

Safety Data Sheet (#12)

acc. to ISO/DIS 11014

Printing date 03/12/2013

Reviewed on 03/12/2013

1 Identification of the substance/mixture and of the company/undertaking

Product identifier

- Trade name: AIA-PACK FT4 CALIBRATOR SET (020368)
AIA-PACK FT3 CALIBRATOR SET (020386)
AIA-PACK CORT CALIBRATOR SET (020387)
AIA-PACK PRL CALIBRATOR SET (020355):
Concerned item: AIA-PACK PRL CALIBRATOR (2)
AIA-PACK IRI CALIBRATOR SET (020360):
Concerned item: AIA-PACK IRI CALIBRATOR (2-6)
AIA-PACK PAP CALIBRATOR SET (020362):
Concerned item: AIA-PACK PAP CALIBRATOR (2)
AIA-PACK PAP CALIBRATION VERIF./LINEARITY TEST SET (020662):
Concerned item: AIA-PACK PAP CALIBRATION VERIFICATION MATERIAL
ST AIA-PACK 25-OH Vitamin D CALIBRATOR SET (025334):
Concerned item: ST AIA-PACK 25-OH Vitamin D CALIBRATOR (2-6)
ST AIA-PACK LH II CALIBRATOR SET (025396):
Concerned item: ST AIA-PACK LH II CALIBRATOR (2-6)
AIA-PACK 25-OH Vitamin D CONTROL SET (025434)

Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the preparation

In Vitro Diagnostics.

Details of the supplier of the safety data sheet

Manufacturer
TOSOH CORPORATION
3-8-2 Shiba, Minato-ku
Tokyo 105 -8623
JAPAN

Supplier:

TOSOH BIOSCIENCE, INC.
6000 Shoreline Ct.; Suite 101
South San Francisco, CA94080
USA

Tel. : + 81 3 5427 5181
Fax : + 81 3 5427 5220

Phone : + 1 614 317 1909 or (800) 248 6764
Fax : + 1 877 898 9883 or (800) 685 7595

Information department:

QA-RA: susan.koss@tosoh.com

www.diagnostics.us.tosohbioscience.com

Emergency telephone number: Poison Control Center: + 1 800 222 1222

2 Hazards identification

Classification of the substance or mixture

The product is not classified according to the Globally Harmonized System (GHS).

Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Harmful

Harmful if swallowed.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of international guidelines.

Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

Label elements

Labelling according to EU guidelines:

The product has been classified and marked in accordance with directives on hazardous materials.

Code letter and hazard designation of product:



Harmful

Hazard-determining components of labelling:

sodium azide

Risk phrases:

Harmful if swallowed.

(Contd. on page 2)

USA

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/12/2013

Reviewed on 03/12/2013

(Contd. of page 1)

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

Keep out of the reach of children.

Keep away from food, drink and animal feedingstuffs.

Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

If swallowed, seek medical advice immediately and show this container or label.

Classification system:

NFPA ratings (scale 0 - 4)



HMIS-ratings (scale 0 - 4)



Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.


vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

26628-22-8	sodium azide	 Acute Tox. 2, H300	≤ 2.5%
------------	--------------	--	--------

4 First aid measures

Description of first aid measures

General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: Immediately call a doctor.

Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

Extinguishing media

Suitable extinguishing agents:

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Special hazards arising from the substance or mixture No further relevant information available.

Advice for firefighters

Protective equipment: No special measures required.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures Not required.

(Contd. on page 3)

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/12/2013

Reviewed on 03/12/2013

(Contd. of page 2)

Environmental precautions:

Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

Reference to other sections

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

Precautions for safe handling

Store in cool, dry place in tightly closed receptacles.
No special precautions are necessary if used correctly.

Information about protection against explosions and fires:

No special measures required.

Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles:

No special requirements.

Information about storage in one common storage facility:

Not required.

Further information about storage conditions:

None.

Specific end use(s)

No further relevant information available.

8 Exposure controls/personal protection

Additional information about design of technical systems:

No further data; see item 7.

