

3. Composition/ information on ingredients

Discrimination of single substance or mixture: Mixture

Reagent name	K-1 reagent			
Chemical name	4-Aminoantipyrine	Ethylenediamine- <i>N,N,N',N'</i> -tetraacetic Acid Tetrasodium Salt Tetrahydrate	Other (not regulated)	Polyethylene
Content	< 0.1%	< 10%	< 5%	> 84.9%
Chemical formula	C ₁₁ H ₁₃ N ₃ O	C ₁₀ H ₁₂ N ₂ Na ₄ O ₈ ·4H ₂ O	-	(C ₂ H ₄) _n
METI No. (reference number under CSCL in Japan)	(9)-62	(2)-1265	-	(6)-1
CAS No.	83-07-8	13235-36-4	-	9002-88-4

4. First-aid measures

If reagents or test solutions;

- Enter in eyes: Immediately rinse 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.

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 reagents with your skin or eyes, and inhalation of those especially powder in tube.
 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 room 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) Not established
 OSHA (PEL) Not established

- Protective equipment: Recommend to wear protective glasses and gloves.

9. Physical and chemical properties

Physical state: Tube containing powder reagent 1.1g x40 tubes/kit (5 tubes per aluminum laminated packaging)
Color: White (powder), semi-transparent (polyethylene tube)
Odor: No odor
pH: 9

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.

4-Aminoantipyrine:

Acute toxicity(Oral): Category 4, Rat LD₅₀ 1,700 mg/kg
Skin corrosion/ irritation: Category 2
Serious eye damage/ eye irritation: Category 2A
Other data: Not available

Ethylenediamine-*N,N,N',N'*-tetraacetic Acid Tetrasodium Salt Tetrahydrate (data on Ethylenediaminetetraacetic acid (CAS 60-00-4) are shown) :

Acute toxicity (Oral) : Not classified

It was classified as "Not classified" in the Classification JIS (Category 5 in UN GHS classification) based on LD₅₀ values for rats of > 2000 mg/kg (EU-RAR 49 (2004)), 2,580, 4,500 mg/kg (the above, Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERI, NEDO, 2007)).

Acute toxicity (Dermal) :Classification not possible
No data available.

Acute toxicity (Inhalation: Gases) : Not applicable
Solid (GHS definition)

Acute toxicity (Inhalation: Vapours) : Classification not possible
No data available.

Acute toxicity (Inhalation: Dusts and mists) : Classification not possible

Classification not possible due to lack of data. Besides, it is reported that there were no dead animals after 8-hour inhalation of a dust atmosphere at 20 or 80 deg C (Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERI, NEDO, 2007)).

Skin corrosion/irritation : Not classified

It was classified as "Not classified" because it is reported that it was not irritating in a Draize test with rabbits (Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERI, NEDO, 2007)), and there was mild irritation at 24 hours in another test by 20-hour application to the ear of one rabbit (EU-RAR 49 (2004)).

Serious eye damage/eye irritation : Category 2B

It was classified in Category 2B because it is described that strong irritation, mild edema, and strong corneal opacity were seen in a test in which 50 mg was applied to the rabbit eye, but there were no findings at 8 days (EU-RAR 49 (2004)).

Respiratory sensitization : Classification not possible
No data available.

Skin sensitization : Classification not possible

No data available. Besides, for the disodium salt of this substance, it is reported that in a guinea pigs maximization test (OECD TG406), a positive rate was 30% (3/10) in the first challenge after 24 hours and 10% (1/10) in a second challenge after 7 days (EU-RAR 49 (2004)), and the substance was assessed as not sensitizing in another guinea pig maximization test (Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERI, NEDO, 2007)).

Germ cell mutagenicity : Not classified

As for in vivo tests on the disodium salt of this substance, negative results were obtained in all of a dominant lethal test by drinking water administration to mice (in vivo heritable germ cell mutagenicity test), a chromosomal aberration test with spermatogonial cells after intraperitoneal administration to mice (in vivo heritable germ cell mutagenicity test), and micronucleus tests with bone marrow after oral or intraperitoneal administration to mice (in vivo somatic cell mutagenicity tests) (all, EU-RAR 49 (2004)). Therefore, this substance was classified as "Not classified." Also, as for in vitro tests, this substance was negative in an Ames test and positive in a mouse lymphoma test, and there were negative results in an Ames test and a mouse lymphoma test on the trisodium salt of this substance (EU-RAR 49 (2004), Mutagenicity Test Data of Existing Chemical Substances based on the toxicity investigation system of the Industrial Safety and Health Law Supplement 2 (2000)). Besides, this substance was reported to be positive in a chromosomal aberration test with bone marrow and spleen cells of mice (in vivo somatic cell mutagenicity test) (Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERi, NEDO, 2007)), but it was not used for classification based on expert judgment, claiming that test details such as administration route and doses are unknown, and the reproducibility of results is questionable for the test.

Carcinogenicity : Classification not possible

No data available. Besides, in 103-week diet administration tests with rats and mice on the trisodium salt of this substance, there were no occurrences of treatment-related tumors in rats or mice, but it is mentioned that the substance was not tested at the maximum tolerated dose (EU-RAR 49 (2004)).

