

Safety Data Sheet

Material Name : New Alkali

SDS ID: CA-205
In compliance with Regulation
(EC) 1907/2006(REACH) as
amended

Section 1 - IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product Identifier:

Product Identifier: New Alkali

Substance Registration Number(s)

This material is imported in amounts < 1 tonne/annum. This product and its components are not subject to REACH.

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Identified Uses

in vitro diagnostic use

Uses Advised Against

Use Supplier Information. For use in recommended identified uses only.

1.3 Details of the supplier of the safety data sheet

SEKISUI MEDICAL CO., LTD.

1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, 103-0027, JAPAN

Phone: +81-3-3272-0828

Email: international@sekisui.com

Contact address for European countries

Medical Device Safety Service GmbH

Schiffgraben 41, 30175 Hannover, Germany

Phone: +49-511-6262-8630

1.4 Emergency Telephone Number

+81-3-3272-0828 (Mon. through Fri. [9:00 a.m. to 5:30 p.m. Japanese standard time])

Section 2 - HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

Classification according to Regulation (EC) No 1272/2008

Skin Corrosion / Irritation, Category 1B

Serious Eye Damage/Eye Irritation, Category 1

Carcinogenicity, Category 2

Classification according to Directives 67/548/EEC and/or 1999/45/EC

C

Xn

Carc. Cat. 3

R35 Causes severe burns.

R40 Limited evidence of a carcinogenic effect.

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2.2 Label Elements

Labelling according to Regulation (EC) 1272/2008/EC

Symbol(s)



Signal Word

DANGER

Hazard Statement(s)

H314 Causes severe skin burns and eye damage

H351 Suspected of causing cancer

Precautionary Statement(s)

Prevention

P260 Do not breathe vapor or mist. **P280** Wear protective gloves/clothing and eye/face protection. **P202** Do not handle until all safety precautions have been read and understood.

Response

P310 Immediately call a POISON CENTER or doctor/physician. **P303+P361+P353** IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Storage

P405 Store locked up.

Disposal

P501 Dispose in accordance with all applicable regulations.

Labelling according to Directive 67/548/EEC and/or 1999/45/EC

C

Xn

Carc. Cat. 3

R35 Causes severe burns.

R40 Limited evidence of a carcinogenic effect.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

2.3 Other Hazards

None known.

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Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

CAS EC No Registration No	Component Synonyms	67/548 EEC (DSD)	1272/2008 (CLP)	Percent
5064-31-3 225-768-6 --	Nitriлотriacetic acid trisodium salt	Xn; R:22-36-40	Acute Tox. 4 (Oral) Eye Irrit. 2 Carc. 2	8-12
1310-58-3 215-181-3 --	Potassium hydroxide	C; R:22-35	Acute Tox. 4 (Oral) Skin Corr. 1A	<5

Section 4 - FIRST AID MEASURES

4.1 Description of First Aid Measures

Inhalation

If adverse effects occur, remove to uncontaminated area. If breathing is difficult, oxygen should be administered by qualified personnel. Immediately call a POISON CENTER or doctor/physician.

Skin

Remove/take off immediately all contaminated clothing. Wash with plenty of soap and water. Wash contaminated clothing before reuse. Immediately call a POISON CENTER or doctor/physician.

Eyes

Immediately flush eyes with plenty of water for at least 60 minutes. Remove contact lenses, if present and easy to do. Immediately call a POISON CENTER or doctor/physician.

Ingestion

Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

4.2 Most Important Symptoms and Effects, both Acute and Delayed

Acute

eye burns, skin burns

Delayed

cancer

4.3 Indication of any Immediate Medical Attention and Special Treatment Needed

Note to Physicians

Treat symptomatically and supportively.

Section 5 - FIRE FIGHTING MEASURES

5.1 Extinguishing Media

Suitable Extinguishing Media

regular dry chemical, carbon dioxide, water spray

Unsuitable Extinguishing Media

Do not use high-pressure water streams.

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5.2 Special Hazards Arising from the Substance or Mixture

Negligible fire hazard.

Thermal Decomposition Products

Combustion: oxides of potassium, oxides of carbon, oxides of nitrogen, oxides of sodium

5.3 Advice for Firefighters

Fire Fighting Measures

Move container from fire area if it can be done without risk. Cool containers with water spray until well after the fire is out.