Control parameters

Components with limit values that require monitoring at the workplace:

26628-22-8 sodium azide

REL	Short-term value: C 0.3** mg/m ³ , C 0.1* ppm *as HN ₃ ; **as NaN ₃ ; Skin
TLV	Short-term value: C 0.29** mg/m ³ , C 0.11* ppm *as HN ₃ vapor **as NaN ₃

Additional information:

The lists that were valid during the creation were used as basis.

Exposure controls

Personal protective equipment:

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.

Breathing equipment:

Not required.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Not required.

USA

(Contd. on page 4)

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/12/2013

Reviewed on 03/12/2013

(Contd. of page 3)

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Spray dried powder

Color: Light beige

· Odor: Odorless

· Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

· Ignition temperature:

Decomposition temperature: Not determined.

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined.

Upper: Not determined.

· Vapor pressure: Not applicable.

· Density: Not determined.

· Relative density: Not determined.

· Vapour density: Not applicable.

· Evaporation rate: Not applicable.

· Solubility in / Miscibility with

Water: Soluble.

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

Dynamic: Not applicable.

Kinematic: Not applicable.

· Solvent content:

Organic solvents: 0.0 %

Solids content: 100.0 %

· Other information: No further relevant information available.

10 Stability and reactivity

· Reactivity

· Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Possibility of hazardous reactions: No dangerous reactions known.

· Conditions to avoid: No further relevant information available.

· Incompatible materials: No further relevant information available.

· Hazardous decomposition products: No dangerous decomposition products known.

USA

(Contd. on page 5)

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/12/2013

Reviewed on 03/12/2013

(Contd. of page 4)

11 Toxicological information

· Information on toxicological effects

· Acute toxicity:

· LD/LC50 values that are relevant for classification:

26628-22-8 sodium azide

Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

· Primary irritant effect:

· on the skin: No irritant effect.

· on the eye: No irritating effect.

· Sensitization: No sensitizing effects known.

· Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:
Harmful

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

· Toxicity

· Aquatic toxicity: No further relevant information available.

· Persistence and degradability: No further relevant information available.

· Bioaccumulative potential: No further relevant information available.

· Mobility in soil: No further relevant information available.

· Ecotoxicological effects:

· Remark: Harmful to fish

· Additional ecological information:

· General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Harmful to aquatic organisms

· Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

· Other adverse effects: No further relevant information available.

13 Disposal considerations

· Waste treatment methods

· Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packagings:

· Recommendation: Disposal must be made according to official regulations.

· Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

· UN-Number

· DOT, ADR, ADN, IMDG, IATA

Void

(Contd. on page 6)

USA

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/12/2013

Reviewed on 03/12/2013

(Contd. of page 5)

· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	-

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara

· Section 355 (extremely hazardous substances):

All ingredients are listed.

· Section 313 (Specific toxic chemical listings):

All ingredients are listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

26628-22-8 sodium azide

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Product related hazard informations:

The product has been classified and marked in accordance with directives on hazardous materials.

· Hazard symbols:



Harmful

(Contd. on page 7)

USA

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/12/2013

Reviewed on 03/12/2013

(Contd. of page 6)

· Hazard-determining components of labelling:

sodium azide

· Risk phrases:

Harmful if swallowed.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· Safety phrases:

Keep out of the reach of children.

Keep away from food, drink and animal feedingstuffs.

Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

If swallowed, seek medical advice immediately and show this container or label.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The information contained herein is prepared based on the available information to Tosoh that is believed to be reliable; however the information is provided by Tosoh WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, AS TO ITS COMPLETENESS, COMPREHENSIVENESS AND ACCURACY.

Since the conditions of handling, storage and disposal of this material are beyond our control, it is the responsibility of the user to determine whether the material is fit for a particular purpose and/or suitable for the user's method of use or application, and to determine safe conditions for use of the material, and to assume full responsibility for loss, injury and expense arising out of or in connection with the use of material. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, REGARDING THE MATERIAL DESCRIBED HEREIN SHALL BE CREATED BY OR INFERRED FROM ANY STATEMENT OR OMISSION FROM THIS MSDS.

Various government agencies and local authorities may have general or specific regulations applicable to the material which may not be covered in this MSDS. It is sole responsibility of the user to examine and confirm for its full compliance with any such regulations.

When the revision of this MSDS is received, please dispose of the old one.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

USA