

Causes damage to thyroid, skin and systemic toxicity through prolonged or repeated exposure.

(applicable only K-1 reagent)

May cause damage to respiratory organs through prolonged or repeated exposure.

(applicable only K-2 reagent)

[Precautionary statements]

Keep out of reach of children and store in the cool, dry, and dark place.

Carefully read instructions before use and do not use for other purposes.

Wear personal protective equipment if necessary.

Do not inhale reagent.

Wash contaminated clothing.

Wash hands well 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		K-3 reagent	
Chemical name	Potassium iodide	Extender	Sulfuric acid	Water	Buffering agent	Water
Content	50%	50%	< 10%	> 90%	<30%	> 70%
Chemical formula	KI	-	H ₂ SO ₄	H ₂ O	-	H ₂ O
METI No. (reference number under CSCL in Japan)	(1)-439	-	(1)-430	-	-	-
CAS No.	7681-11-0	-	7664-93-9	7732-18-5	-	7732-18-5

Reagent name	K-4 reagent		
Chemical name	N,N-Diethyl-1,4-phenylene diamine sulfate	Extender	Polyethylene
Content	< 1%	< 10%	> 89%
Chemical formula	(C ₂ H ₅) ₂ NC ₆ H ₄ NH ₂ · H ₂ SO ₄	-	(C ₂ H ₄) _n
METI No. (reference number under CSCL in Japan)	(3)-243 (1)-430	-	(6)-1
CAS No.	6283-63-2	—	9002-88-4

4. First-aid measures

If reagents or test solutions;

Enter in eyes: Immediately rinse with water for more than 15 minutes followed by the treatment by an ophthalmologist.

Contact with skin: Immediately wash out contaminated site with plenty of water.

Enter into mouth: Immediately rinse mouth with plenty of water.

If 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. Do not contact with eyes or skin.

Concentrated waste solutions should not be released into sewer or rivers.

7. Handling and storage

Handling: Care should be made so that reagents will not contact with eyes or skin and to avoid ingestion. pHs of K-2 reagent and a sample solution after addition of K-2 reagent are below 2, strong acid. Care should be made so as to avoid contact with eyes or skin.

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, cool, dry, and dark place.

8. Exposure controls and personal protection

Administrative control level

Working environment standard: Not established

Occupational exposure limits

Japan Society for Occupational health: 1 mg/ m³

ACGIH (TLVs): TWA 1 mg/ m³

OSHA (PEL): air TWA 1 mg/ m³ (only for 100% Sulfuric acid)

Protective equipment: Recommended to wear protective glasses and gloves

9. Physical and chemical properties

Physical state: K-1: Powder reagent 0.06 g x 40 poly-tubes in an aluminum laminated bag

K-2: Liquid reagent 3mL x 1 poly-bottle in a poly bag

K-3: Liquid reagent 6mL x 1 poly-bottle in a poly bag

K-4: Tube containing powder reagent

1.1 g x 40 tubes/kit, (5 tubes per one aluminum laminate packaging)

Color: K-1: white (powder), K-2: colorless (liquid), K-3: colorless (liquid)

K-4: white (powder), semi-transparent (polyethylene tube)

Odor: No odor

pH: ≤ 2 (K-2 reagent and a sample solution added K-2 reagent)

5(K-3 reagent and final measurement solution)

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

10. Stability and reactivity

Avoid leaving in a place where high temperature, humid or under direct sunlight. Stable under normal use conditions and no dangerous reactions under specific conditions are expected. No information on hazardous decomposition product is available.

11. Toxicological information

No data on mixture is available. Data on each substance are shown.

K-1 reagent

Potassium iodide:

Acute toxicity: Classification is not possible based on the following data.

Oral: Mouse LDLo 1,862 mg/kg (PATTY (5th, 2001))

Skin corrosion/irritation: No data available.

Serious eye damage/eye irritation: Category 2B is based on the following data.

Rabbit's cornea test of 3% potassium iodide solution causes only slight reaction. 17 in 100 samples recognized irritation. (HSDB (2006))

Respiratory sensitization: No data.