Protective Equipment and Precautions for Firefighters

Wear self-contained breathing apparatus and protective clothing.

* * *Section 6 - ACCIDENTAL RELEASE MEASURES* * *

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Wear personal protective clothing and equipment, see Section 8. Do not touch or walk through spilled material. Do not breathe vapor or mist.

6.2 Environmental Precautions

Avoid release to the environment. Prevent entry into sewers, drains, ditches, underground or confined spaces and waterways.

6.3 Methods and Material for Containment and Cleaning up

Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

6.4 Reference to Other Sections

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations. See Section 13 for Disposal Considerations.

* * *Section 7 - HANDLING AND STORAGE* * *

7.1 Precautions for Safe Handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep only in the original container. Do not breathe vapor or mist. Do not touch or walk through spilled material. Wear protective gloves/clothing and eye/face protection. Use personal protective equipment as required. Wash thoroughly after handling.

7.2 Conditions for Safe Storage, Including any Incompatibilities

Store and handle in accordance with all current regulations and standards. Store in corrosive resistant container with a resistant inner liner. Store locked up. Keep separated from incompatible substances.

Incompatible materials include acids, combustible materials, metals, halo carbons, oxidizing materials, metal salts, and reducing agents.

7.3 Specific End Use(s)

None known.

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Component Exposure Limits

Potassium hydroxide (1310-58-3)

Austria:	2 mg/m3 TWA (inhalable fraction)
Bulgaria:	2.0 mg/m3 TWA
Czech Republic:	1 mg/m3 TWA 2 mg/m3 Ceiling
Denmark:	2 mg/m3 Ceiling
Estonia:	2 mg/m3 TWA
Finland:	2 mg/m3 STEL 2 mg/m3 Ceiling
France:	2 mg/m3 STEL [VLCT]
Greece:	2 mg/m3 TWA 2 mg/m3 STEL
Hungary:	2 mg/m3 TWA [AK] 2 mg/m3 STEL [CK]
Ireland:	2 mg/m3 STEL
Poland:	0.5 mg/m3 TWA 1 mg/m3 STEL [NDSCh]
Portugal:	2 mg/m3 Ceiling [VLE-CM]
Spain:	2 mg/m3 STEL [VLA-EC]
Sweden:	1 mg/m3 LLV (inhalable dust) 2 mg/m3 CLV (inhalable dust)
United Kingdom:	2 mg/m3 STEL

Component Biological Limit Values

There are no biological limit values for any of this product's components

Derived No Effect Levels (DNELs)

No DNELs available.

Predicted No Effect Concentrations (PNECs)

No PNECs available.

8.2 Exposure Controls

Appropriate Engineering Controls

Provide local exhaust or process enclosure ventilation system. Ensure compliance with applicable exposure limits.

Personal Protective Equipment

Eye / Face Protection

Wear splash resistant safety goggles with a faceshield. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

Skin Protection

Wear appropriate chemical resistant clothing.

Glove Recommendations

Wear appropriate chemical resistant gloves.

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Respiratory Protection

Approved respirators should be worn when airborne concentrations are expected to exceed occupation exposure limits.

Follow the respiratory regulations found in European Standard EN 149.

Environmental Exposure Controls

Avoid release to the environment.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties

Physical State: Liquid	Appearance: colorless to pale yellow liquid
Color: colorless to pale yellow	Physical Form: Liquid
Odor: faint odor	Odor Threshold: Not available
pH: 12.1 (at 2% solution)	Melting Point: Not available
Boiling Point: Not available	Flash Point: Not available
Decomposition Temperature: Not available	Evaporation Rate: Not available
LEL: Not available	UEL: Not available
Vapor Pressure: Not available	Vapor Density (air = 1): Not available
Density: Not available	Specific Gravity (water = 1): 1.18
Water Solubility: Not available	Log KOW: Not available
Coeff. Water/Oil Dist: Not available	Auto Ignition Temperature: Not available
Viscosity: Not available	Oxidizing Properties: Not available
Explosive Properties: Not available	

9.2 Other Information

No additional information is available.

