

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

· **Product identifier**

- **Trade name:** AIA-PACK CALIBRATOR SET SERIES 1 : Please refer to ANNEX I
- AIA-PACK SAMPLE DILUTING SOLUTION Series : Please refer to ANNEX II
- AIA-PACK TPOAb CONTROL SET : 020490
- AIA-PACK TPOAb CONJUGATE : 020708
- AIA-PACK TgAb CONJUGATE : 020709
- AIA-PACK RBC FOLATE HEMOLYZING REAGENT 2: 020711
- ST AIA-PACK Cystatin C CONTROL SET : 025417

- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** In Vitro Diagnostics.

· **Details of the supplier of the safety data sheet**

· **Manufacturer / Supplier:**

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

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 Composition/information on ingredients

· **Chemical characterization: Substances**

· **CAS No. Description**

7732-18-5 water, distilled, conductivity or of similar purity

· **Identification number(s)**

· **EINECS Number:** 231-791-2

· **Chemical characterization: Mixtures**

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

· **Dangerous components:** Void

3 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** Not applicable.

· **Information concerning particular hazards for human and environment:**

The product does not have 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**

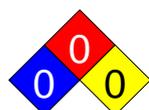
· **Labelling according to EU guidelines:**

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

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ST AIA-PACK Cystatin C CONTROL SET	: <u>025417</u>

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· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **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:** If symptoms persist consult doctor.
- **Information for 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.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
No dangerous substances are released.
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

- **Handling:**
- **Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.

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- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **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:** Goggles recommended during refilling.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solution
Color:	Colorless
Odor:	Odorless
Odour threshold:	Not determined.
- **pH-value:** Not determined.

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· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· 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 at 20°C (68°F):	23 hPa (17 mm Hg)
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
Water:	Fully miscible.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
· 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.

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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 is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **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:** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **DOT regulations:**
- **Hazard class:** -

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· **Land transport ADR/RID (cross-border):**
 · **ADR/RID class:** -

· **Maritime transport IMDG:**
 · **IMDG Class:** -
 · **Marine pollutant:** No

· **Air transport ICAO-TI and IATA-DGR:**
 · **ICAO/IATA Class:** -

· **UN "Model Regulation":** -
 · **Special precautions for user** Not applicable.
 · **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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.

· **IARC (International Agency for Research on Cancer)**
 None of the ingredients is listed.

· **NTP (National Toxicology Program)**
 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.

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· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Product related hazard informations:

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

· 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.

· 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)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

ANNEX I:

AIA-PACK CALIBRATOR SET Series 1:

Revision:

3/05/2011

Catalogue Number	Description	
020302	AIA-PACK 27.29 CALIBRATOR SET	
020352	AIA-PACK AFP CALIBRATOR SET	
020353	AIA-PACK FER CALIBRATOR SET	
020354	AIA-PACK CEA CALIBRATOR SET	
020358	AIA-PACK T4 CALIBRATOR SET	
020361	AIA-PACK β HCG CALIBRATOR SET	
020363	AIA-PACK PA CALIBRATOR SET	
020365	AIA-PACK FSH CALIBRATOR SET	
020381	AIA-PACK PROG CALIBRATOR SET	
020382	AIA-PACK TT3 CALIBRATOR SET	
020390	AIA-PACK TPOAb CALIBRATOR SET	
020394	AIA-PACK TSH 2rd-Gen CALIBRATOR SET	
020395	AIA-PACK IgEII CALIBRATOR SET	
025304	ST AIA-PACK Testosterone CALIBRATOR SET	
025312	ST AIA-PACK PSA II CALIBRATOR SET	
025317	ST AIA-PACK Cystatin C CALIBRATOR SET	
025322	ST AIA-PACK DHEA-S CALIBRATOR SET	
0025374	ST AIA-PACK E2 CALIBRATOR SET	
	Description (on outer packaging)	Description concerned item(as on label)
	ST AIA-PACK cTnI 2nd-Gen CALIBRATOR SET (025305)	ST AIA-PACK cTnI 2nd-Gen CALIBRATOR (1)
	ST AIA-PACK Intact PTH CALIBRATOR SET(025313)	ST AIA-PACK Intact PTH CALIBRATOR (1)
	AIA-PACK RBC FOLATE CALIBRATOR SET (020314)	AIA-PACK RBC FOLATE CALIBRATOR (1)
	ST AIA-PACK ACTH CALIBRATOR SET (025321)	ST AIA-PACK ACTH CALIBRATOR (1)
	AIA-PACK PRL CALIBRATOR SET (020355)	AIA-PACK PRL CALIBRATOR (1)
	AIA-PACK BMG CALIBRATOR SET (020359)	AIA-PACK BMG CALIBRATOR (1)
	AIA-PACK IRI CALIBRATOR SET (020360)	AIA-PACK IRI CALIBRATOR (1)
	AIA-PACK PAP CALIBRATOR SET (020362)	AIA-PACK PAP CALIBRATOR (1)
	AIA-PACK HGH CALIBRATOR SET(020366)	AIA-PACK HGH CALIBRATOR (1)
	AIA-PACK CK-MB CALIBRATOR SET (020369)	ST AIA-PACK CK-MB CALIBRATOR (1)
	AIA-PACK C-Peptide CALIBRATOR SET(020384)	AIA-PACK C-Peptide CALIBRATOR (1)
	AIA-PACK 19-9 CALIBRATOR SET (020371)	AIA-PACK 19-9 CALIBRATOR (1)
	AIA-PACK CA 125 CALIBRATOR SET (020388)	AIA-PACK CA 125 CALIBRATOR (1)
	AIA-PACK TgAb CALIBRATOR SET (020391)	AIA-PACK TgAb CALIBRATOR (1)
	AIA-PACK FOLATE CALIBRATOR SET (020392)	ST AIA-PACK FOLATE CALIBRATOR (1)
	ST AIA-PACK LH II CALIBRATOR SET (025396)	ST AIA-PACK LH II CALIBRATOR (1)
	ST AIA-PACK Myoglobin CALIBRATOR SET (025397)	ST AIA-PACK Myoglobin CALIBRATOR (1)



