Safety Data Sheet (#06)
acc. to OSHA HCS

Printing date 02/09/2015 Reviewed on 02/09/2015

1 Identification

· **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 020290: concerned item TPOAb Conjugate
AIA-PACK TgAb 020291: concerned item TgAb Conjugate
AIA-PACK RBC FOLATE HEMOLYZING REAGENT 020711:
concerned item AIA-PACK RBC FOLATE HEMOLYZING REAGENT 2
AIA-PACK Homocysteine CONTROL SET: 025426

· **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 / Supplier:**

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

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Fax : + 81 3 5427 5220

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

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 Hazard(s) 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 labeled due to the calculation procedure of international guidelines.

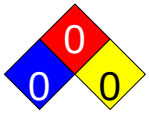
· **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **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

· **HMIS-ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

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· **vPvB:** Not applicable.

3 Composition/information on ingredients

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

· **Dangerous components:** Void

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.
· **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 Fire-fighting 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**
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.
· **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.

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· **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.
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	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:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible.
· **Partition coefficient (n-octanol/water):**	Not determined.

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· **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.

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.

· **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.
· **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.

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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

· **UN-Number**	
· **DOT, ADR, ADN, IMDG, IATA**	Void
· **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)**

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· **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:**
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.

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
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

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ANNEX I: AIA-PACK CALIBRATOR SET Series 1:

Revision: 02/03/2015

Catalog Number	Description
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 βHCG CALIBRATOR SET
020363	AIA-PACK PSA 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
025317	ST AIA-PACK Cystatin C CALIBRATOR SET
025322	ST AIA-PACK DHEA-S CALIBRATOR SET
025326	ST AIA-PACK Homocysteine CALIBRATOR SET
025339	ST AIA-PACK PROG II CALIBRATOR SET
025374	ST AIA-PACK E2 CALIBRATOR SET

Catalog Number	Description (Set) (on outer packaging)	Description Component/concerned item
020355	AIA-PACK Prolactin (PRL) CALIBRATOR SET	AIA-PACK PRL CALIBRATOR (1)
020360	AIA-PACK Insulin (IRI) CALIBRATOR SET	AIA-PACK IRI CALIBRATOR (1)
020362	AIA-PACK PAP CALIBRATOR SET	AIA-PACK PAP CALIBRATOR (1)
020369	AIA-PACK CK-MB CALIBRATOR SET	ST AIA-PACK CK-MB CALIBRATOR (1)
020371	AIA-PACK CA 19-9 CALIBRATOR SET	AIA-PACK CA 19-9 CALIBRATOR (1)
020384	AIA-PACK C-Peptide CALIBRATOR SET	AIA-PACK C-Peptide CALIBRATOR (1)
020388	AIA-PACK CA125 CALIBRATOR SET	AIA-PACK CA125 CALIBRATOR (1)
020391	AIA-PACK TgAb CALIBRATOR SET	AIA-PACK TgAb CALIBRATOR (1)
020652	AIA-PACK AFP Calibration Verification/Linearity Test Set	AIA-PACK AFP Calibration Verification Material
020653	AIA-PACK FER Calibration Verification/Linearity Test Set	AIA-PACK FER Calibration Verification Material
020654	AIA-PACK CEA Calibration Verification/LinearityTest Set	AIA-PACK CEA Calibration Verification Material
020661	AIA-PACK βHCG Calibration Verification/Linearity Test Set	AIA-PACK βHCG Calibration Verification Material
020663	AIA-PACK PSA/PA Calibration Verification/Linearity Test Set	AIA-PACK PSA/PA Calibration Verification Material
020665	AIA-PACK FSH Calibration Verification/Linearity Test Set	AIA-PACK FSH Calibration Verification Material
025305	ST AIA-PACK cTnI (Troponin) 2nd-Gen CALIBRATOR SET	ST AIA-PACK cTnI 2nd-Gen CALIBRATOR (1)
025313	ST AIA-PACK Intact PTH CALIBRATOR SET	ST AIA-PACK Intact PTH CALIBRATOR (1)
025321	ST AIA-PACK ACTH CALIBRATOR SET	ST AIA-PACK ACTH CALIBRATOR (1)
025334	ST AIA-PACK 25-OH Vitamin D CALIBRATOR SET	ST AIA-PACK 25-OH Vitamin D CALIBRATOR (1)
025383	ST AIA-PACK C-Peptide II CALIBRATOR SET	ST AIA-PACK C-Peptide II CALIBRATOR (1)
025396	ST AIA-PACK LHII CALIBRATOR SET	ST AIA-PACK LH II CALIBRATOR (1)

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ANNEX II: AIA-PACK SAMPLE DILUTING SOLUTION Series:

Revision: 02/03/2015

Catalog Number	Description
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
020560	AIA-PACK IRI SAMPLE DILUTING SOLUTION
020561	AIA-PACK βHCG SAMPLE DILUTING SOLUTION
020562	AIA-PACK PAP SAMPLE DILUTING SOLUTION
020563	AIA-PACK PSA SAMPLE DILUTING SOLUTION
020565	AIA-PACK FSH SAMPLE DILUTING SOLUTION
020569	AIA-PACK CK-MB SAMPLE DILUTING SOLUTION
020571	AIA-PACK CA 19-9 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
020587	AIA-PACK CORT SAMPLE DILUTING SOLUTION
020588	AIA-PACK CA125 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
025505	ST AIA-PACK cTnI 2nd-Gen SAMPLE DILUTING SOLUTION
025513	AIA-PACK Intact PTH SAMPLE DILUTING SOLUTION
025517	ST AIA-PACK Cystatin C SAMPLE DILUTING SOLUTION
025521	ST AIA-PACK ACTH SAMPLE DILUTING SOLUTION
025522	ST AIA-PACK DHEA-S SAMPLE DILUTING SOLUTION
025526	ST AIA-PACK Homocysteine SAMPLE DILUTING SOLUTION
025539	ST AIA-PACK PROG II SAMPLE DILUTING SOLUTION
025583	ST AIA-PACK C-Peptide II SAMPLE DILUTING SOLUTION

Catalog Number	Description (Set) (on outer packaging)	Description Component/concerned item (as on label)
020652	AIA-PACK AFP Calibration Verification/Linearity Test Set	AIA-PACK AFP Sample Diluting Solution
020653	AIA-PACK FER Calibration Verification/Linearity Test Set	AIA-PACK FER Sample Diluting Solution
020654	AIA-PACK CEA Calibration Verification/Linearity Test Set	AIA-PACK CEA Sample Diluting Solution
020655	AIA-PACK PRL Calibration Verification/Linearity Test Set	AIA-PACK PRL Sample Diluting Solution
020661	AIA-PACK βHCG Calibration Verification/Linearity Test Set	AIA-PACK βHCG Sample Diluting Solution
020662	AIA-PACK PAP Calibration Verification/Linearity Test Set	AIA-PACK PAP Sample Diluting Solution
020663	AIA-PACK PSA/PA Calibration Verification/Linearity Test Set	AIA-PACK PSA/PA Sample Diluting Solution
020665	AIA-PACK FSH Calibration Verification/Linearity Test Set	AIA-PACK FSH Sample Diluting Solution