Skin sensitization: Classification is not possible because of data lack.

Germ cell mutagenicity: Classification is not possible because of data lack.

Carcinogenicity: Classification is not possible because of data lack.

Reproductive toxicity: Category 1B and additional category on effects on or via lactation are based on the following data.

The intake of excessive amount of iodine causes human thyroid gland deficiency, and it may cause sexual functions disorder such as abnormality of menstruation as second effect. There is a knowledge that absorbed iodine is excreted in breast milk, iodine that transmits to newborn infants through breast milk may cause developmental impairment of infants. As the evidence of overexposure of iodine compounds about effects on human reproductive system is insufficient, the effect on breast feeding is added as category 1B.

Specific target organ toxicity (Single exposure): Category 1 (Thyroid) is based on the following data.

The acute intake of excessive amount of iodine causes a transient decline of production of human thyroid hormone.(ATSDR (2004))

Specific target organ toxicity (Repeated exposure): Category 1 (Thyroid, Skin, Systemic Toxicity) is based on the following data.

Proliferative skin lesions on face, scalp, arm and body were developed for pulmonary disease patients who have been receiving the drug include the substance. And oral intake caused drug rash by iodine to the patients. (ATSDR (2004))

Enlargement of the thyroid gland and hypothyroidism were developed for patients who has been receiving the drug include the substance. (ATSDR (2004))

Meanwhile, there are reports of overactive thyroid gland. (CICAD 72 (2009), JECFA 24 (1989))

Long-term ingestion of iodide or serious side effects may cause iodine intoxication. (HSDB (2006))

In addition to the symptoms associated with thyroid, irritation of eyes, mouth and respiratory, asthma, gastric inflammation and general debility were caused by iodine intoxication. (HSDB (2006))

There are some reports of fever, which is considered on the basis of immune function in patients who has ingested orally. (CICAD 72 (2009)) It is difficult to specify target organs from these reports. Therefore, classification is set to Category 1(systemic toxicity)

Other data: Not available

K-2 reagent

Concentrated sulfuric acid:

Acute toxicity: Category 5 based on the following data; Oral-rat: LD₅₀: 2,140 mg/kg (SIDS, 2001) and death case in human ingestion (dose level not known).

Acute toxicity (dust-mist): Category 2 based on; Rat 4Hr-LC₅₀: 0.375 mg/L: 1Hr-LC₅₀ = 347 ppm (4Hr converted value 0.347 mg/L) (SIDS, 2001)

Skin corrosion/ irritation: Category 1 based on the following data; pH of concentrated sulfuric acid is ≤ 1 and is considered as corrosive according to the GHS classification criteria.

Serious eye damage/ eye irritation: Category 1 based on the following data;

Rabbit: Severe eye irritation 1380 μ g

In a human accidental case, serious eye damage associated with melting of anterior eye chamber was observed (ATSDR, 1998). 5% solution: moderate and 10% solution: severe irritation in rabbit eyes (SIDS, 2001). pH of the substance is ≤ 2 .

Skin sensitization: Not classified based on the following data;

No data on skin sensitization is available. Sulfuric acid has been industrially used for several tens of years and is well known as skin trouble because of its skin irritation, however no case is reported as a sensitization. No allergic reaction occurs although there is a large amount of sulfuric ions in human body. In allergic tests of metal sulfates, positive result were caused due to a metal allergy but negative by sulfuric acid this is supported by the negative result of zinc sulfate. Based on the above results, it can be concluded that sulfuric acid does not have allergic potential (SIDS, 1998).

Germ cell mutagenicity: Classification not possible based on the following data.

No *in vivo* data in germ cell or somatic cell is available. Only single positive result in a mutagenicity test (chromosome aberration test) is reported (ATSDR, 1998), however all in negative.

Carcinogenicity: Classification not possible based on the following data.