TOSOH BIOSCIENCE

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ANNEX II:

AIA-PACK SAMPLE DILUTING SOLUTION Series:

Revision: 16/05/2011

Catalogue Number	Description
020502	AIA-PACK 27.29 SAMPLE DILUTING SOLUTION
020514	AIA-PACK RBC FOLATE SAMPLE DILUTING SOLUTION
020552	AIA-PACK AFP SAMPLE DILUTING SOLUTION
020553	AIA-PACK FER SAMPLE DILUTING SOLUTION
020554	AIA-PACK CEA SAMPLE DILUTING SOLUTION
020555	AIA-PACK PRL SAMPLE DILUTING SOLUTION
020558	AIA-PACK T4 SAMPLE DILUTING SOLUTION
020560	AIA-PACK IRI SAMPLE DILUTING SOLUTION
020561	AIA-PACK βHCG SAMPLE DILUTING SOLUTION
020562	AIA-PACK PAP SAMPLE DILUTING SOLUTION
020563	AIA-PACK PA SAMPLE DILUTING SOLUTION
020565	AIA-PACK FSH SAMPLE DILUTING SOLUTION
020566	AIA-PACK HGH SAMPLE DILUTING SOLUTION
020569	AIA-PACK CK-MB SAMPLE DILUTING SOLUTION
020574	AIA-PACK E2 SAMPLE DILUTING SOLUTION
020581	AIA-PACK PROG SAMPLE DILUTING SOLUTION
020582	AIA-PACK TT3 SAMPLE DILUTING SOLUTION
020584	AIA-PACK C-Peptide SAMPLE DILUTING SOLUTION
020571	AIA-PACK FIE/S SAMPLE DILUTING SOLUTION
020587	AIA-PACK CORT SAMPLE DILUTING SOLUTION
020588	AIA-PACK OATG SAMPLE DILUTING SOLUTION
0020590	AIA-PACK TPOAb/TgAb SAMPLE DILUTING SOLUTION
020592	AIA-PACK FOLATE SAMPLE DILUTING SOLUTION
020593	AIA-PACK B12 SAMPLE DILUTING SOLUTION
020594	AIA-PACK TSH 3rd-Gen SAMPLE DILUTING SOLUTION
020595	AIA-PACK IgEII SAMPLE DILUTING SOLUTION
020596	AIA-PACK LH II SAMPLE DILUTING SOLUTION
025504	ST AIA-PACK Testosterone SAMPLE DILUTING SOLUTION
025505	ST AIA-PACK cTnl 2nd-Gen SAMPLE DILUTING SOLUTION
025512	ST AIA-PACK PSA II SAMPLE DILUTING SOLUTION
025513	ST AIA-PACK Intact PTH SAMPLE DILUTING SOLUTION
025517	ST AIA-PACK Cystcin C SAMPLE DILUTING SOLUTION
025521	ST AIA-PACK ACTH SAMPLE DILUTING SOLUTION
025522	ST AIA-PACK DHEA-S SAMPLE DILUTING SOLUTION
025597	ST AIA-PACK Myoglobin SAMPLE DILUTING SOLUTION