Reproductive toxicity : Category 2

It is reported that after gavage administration to rats on gestational days 7-14, there were no effects in fetuses at the dose where effects such as death, diarrhea, and behavioral suppression were seen in parent animals (Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERi, NEDO, 2007)), while it is reported that cleft palate, brain and eye defects, and skeletal anomalies occurred in fetuses in a test by diet administration to rats after day 6 of gestation (Teratogenic (12th, 2007)), although there is no description of general toxicity in parent animals, and incidences of malformations in fetuses were also reported after intraperitoneal or intramuscular administration to pregnant rats (Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERi, NEDO, 2007), JECFA 796 (1993)). Therefore, it was classified in Category 2.

Specific target organ toxicity - Single exposure : Classification not possible

No data available. Besides, as for effects of the related substance in humans, as acute symptoms when the disodium salt of EDTA (Na₂EDTA) was intravenously administered as an antidote for lead poisoning, numbness and tingling pain, arising around the hands and mouth, were reported (Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERi, NEDO, 2007)).

Specific target organ toxicity - Repeated exposure : Category 1 (kidney)

As effects in humans, it is described that renal tubular defects were seen when EDTA or its salts (sodium, calcium disodium) were ingested for a long time and in a large amount (Initial Risk Assessment Report Ver.1.1, 14 (NITE, CERi, NEDO, 2007)). Therefore, it was classified in Category 1 (kidney). Besides, the formulation of CaNa₂EDTA, the related substance, is commercially sold as an antidote for lead poisoning, side effect information includes renal tubular defects after long-term administration of tablets, transient proteinuria for infusion, and renal tubular defects after long-term infusion, and it is described in other remarks that acute and large-amount administration may cause serious consequences such as death due to renal toxicity (Environmental Risk Assessment for Chemical Substances vol. 3 (Ministry of the Environment, 2004)).

Aspiration hazard : Classification not possible

No data 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 results as a mixture are shown below.

[Reproductive toxicity]

Classified as Category 2 (Warning, Suspected of damaging fertility or the unborn child.) because more than or equal to 3% of a category 2 substance is contained.

[Specific target organ toxicity-Repeated exposure]

Classified as Category 2 (Warning, May cause damage to kidneys through prolonged or repeated exposure.) because more than or equal to 1% but less than 10% of a category 1 (kidneys) substance is contained.

[Acute toxicity (Oral, Skin, Inhalation)], [Skin corrosion/ irritation], [Serious eye damage/ eye irritation],

[Respiratory or skin sensitization], [Germ cell mutagenicity], [Carcinogenicity],

[Specific target organ toxicity-Single exposure], [Aspiration hazard]

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

12. Ecological information

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

4-Aminoantipyrine, Polyethylene: No eco-toxicological information available.

Ethylenediamine-*N,N,N',N'*-tetraacetic Acid Tetrasodium Salt Tetrahydrate (data on Ethylenediaminetetraacetic acid (CAS 60-00-4) are shown) :

Hazardous to the aquatic environment, short-term (acute): Category 3

It was classified in Category 3 from 96-hour LC₅₀ = 41 mg/L for fish (*Lepomis macrochirus*) (EU-RAR, 2005, etc.).

Hazardous to the aquatic environment, long-term (chronic): Category 3

"If chronic toxicity data are used, then it is classified as ""Not classified"" due to 21-day NOEC = 5.5 mg/L for crustacea (*Daphnia magna*) (Results of Aquatic Toxicity Tests of Chemicals conducted by Ministry of the Environment in Japan (Ministry of the Environment, 2002), etc.), although it is not rapidly degradable (a 4-week degradation rate by BOD: 0% (Biodegradation and Bioconcentration Results of Existing Chemical Substances under the Chemical Substances Control Law, 1994)).

If acute toxicity data are used for a trophic level for which chronic toxicity data are not obtained, then it is classified in Category 3 due to being not rapidly degradable (a 4-week degradation rate by BOD: 0% (Biodegradation and Bioconcentration Results of Existing Chemical Substances under the Chemical Substances Control Law, 1994)), and 96-hour LC₅₀ = 41 mg/L for fish (*Lepomis macrochirus*) (EU-RAR, 2005, etc.).

By drawing a comparison between the above results, it was classified in Category 3.

Hazardous to the ozone layer: Classification not possible

This substance is not listed in the Annexes to the Montreal Protocol.

GHS classifications as a mixture are shown below.

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

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

Classifications are not possible 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

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 the handling and the storage, avoid rough handling that may cause damaging the containers. It is recommended to ship by air because of the storage under high temperature for long period of time may lead to deterioration.

UN classification and number: Not applicable

Civil Aeronautics Act: Not regulated as per IATA

Fire Service Act: Not applicable

Total weight of the product: ca.140 g/kit

15. Regulatory information

Poisonous and Deleterious Substances Control Act: Not applicable

PRTR Act: Ethylenediamine-*N,N,N',N'*-tetraacetic Acid Tetrasodium Salt Tetrahydrate is applicable as "Class I Designated Chemical Substances No. 595 Ethylenediaminetetraacetic acid and its potassium and sodium salts.

Industrial Safety and Health Act: Not applicable

16. Other information

Reference literature

15,911 no Kagaku Shouhin, The Chemical Diary Co., Ltd. (2011)
Safety Data Sheet No. W01W0101-0227 JGHEEN, FUJIFILM Wako Pure Chemical Corporation, Ltd. (2023.01.26)
NITE, GHS Classification, ID m-nite-60-00-4_v1, Ethylenediaminetetraacetic acid
Material Safety Data Sheet No.051110033, TOSOH CORPORATION (2004.07.09)
Koukoku 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.