Safety Data Sheet

Reference No. 1038-2

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1. Chemical product and company identification

Product namePACKTEST CalciumModelWAK-Ca-2Company nameKYORITSU CHEMICAL-CHECK Lab., Corp.Address1-18-2 Hakusan, Midori-ku, Yokohama, Kanagawa 226-0006, JAPANTel+81-45-482-6937Fax+81-45-507-3418Dept. in chargeSales Department

Recommended uses and restrictions Reagent for water quality measurement

2. Hazards identification

 [GHS Classification]
 Physical hazards:
 Classification not possible (no data for GHS classification available)

 Health hazards:
 Reproductive toxicity:
 Category 1B

 Specific target organ toxicity (single exposure):
 Category 2 (central nervous system, gastrointestinal tract)

 Specific target organ toxicity (repeated exposure):
 Category 2 (central nervous system, gastrointestinal tract)

 Specific target organ toxicity (repeated exposure):
 Category 2 (respiratory organs, nervous system)

 For those health hazards not listed above are not classified or classification not possible (no data for GHS classification available)

Environmental hazards:

Classification not possible (no data for GHS classification available)

[GHS labeling elements]



[Signal word] Danger

[Hazard statements]

May damage fer^tility or the unborn child May cause damage to central nervous system, gastrointestinal tract May cause damage to respiratory organs, nervous system through prolonged or repeated exposure

[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 well before and after handling.

Avoid release to the environment.

3. Composition/ information on ingredients

Reagent name		K-1 reagent	
Chemical name	Sodium tetraborate decahydrate	Others (not regulated)	Polyethylene
Content	1 – 4.9 %	0.1 – 0.49 %	90 – 99 %
Chemical formula	Na₂B₄O ₇ ⋅ 10H₂O	-	(C ₂ H ₄) _n
METI No. (reference number under CSCL in Japan)	(1)-69	_	(6)-1
CAS No.	1303-96-4	_	9002-88-4

Discrimination of single substance or mixture: Mixture

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 any symptoms appear after above measures, immediately get medical advice or treatment. Especially in case ingested reagents or test solutions, immediately 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 or waste solution. In case of indoor use: if spilled on a table or floor, wipe off immediately spilled reagent and dispose of them. Concentrated waste solution should not be released into sewer or rivers.

7. Handling and storage

Handling: Do not inhale or ingest the reagent. Avoid contacting the reagent with eyes and 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, 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):	STEL 6mg/m ³ (inhalable particulate matter)
	(only for Sodium tetraborate decahydrate)
	TWA 2mg/m ³ (inhalable particulate matter)
	(only for Sodium tetraborate decahydrate)
OSHA (PEL):	Not established

Protective equipment: Recommended to wear protective glasses and gloves.

9. Physical and chemical properties

Physical state:	Tube containing powder reagent
	1.1 g x 50 tubes/kit, aluminum laminate packaging each of 5 tubes
Color:	Yellow (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.

Sodium tetraborate decahydrate:

Acute toxicity(Oral):

There were reports of LD50 values for rats of 3,493 mg/kg, 4,500 mg/kg, 4,980 mg/kg, 5,660 mg/kg, 6,080 mg/kg (EHC 204 (1998)), and 4,500-6,000 mg/kg (ECETOC TR63 (1995), PATTY (6th, 2012)). Three cases correspond to "Not classified" (Category 5 in UN GHS classification), and 3 cases correspond to "Not classified." This substance was classified as "Not classified" (Category 5 in UN GHS classification) by adopting a category with higher hazard.

Acute toxicity (Dermal):

Based on the report of the LD50 value of > 10,000 mg/kg for rabbits (HSDB (Access on August 2017)), the substance was classified as "Not Classified."

Acute toxicity (Inhalation: Dusts and mists):

There was a report of an LC50 value of > 2 mg/L in a 4-hour inhalation exposure test with rats

(PATTY (6th, 2012)), and this value corresponds to Category 4 or "Not classified." However, it was classified as "Classification not possible" since it is not possible to specify the category only from this data.

Skin corrosion/ irritation:

Based on the description that dermatitis was observed in workers exposed to this substance (borax dust) in the mine production section and crushing equipment (ACGIH (7th, 2001)) and the results that skin irritation was observed in skin irritation tests with rabbits and guinea pigs (ECETOC TR63 (1995), Initial Risk Assessment Report (NITE, CERI, NEDO, 2008)), this substance was classified in Category 2.

Serious eye damage/ eye irritation:

There are descriptions that eye irritation was observed after exposures to 0.44–3.1 mg boron/m3 (5.7–14.6 mg particulates/m3, weighted mean in 6 hours) among borax processing facility workers (ATSDR (2010)) and that a significant difference was observed in the frequency of eye irritation, which was observed in 12.4% of workers in a borax crushing and refining plant but in 2.8% of workers in a low-exposure area (EHC 204 (1998)). In addition, there are descriptions that severe irritation was observed in an eye irritation test with rabbits (PATTY (6th, 2012)), and that in another test with rabbits, conjunctiva discoloration, blistering, and thickening developed and corneal irritation resolved after 8-21 days (ECETOC TR63 (1995)). Therefore, this substance was classified in Category 2.