Section 10 - STABILITY AND REACTIVITY

10.1 Reactivity

No reactivity hazard is expected.

10.2 Chemical Stability

Stable at standard temperatures and pressure.

10.3 Possibility of Hazardous Reactions

Will not polymerize.

10.4 Conditions to Avoid

Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials. Dangerous gases may accumulate in confined spaces.

10.5 Incompatible Materials

acids, combustible materials, metals, halo carbons, oxidizing materials, metal salts, reducing agents

10.6 Hazardous Decomposition Products

Thermal Decomposition Products

Combustion: oxides of potassium, oxides of carbon, oxides of nitrogen, oxides of sodium

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Section 11 - TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects

Acute and Chronic Toxicity

Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and the following selected endpoints are published:

Nitrilotriacetic acid trisodium salt (5064-31-3)

Inhalation LC50 Rat >5 mg/L 4 h; Oral LD50 Rat 920 mg/kg

Potassium hydroxide (1310-58-3)

Oral LD50 Rat 214 mg/kg

Irritation / Corrosivity

eye burns, skin burns

Respiratory Sensitization

No information available for the product.

Skin Sensitization

No information available for the product.

Germ Cell Mutagenicity

No information available for the product.

Carcinogenicity

Component Carcinogenicity

Nitrilotriacetic acid trisodium salt (5064-31-3)

IARC: Monograph 73 [1999]; Monograph 48 [1990] (evaluated as a group) (Group 2B (possibly carcinogenic to humans))

Reproductive Toxicity

No information available for the product.

Specific Target Organ Toxicity - Single Exposure

No target organs identified.

Specific Target Organ Toxicity - Repeated Exposure

No target organs identified.

Aspiration Hazard

No information available for the product.

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Section 12 - ECOLOGICAL INFORMATION

12.1 Toxicity

Component Analysis - Aquatic Toxicity

Nitrilotriacetic acid trisodium salt (5064-31-3)

Fish: 96 Hr LC50 Pimephales promelas: 93 - 170 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 175 - 225 mg/L [static]; 96 Hr LC50 Lepomis macrochirus: 252 mg/L; 96 Hr LC50 Pimephales promelas: 470 mg/L [static]; 96 Hr LC50 Oryzias latipes: 560 - 1000 mg/L; 96 Hr LC50 Oryzias latipes: 560 - 1000 mg/L [semi-static]; 96 Hr LC50 Oncorhynchus mykiss: 72 - 133 mg/L [static]; 96 Hr LC50 Poecilia reticulata: 560 - 1000 mg/L [semi-static]; 96 Hr LC50 Poecilia reticulata: 560 - 1000 mg/L; 96 Hr LC50 Pimephales promelas: 114 mg/L

Algae: 96 Hr EC50 Chlorella vulgaris: 560 - 1000 mg/L

Invertebrate: 48 Hr LC50 Daphnia magna: 560 - 1000 mg/L

Potassium hydroxide (1310-58-3)

Fish: 96 Hr LC50 Gambusia affinis: 80 mg/L [static]

12.2 Persistence and Degradability

No information available for the product.

12.3 Bioaccumulative Potential

No information available for the product.

12.4 Mobility in Soil

No information available for the product.

12.5 Results of PBT and vPvB Assessment

No information available.

EU - Interim Strategy for Management of PBT and vPvB Substances (PBT Assessments)

No components of this material are listed.

12.6 Other Adverse Effects

No information available.

Section 13 - DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods

Dispose in accordance with all applicable regulations.






Section 14 - TRANSPORT INFORMATION

	ADR	RID	ICAO	ADN	IMDG
14.1 UN Number	3266	3266	3266	3266	3266
14.2 UN Proper Shipping Name	Corrosive liquid, basic, inorganic, n.o.s. (Contains: Potassium hydroxide)	Corrosive liquid, basic, inorganic, n.o.s. (Contains: Potassium hydroxide)	Corrosive liquid, basic, inorganic, n.o.s. (Contains: Potassium hydroxide)	Corrosive liquid, basic, inorganic, n.o.s. (Contains: Potassium hydroxide)	Corrosive liquid, basic, inorganic, n.o.s. (Contains: Potassium hydroxide)
14.3 Transport Hazard	Hazard	Hazard	Hazard	Hazard	Hazard