Regarding mists of inorganic strong acids including sulfuric acid, following classifications are reported, IARC (1992) Group 1, ACGIH (2004) A2 and NTP (2005) K. If classifications made by IARC and recent NTP are respected, category 1 can chosen, however, sulfuric acid itself is classified as category 4 by DFGOT (vol.15, 2001) and no classification has been made by other organization.

Reproductive toxicity: Not classified based on the following data.

No toxicity to unborn child or teratogenic effects was reported at dose levels where no maternal toxicity were seen in inhalation test in rabbits and mice administered during fetal organ developmental stage (SIDS, 2001). It is reported that no reproductive toxicity is concerned because no effects on reproductive organs in both males and females were seen and dominant effects were due to primary irritation/corrosion in a combined chronic and carcinogenicity test (SIDS, 2001).

Specific target organ toxicity (single exposure): Category 1 (respiratory organs) based on the following data.

In human cases, respiratory irritation such as cough and breath shortness were observed by inhalation exposure of low concentration levels (DEGOT, 2001). At high concentration level, in addition to acute

effects such as cough, breath shortness and blood in the sputum, prolonged effects such as dysfunction of lung, fibrosing disease and emphysema were reported (ATSDR, 1998). Bleeding or dysfunctions of lungs are observed in a guinea pig 8-h inhalation test (ATSDR, 1998).

Specific target organ toxicity (repeated exposure): Category 1 (respiratory organs) based on the following data. Cell proliferation of throat mucosa was observed at dose levels within the guidance value of category 1 in a rat 28-day inhalation test (SIDS, 2001). A series of diseases in lungs and airways were reported in a guinea pig repeated (14-139-days) inhalation test at dose levels within the guidance value of category 1, such as edema of nasal septum, lung emphysema, atelectasis, hyperemia of bronchial tubes, edema, bleeding, blocked blood vessel. Furthermore, histo-pathological changes in lung bronchial tubes including hyperplasia and increased thickness were also observed in a 78-week monkey inhalation test at dose levels within the guidance value of category 1 (0.048 mg/L, 23.5 Hr/Day) (ATSDR, 1998).

Other data: Not available.

Water:

Acute toxicity: Oral-rat LD₅₀ >90 mL/kg (used 90g/kg for the calculation of ATEmix below)

Other data: Not available

K-3 reagent

Water:

Acute toxicity: Oral-rat LD₅₀ >90 mL/kg (used 90g/kg for the calculation of ATEmix below)

Other data: Not available

K-4 reagent

N,N-Diethyl-1,4-phenylenediamine sulfate:

Acute toxicity:

Oral: rats LD₀ 100 mg/kg, trembling, convulsion, epilepsy, rigor (RTECS)

Mouse LD₀ 300 mg/kg, rigor, methemoglobinemia (RTECS)

Serious eye damage/eye irritation: Rabbit Mild 500mg/24H (RTECS)

Other data: Not available

Polyethylene:

Acute toxicity:

Oral: Rat LD₅₀ > 7,950 mg/kg (used 7,950 mg/kg for the calculation of ATEmix below)

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

Other data: Not available

GHS classifications as a mixture are shown below.

[Acute toxicity (oral)]

Every reagent: Not classified based on application of the additive equation.

[Acute toxicity (inhalation: dust, mist)]

K-2 reagent: Classified as Category 4 (Warning, harmful if inhaled.) based on application of the additive equation

K-1, K-3, K-4 reagent: Classification is not possible because of data lack.

[Skin corrosion/ irritation]

K-2 reagent: pH < 2; Classified as Category 1 (Danger, Causes severe skin burns and eye damage.).

K-1, K-3, K-4 reagent: Classification is not possible because of data lack.

[Serious eye damage/ eye irritation]

K-1, K-3 reagent: Contains >3% of category 2B; Classified as Category 2B (Warning, Causes eye irritation.)

K-2 reagent: pH ≤ 2; Classified as Category 1 (Danger, Causes severe skin burns and eye damage.).

K-4 reagent: Classification is not possible because of data lack.