Germ cell mutagenicity:

Classification not possible due to lack of data. No data were available for in vivo. As for in vitro, bacterial reverse mutation tests and mammalian cell gene mutation tests were negative (Initial Risk Assessment Report (NITE, CERI, NEDO, 2008), EHC 204 (1998)).

Reproductive toxicity:

In a test in which male rats were dosed with this substance by feeding at 1000 or 2000 ppm for up to 60 days before mating with untreated females, and male fertility was investigated, a reversible decrease of fertility was observed at 1,000 ppm (50 mg Boron/kg/day), and male fertility disappeared completely at 2,000 ppm (100 mg Boron/kg/day) during the 12-week observation period (Initial Risk Assessment Report (NITE, CERI, NEDO, 2008), ATSDR (2010)). In addition, in a reproductive toxicity study in which this substance was administered to female and male rats by feeding at up to 1,170 ppm (58.5 mg Boron/kg/day), testis atrophy, a decrease of ovulation count, and complete infertility were observed in the dosed groups at 1,170 ppm. Moreover, infertility was also observed when females in the administration group at 1,170 ppm were mated with males in the control group (Initial Risk Assessment Report (NITE,

CERI, NEDO, 2008), ATSDR (2010)). From the above, as for experimental animals, this substance decrease the fertility both of males and females at doses where general toxicity was not observed clearly. Therefore, this substance was classified in Category 1B. Besides, the EU also classified this substance as Repr. 1B (ECHA CL Inventory (Access on August 2017)). The category was changed from the previous classification based on new information sources.

Specific target organ toxicity (Single exposure):

Sodium borates including this substance dissolve in water to form boric acid at biological pH (CAS RN 10043-35-3) (PATTY (6th, 2012)). The main hazard information on boric acid and borax are reported as below.

As for humans, it is reported that a 77-year-old man who ingested 30 g of boric acid once with water developed nausea, vomiting, abdominal pain, diarrhea, erythema, cyanotic extremities, acute renal failure and cardiopulmonary hypotension, and died from cardiac insufficiency (ATSDR (2010), Initial Risk Assessment Report (NITE, CERI, NEDO, 2008)). In addition, it is reported that eleven newborns who ingested milk containing 4.5-14 g of boric acid showed symptoms of the central nervous system including headache, tremors, restlessness, convulsions, weakness, and coma in addition to vomiting and diarrhea, and five of them died within three days (ATSDR (2010), Initial Risk Assessment Report (NITE, CERI, NEDO, 2008)). Moreover, it was reported that in a single inhalation exposure study with volunteers given boric acid or tetraborate disodium heptaoxide pentahydrate (Na2B4O7.5H2O, CAS RN 12179-04-3), an increase in nasal secretion was observed (ACGIH (7th, 2005), ATSDR (2010), DFGOT (2013) (Access on May 2017)).

As for experimental animals, it was reported that the acute oral effects on experimental animals of boric acid or this substance were central nervous system depression, convulsions and death with death, and the doses were above the guidance value range of Category 2 (rat, mouse: 2,403-6,080 mg/kg) (ACGIH (7th, 2005), ECETOC TR63 (1995)).

Putting together the above mentioned information on this substance and tetraboron disodium heptaoxide pentahydrate, this substance was classified in Category 1 (central nervous system, gastrointestinal tract), Category 3 (respiratory tract irritation).

Besides, although it was not adopted as evidence of the classification due to unknown details, as for humans, there is a description that serious gastrointestinal irritation, kidney problems, central nervous system depression or vascular prostration may occur and may lead to death if this substance not less than 1g is absorbed from the gastrointestinal tract or skin rapidly (ACGIH (7th, 2001)). The kidney was adopted as the target organ in the previous classification based on the above information. However, there were no details. Also, there was no information on acute or chronic effects on the kidney also in experimental animals. Thus, it was not adopted. Moreover, with regard to Category 1 (respiratory organs) in the previous classification, there was no information on the original source in ACGIH (7th, 2001) in the description, "respiratory organs disease, lung disease, abnormal radiograph of chest X-ray and respiratory tract irritation," which was adopted as the evidence, and the details could not be confirmed. In the other evaluation reports, there is only the information that an increase in nasal secretion was observed in an inhalation exposure study of boric acid or tetraboron disodium heptaoxide pentahydrate. Therefore, it was judged that classification in Category 3 (respiratory tract irritation) was appropriate. From the above, the classification was changed from the previous one.

