

Safety Data Sheet (#06)

acc. to OSHA HCS

Printing date 09/24/2013

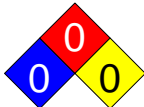
Reviewed on 09/24/2013

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 / TOSOH BIOSCIENCE, INC.
3-8-2 Shiba, Minato-ku / 6000 Shoreline Ct.; Suite 101
Tokyo 105 -8623 / South San Francisco, CA94080
JAPAN / USA

Tel. : + 81 3 5427 5181 / Phone : + 1 614 317 1909 or (800) 248 6764
Fax : + 81 3 5427 5220 / 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 | Health = 0 |
| FIRE | 0 | Fire = 0 |
| REACTIVITY | 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) | |
| 26628-22-8 | sodium azide |

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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

USA



ANNEX I:

AIA-PACK CALIBRATOR SET Series 1:

Revision: 03/17/2014

| Catalogue 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 | |
| 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/Linearity Test 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) |
| 025396 | ST AIA-PACK LHII CALIBRATOR SET | ST AIA-PACK LH II CALIBRATOR (1) |



ANNEX II: AIA-PACK SAMPLE DILUTING SOLUTION Series:

Revision: 03/17/2014

| Catalogue 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 β HCG 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 | |
| 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 β HCG Calibration Verification/Linearity Test Set | AIA-PACK β HCG 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 |