[Reproductive toxicity]

K-1 reagent: Contains >0.3% of category 1B and additional category on effects on or via lactation; Classified as Category 1B (Danger, May damage fertility or the unborn child.) and Additional Category (May cause harm to breast-fed children.).

K-2, K-3, K-4 reagent: Classification is not possible because of data lack.

[Specific target organ toxicity (single exposure)]

K-1 reagent: Contains >10% of category 1; Classified as Category 1 (Danger, Causes damage to thyroid.)

K-2 reagent: Contains 1 to 10% of category 1 substances; Classified as Category 2 (Warning, May cause damage to respiratory organs.).

K-3 and K-4 reagent: Classification is not possible because of data lack.

[Specific target organ toxicity (repeated exposure)]

K-1 reagent: Contains >10% of category 1; Classified as Category 1 (Danger, Causes damage to thyroid, skin and systemic toxicity through prolonged or repeated exposure.)

K-2 reagent: Contains 1 to 10% of category 1 substances; Classified as Category 2 (Warning, May cause damage to respiratory organs through prolonged or repeated exposure.)

K-3, K-4 reagent: Classification is not possible because of data lack.

[Acute toxicity (Dermal)], [Respiratory or skin sensitization], [Germ cell mutagenicity], [Carcinogenicity], [[Aspiration hazard]

Classifications are not possible because of data lack.

12. Ecological information

No data on mixture is available. Data on each substance are shown.

N,N-Diethyl-1,4-phenylenediamine sulfate, Polyethylene: No eco-toxicological information is available.

K-1 reagent

Potassium iodide:

Hazards to the aquatic environment, acute: Classification is not possible because of data lack.

Hazardous to the aquatic environment, chronic: Classification is not possible because of data lack.

Other data: Not available.

K-2 reagent

Sulfuric acid:

Aquatic hazard Acute: Fish (Bluegill): 96-h LC₅₀ = 16-28 mg/L (SIDS, 2003); Category 3

Aquatic hazard Chronic: Toxicity may be caused because solutions become strong acid however it should be lowered in the environment due to buffering effects; Not classified.

Other data: Not available.

GHS classifications as a mixture are shown below.

[Hazards to the aquatic environment, short-term (Acute)].

K-2 reagent contains less than 25% of category substances; Not classified

K-1, K-3 and K-4 reagents: Classifications are not possible because of data lack.

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

Every reagent: Classifications are not possible because of data lack .

[Harmful effects on the ozone layer]:

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

13. Disposal considerations

pHs of remaining solution of K-2 reagent and a sample solution added K-2 reagent are ≤ 2 .

pHs of remaining solution of K-3 reagent and waste solution after the measurement are 5.

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	2796
Proper shipping name:	SULPHURIC ACID with 51% or less acid (applicable only K-2 reagent)
UN classification:	Class 8 (corrosive substances)
Packing group:	II
Civil Aeronautics Act:	Same as above. Applicable as Excepted Quantities of Dangerous Goods.
Poisonous and Deleterious Substances Control Act:	Not applicable (The product contains less than 10% of sulfuric acid and not applicable as a deleterious substance)
Fire Service Act:	Not applicable
Total weight of the product:	ca. 160g/kit

15. Regulatory information

PRTR Act: Not applicable

Industrial Safety and Health Act: Applicable

K-1 reagent contains more than 1% of Potassium iodide.

: "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"

K-2 reagent contains more than 1% of sulfuric acid.

: "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"

: "Designated substances class 3"

Waste Disposal and Cleaning Act: Applicable

Applicable as the Special Controlled Industrial Waste under the Act because pHs of remaining solution of K-2 reagent and a sample solution added K-2 reagent are less than 2.

16. Other information

Reference literature

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Material Safety Data Sheet No.051110033, TOSOH CORPORATION (2004.07.09)

Koukoku Kikenbutsu Yusou Houreisyu, Ed. MLIT, HOUBUN SHORIN CO., LTD. (2015)

JIS Z 7252:2014 Classification of chemicals based on "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)" (Japanese Industrial Standards Committee)

JIS Z 7253:2012 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.