Specific target organ toxicity (repeated exposure):

As for humans, in a cross-sectional study of 629 workers (including 26 women) working in a large scale borax mining and refining plant in the US for more than five years, there was a significantly increased trend of cough, mucus hypersecretion, chronic bronchitis in nonsmoking workers, and shortness of breath in workers with a smoking history. There is a report that no association with the results of pulmonary function examinations or chest X-rays and the exposure concentration (Environmental Risk Assessment for Chemical Substances Vol.14 (Ministry of the Environment, 2016), EHC 204 (1998)). Additionally, there is a report that seven cases of newborn infants (aged 6 to 16 weeks) who used a pacifier to which borax and honey mixture was applied for 4 to 10 weeks showed convulsions, irritability, gastrointestinal disorders (diarrhea, vomiting), and the symptoms disappeared with discontinuation of the use (EHC 204 (1998), Initial Risk Assessment Report (NITE, CERI, NEDO, 2008), ATSDR (2010)).

As for experimental animals, atrophy of the testes was observed in multiple studies with rats given in the diet (Initial Risk Assessment Report (NITE, CERI, NEDO, 2008), ATSDR (2010)). However, all were outside the guidance value range of Category 2.

From the above, as the effects on the respiratory organs and nervous system were observed in humans, this substance was classified in Category 1 (respiratory organs, nervous system).

Besides, among the human findings, "generalized or alternating focal motor seizure, irritability, cloudy swelling and granular degeneration of the renal tubules" (EHC 204 (1998)), in the previous classification, the effect on the nervous system was in the infants' report described above, however, the finding of the kidney was not adopted due to no details. Additionally, the finding in the testes of experimental animals was based on the exposure level as Boron, and the dose exceeded the guidance value range for Category 2 when converted to this substance. Thus, the classification was changed from the previous one.

Other data: Not available

Polyethylene:

Acute toxicity: Not classified; Not acute toxic to human; 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 are shown below.

[Reproductive toxicity]

The content of Category 1B substance is ≥ 0.3%; Classified as Category 1B (Danger, May damage fertility or the unborn child.).

[Specific target organ toxicity (single exposure)]

The content of Category 1 (central nervous system, gastrointestinal tract)) is ≥ 1% and < 10%;

Classified Category 2 (Warning, May cause damage to central nervous system, gastrointestinal tract).

The content of Category 3 (respiratory tract irritation) is < 20%;

Classifications are not possible because of lack of data.

[Specific target organ toxicity (repeated exposure)]

The content of Category 1 (respiratory organs, nervous system) is \geq 1% and < 10%;

Classified Category 2 (Warning, May cause damage to respiratory organs, nervous system through prolonged or repeated exposure).

[Acute toxicity(Oral, Dermal, Inhalation)], [Skin corrosion/ irritation], [Serious eye damage/ eye irritation], [Respiratory or skin sensitization], [Germ cell mutagenicity], [Carcinogenicity], [Aspiration hazard] Classification is not possible because of data lack.

12. Ecological information

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

Sodium tetraborate decahydrate:

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

From 96-hour LC50 = 125 mg/L [converted value 14.2 mgB/L] for fish (Brachydanio rerio), and 24-hour LC50 = 644 mg/L [converted value 73 mgB/L] for crustacea (Daphnia magna) (WHO EHC: 1998), it was classified as "Not classified."

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

Chronic toxicity data were not obtained. Metals are regarded to be non-biodegradable due to an element, and bioaccumulation cannot be estimated form LogKow. In addition, because the possibility of high bioaccumulation cannot be denied, there is a possibility of having chronic toxicity in spite of high water solubility (59,300 mg/L), it was classified in Category 4.

Hazardous to the ozone layer:

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

Polyethylene: No eco-toxicological information available.

GHS classifications as a mixture are shown below.

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

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

Classification is 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

Since pH of waste solution in tube is alkali, pH = 9. Waste solution contains 6mg- boron/time. 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 classification and number: Not applicable Civil Aeronautics Act: Not applicable Fire Service Act: Not applicable Total weight of the product: ca.140 g/kit

15. Regulatory information

Poisonous and Deleterious Substa	ances Control Act:
	Not applicable
PRTR Act:	Not applicable (As boron in this product is lower than1%)
Industrial Safety and Health Act:	Applicable
	This product contains more than 1% of sodium tetraborate decahydrate. "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"
Water Pollution Control Act:	Applicable
	Waste solution after measurement contains sodium tetraborate decahydrate. "Cabinet Order set forth in Item (24) of Article 2".
Sewerage Act:	Applicable.
	Waste solution after measurement contains sodium tetraborate decahydrate. "Cabinet Order set forth in Item (25) of Article 9-4".

16. Other information

Reference literature

15,911 Kagaku Shouhin, The Chemical Diary Co., Ltd. (2011)

NITE, GHS Classification, ID H29-B-092 Sodium tetraborate decahydrate (2017)

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

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-Labelling 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.