment, short-term (acute)],

[Hazardous to the aquatic environment, long-term (chronic)]:

Not classified or classification is not possible for other reagents because of data lack.

[Harmful effects on the ozone layer]:

Classification is not possible because each of the substances is not described in Annex to Montreal Protocol.

13. Disposal considerations

Since pH of waste solution in tube is alkali, pH = 9.

Always dispose of in accordance with local regulations.

14. Transport information

In addition to precautionary measures regarding handling and storage, avoid rough handling so as not to break containers. It is recommended to ship by air because under high temperature for long period may lead to deterioration.

UN number	1170
Proper shipping name:	Ethanol solution
UN classification:	Class 3 (Flammable Liquids)
Packing group:	II
Civil Aeronautics Act:	Same as above. Applicable to Excepted Quantities of Dangerous Goods
Fire Service Act:	Not applicable
Total weight of the product:	ca.250 g/kit

15. Regulatory information

Poisonous and Deleterious Substances Control Act: Not applicable

PRTR Act: Not applicable

Industrial Safety and Health Act: Applicable

This product contains more than 0.1% of ethanol.

: "Cabinet order, article 18, shall be notified the Name of the substances, #2"

: "Cabinet order, article 18-2, shall be indicated the Name of the substances, #2"

16. Other information

Reference literature

15,911 no Kagaku Shouhin, The Chemical Diary Co., Ltd. (2011)
NITE, GHS Classification, ID 21B3016 Ethanol (2010.02.19)
Material Safety Data Sheet No.JW050044, Wako Pure Chemical Industries, Ltd. (2011.04.07)
Material Safety Data Sheet No.JW041678, Wako Pure Chemical Industries, Ltd. (2009.05.18)
Koukuu Kikenbutsu Yusou Houreisyu, Ed. MLIT, HOUBUN SHORIN CO., LTD. (2019)
JIS Z 7252:2019 Classification of chemicals based on "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)" (Japanese Industrial Standards Committee)
JIS Z 7253:2019 Hazard communication of chemicals based on GHS-Labeling and Safety Data Sheet (SDS) (Japanese Industrial Standards Committee)
UN GHS (tentative translation, forth revised version), GHS Kankei Syocho Renraku Kaigi (2011)
Ministry of Economy, Trade and Industry, GHS Classification Guidance for Enterprises 2013 Revised Edition (2013)

NOTE) This information is not always exhaustive and use with care.
This data sheet only provides information but any description cannot be warranted.
Descriptions may possibly be changed because of new findings or modification of the current knowledge.
Precautions only cover normal handling.
This English SDS is prepared in the cooperation with the Chemicals Evaluation and Research Institute (CERI), Japan.