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Class(es)	Class: 8	Class: 8	Class: 8	Class: 8	Class: 8
					
14.4 Packing Group	Packing Group: II	Packing Group: II	Packing Group: II	Packing Group: II	Packing Group: II
14.5 Environmental Hazards	--	--	--	--	--
14.6 Special Precautions For User	--	--	--	--	--
14.7 Transport in Bulk According to Annex II or MARPOL 73/78 and the IBC Code	--	--	--	--	--

International Bulk Chemical Code

This material contains one or more of the following chemicals required by the IBC Code to be identified as dangerous chemicals in bulk.

Nitrotriacetic acid trisodium salt (5064-31-3)

IBC Code: Category Y (solution)

Potassium hydroxide (1310-58-3)

IBC Code: Category Y (solution)

* * *Section 15 - REGULATORY INFORMATION* * *

15.1 Safety, Health and Environmental Regulations / Legislation Specific for the Substance or Mixture

EU - REACH (1907/2006) - Annex XIV List of Substances Subject to Authorisation

No components of this material are listed.

EU - REACH (1907/2006) - Article 59(1) Candidate List of Substances Subject to Authorisation

No components of this material are listed.

EU - REACH (1907/2006) - Annex XVII Restrictions of Certain Dangerous Substances, Mixtures and Articles

No components of this material are listed.

EU - REACH (1907/2006) - Potential Substances of Very High Concern

No components of this material are listed.

EU - Biocides (1451/2007) - Existing Active Substance

Potassium hydroxide (1310-58-3)

EU Biocidal Present

EU - REACH (1907/2006) - Article 15(2) - Substances Regarded as Being Registered - Biocidal Products

No components of this material are listed.

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Germany Regulations

Germany Water Classification

Nitrilotriacetic acid trisodium salt (5064-31-3)

ID Number 160, hazard class 2 - hazard to waters

Potassium hydroxide (1310-58-3)

ID Number 345, hazard class 1 - low hazard to waters

Denmark Regulations

Environmental Protection Agency List of Undesirable Substances

Nitrilotriacetic acid trisodium salt (5064-31-3)

Biocides; Sequestering agents; pH regulating agents; Cleaning agents

Problematic properties according to the List of Dangerous Substances

Substance Analysis - Inventory

Component	CAS	EEC
Nitrilotriacetic acid trisodium salt	5064-31-3	EIN
Potassium hydroxide	1310-58-3	EIN

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for the substance/mixture.

Section 16 - OTHER INFORMATION

16.1 Indication of changes

Date Issued: July 17, 2015

Date Revised: November 10, 2015

Date Revised: January 22, 2016

Date Revised: January 1, 2017

Date Revised: April 12, 2019

16.2 Key or legend to abbreviations and acronyms used in the safety data sheet

ADR - European Road Transport; CAS No. - Chemical Abstract Service Registry Number; CLP - Classification, Labelling and Packaging; EINECS - European Inventory of Existing Commercial Chemical Substances; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC Code - International Bulk Chemical Code; ICAO - International Civil Aviation Organization; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration, 50%; LD50 - Lethal Dose, 50%; LEL - Lower Explosive Limit; REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - European Rail Transport; STEL - Short-term Exposure Limit; TWA - Time Weighted Average; UEL - Upper Explosive Limit

16.3 Key literature references and sources for data

Available upon request

16.4 Methods used for classification of mixture according to Regulation (EC) No 1272/2008

Available upon request

16.5 Full text of R phrases in Section 3

R22 Harmful if swallowed.

R35 Causes severe burns.

R36 Irritating to eyes.

R40 Limited evidence of a carcinogenic effect.

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16.6 Training Advice

Read the Safety Data Sheet before handling product.

16.7 Other Information

Disclaimer: Supplier gives no warranty whatsoever, including the warranties of merchantability or of fitness for a particular purpose. Any product purchased is sold on the assumption the purchaser shall determine the quality and suitability of the product. Supplier expressly disclaims any and all liability for incidental, consequential or any other damages arising out of the use or misuse of this product. No information provided shall be deemed to be a recommendation to use any product in conflict with any existing patent rights.

End of Sheet CA-205