

# Safety Data Sheet

acc. to OSHA HCS

Printing date 02/01/2016

Reviewed on 02/01/2016

## 1: Identification

- **1.1 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 (020711): concerned item:**  
**AIA-PACK RBC FOLATE HEMOLYZING REAGENT 2**  
**ST AIA-PACK hSE2 (025225): concerned item: ST AIA-PACK hSE2 CONJUGATE**  
**AIA-PACK Cystatin C CONTROL SET: 025417**  
**AIA-PACK Homocysteine CONTROL SET: 025426**
- **Application of the substance / the mixture** In Vitro Diagnostics.
- **1.3 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
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- **Information department:**  
 QA-RA: susan.koss@tosoh.com www.diagnostics.us.tosohbioscience.com
- **1.4 Emergency telephone number:** Poison Control Center: + 1 800 222 1222

## 2: Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
 The product is not classified according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**  


Health = 0  
Fire = 0  
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**  

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3: Composition/information on ingredients

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

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- **Dangerous components:** Void

## 4: First-aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

## 5: Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

## 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Dilute with plenty of water.
- **6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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

- **7.1 Precautions for safe handling**

Store in cool, dry place in tightly closed receptacles.  
No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **7.2 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.
- **7.3 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.
- **8.1 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.

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- **8.2 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

### · 9.1 Information on basic physical and chemical properties

#### · General Information

#### · Appearance:

· <b>Form:</b>	Solution
· <b>Color:</b>	Colorless
· <b>Odor:</b>	Odorless
· <b>Odor threshold:</b>	Not determined.

· **pH-value:** Not determined.

#### · Change in condition

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** 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:

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapor pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapor density** Not determined.

· **Evaporation rate** Not determined.

#### · Solubility in / Miscibility with

· **Water:** Fully miscible.

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

#### · Viscosity:

· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.

#### · Solvent content:

· **Organic solvents:** 0.0 %

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**· 9.2 Other information**

No further relevant information available.

### 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.

**· 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:** Based on available data, the classification criteria are not met.
- **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**

· **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.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

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

### 14: Transport information

· <b>14.1 UN-Number</b> · DOT, ADR, ADN, IMDG, IATA	Void
· <b>14.2 UN proper shipping name</b> · DOT, ADR, ADN, IMDG, IATA	Void
· <b>14.3 Transport hazard class(es)</b> · DOT, ADR, ADN, IMDG, IATA · <b>Class</b>	Void
· <b>14.4 Packing group</b> · DOT, ADR, IMDG, IATA	Void
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Void

### 15: Regulatory information

· <b>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b> · <b>Sara</b>
· <b>Section 355 (extremely hazardous substances):</b> All ingredients are listed.
· <b>Section 313 (Specific toxic chemical listings):</b> All ingredients are listed.
· <b>TSCA (Toxic Substances Control Act):</b> All ingredients are listed.
· <b>Proposition 65</b>
· <b>Chemicals known to cause cancer:</b> None of the ingredients is listed.
· <b>Chemicals known to cause reproductive toxicity for females:</b> None of the ingredients is listed.
· <b>Chemicals known to cause reproductive toxicity for males:</b> None of the ingredients is listed.
· <b>Chemicals known to cause developmental toxicity:</b> None of the ingredients is listed.
· <b>Carcinogenic categories</b>
· <b>EPA (Environmental Protection Agency)</b> None of the ingredients is listed.
· <b>TLV (Threshold Limit Value established by ACGIH)</b> 26628-22-8 sodium azide <span style="float: right;">A4</span>
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b> None of the ingredients is listed.
· <b>Labelling according to Regulation (EC) No 1272/2008</b> Void
· <b>Hazard pictograms</b> Void
· <b>Signal word</b> Void
· <b>Hazard statements</b> Void

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· **15.2 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 SDS.

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

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

· **Date of preparation / last revision** 02/01/2016 / -

· **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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified 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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit



**ANNEX I:**

**AIA-PACK CALIBRATOR SET Series 1:**

**Revision:**

**1/02/2016**

<b>Catalogue Number</b>	<b>Description</b>	
020352	AIA-PACK AFP CALIBRATOR SET	
020353	AIA-PACK FER CALIBRATOR SET	
020354	AIA-PACK CEA CALIBRATOR SET	
020356	AIA-PACK HCG CALIBRATOR SET	
020358	AIA-PACK T4 CALIBRATOR SET	
020361	AIA-PACK βHCG 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 3rd-Gen CALIBRATOR SET	
020395	AIA-PACK IgEII CALIBRATOR SET	
025304	ST AIA-PACK Testosterone CALIBRATOR SET	
025311	ST AIA-PACK free PSA 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	
025324	ST AIA-PACK iE2 CALIBRATOR SET	
025325	ST AIA-PACK hsE2 CALIBRATOR SET	
025326	ST AIA-PACK Homocysteine CALIBRATOR SET	
025339	ST AIA-PACK PROGII CALIBRATOR SET	
025340	ST AIA-PACK PROGIII CALIBRATOR SET	
025374	ST AIA-PACK E2 CALIBRATOR SET	
	<b>Description ( on outer packaging)</b>	<b>Description concerned item( as on label)</b>
	AIA-PACK PRL CALIBRATOR SET (0020355)	AIA-PACK PRL CALIBRATOR (1)
	AIA-PACK IRI CALIBRATOR SET (0020360)	AIA-PACK IRI CALIBRATOR (1)
	AIA-PACK PAP CALIBRATOR SET (0020362)	AIA-PACK PAP CALIBRATOR (1)
	AIA-PACK CK-MB CALIBRATOR SET (0020369)	ST AIA-PACK CK-MB CALIBRATOR (1)
	AIA-PACK C-Peptide CALIBRATOR SET(0020384)	AIA-PACK C-Peptide CALIBRATOR (1)
	AIA-PACK SLa CALIBRATOR SET (0020385)	AIA-PACK SLa CALIBRATOR (1)
	AIA-PACK OVCA CALIBRATOR SET (0020389)	AIA-PACK OVCA CALIBRATOR (1)
	AIA-PACK TgAb CALIBRATOR SET (0020391)	AIA-PACK TgAb CALIBRATOR (1)
	ST AIA-PACK Intact PTH CALIBRATOR SET(0025313)	ST AIA-PACK Intact PTH CALIBRATOR (1)
	ST AIA-PACK cTnl 3rd-Gen CALIBRATOR SET (0025315)	ST AIA-PACK cTnl 3rd-Gen CALIBRATOR (1)
	ST AIA-PACK HCGII CALIBRATOR SET (0025319)	ST AIA-PACK HCGII CALIBRATOR (1)
	ST AIA-PACK βHCGII CALIBRATOR SET (0025320)	ST AIA-PACK βHCGII CALIBRATOR (1)
	ST AIA-PACK ACTH CALIBRATOR SET (0025321)	ST AIA-PACK ACTH CALIBRATOR (1)
	ST AIA-PACK Whole PTH CALIBRATOR SET (0025330)	ST AIA-PACK Whole PTH CALIBRATOR (1)
	ST AIA-PACK D-Dimer CALIBRATOR SET (0025332)	ST AIA-PACK D-Dimer CALIBRATOR (1)
	ST AIA-PACK 25-OH Vitamin D CALIBRATOR SET (0025334)	ST AIA-PACK 25-OH Vitamin D CALIBRATOR (1)
	ST AIA-PACK Osteocalcin CALIBRATOR SET (0025336)	ST AIA-PACK Osteocalcin CALIBRATOR (1)
	ST AIA-PACK SCC CALIBRATOR SET (0025337)	ST AIA-PACK SCC CALIBRATOR (1)
	ST AIA-PACK SHBG CALIBRATOR SET (0025338)	ST AIA-PACK SHBG CALIBRATOR (1)
	ST AIA-PACK C-Peptidell CALIBRATOR SET (0025383)	ST AIA-PACK C-Peptidell CALIBRATOR (1)
	ST AIA-PACK LH II CALIBRATOR SET (0025396)	ST AIA-PACK LH II CALIBRATOR (1)



**ANNEX II:                    AIA-PACK SAMPLE DILUTING SOLUTION Series:**

**Revision: 1/02/2016**

<b>Catalogue Number</b>	<b>Description</b>
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
020556	AIA-PACK HCG SAMPLE DILUTING SOLUTION
020560	AIA-PACK IRI SAMPLE DILUTING SOLUTION
020561	AIA-PACK $\beta$ HCG SAMPLE DILUTING SOLUTION
020562	AIA-PACK PAP SAMPLE DILUTING SOLUTION
020565	AIA-PACK FSH 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
020585	AIA-PACK SLa SAMPLE DILUTING SOLUTION
020587	AIA-PACK CORT SAMPLE DILUTING SOLUTION
020589	AIA-PACK OVCA SAMPLE DILUTING SOLUTION
020590	AIA-PACK TPOAb/TgAb 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
025511	ST AIA-PACK free PSA SAMPLE DILUTING SOLUTION
025512	ST AIA-PACK PSA II SAMPLE DILUTING SOLUTION
025513	ST AIA-PACK Intact PTH SAMPLE DILUTING SOLUTION
025515	ST AIA-PACK cTnI 3rd-Gen SAMPLE DILUTING SOLUTION
025517	ST AIA-PACK Cystcin C SAMPLE DILUTING SOLUTION
025519	ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION
025520	ST AIA-PACK $\beta$ HCGII SAMPLE DILUTING SOLUTION
025521	ST AIA-PACK ACTH SAMPLE DILUTING SOLUTION
025522	ST AIA-PACK DHEA-S SAMPLE DILUTING SOLUTION
025524	ST AIA-PACK iE2 SAMPLE DILUTING SOLUTION
025525	ST AIA-PACK hsE2 SAMPLE DILUTING SOLUTION
025526	ST AIA-PACK Homocysteine SAMPLE DILUTING SOLUTION
025527	ST AIA-PACK Thyroglobulin SAMPLE DILUTING SOLUTION
025530	ST AIA-PACK Whole PTH SAMPLE DILUTING SOLUTION
025532	ST AIA-PACK D-Dimer SAMPLE DILUTING SOLUTION
025536	ST AIA-PACK Osteocalcin SAMPLE DILUTING SOLUTION
025537	ST AIA-PACK SCC SAMPLE DILUTING SOLUTION
025538	ST AIA-PACK SHBG SAMPLE DILUTING SOLUTION
025539	ST AIA-PACK PROGII SAMPLE DILUTING SOLUTION
025540	ST AIA-PACK PROGIII SAMPLE DILUTING SOLUTION
025583	ST AIA-PACK C-Peptidell SAMPLE DILUTING SOLUTION