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
    Phone : + 81 3 5427 5181
    Fax : + 81 3 5427 5220
  - TOSOH BIOSCIENCE, INC.
    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 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

(Contd. on page 2)
Material Safety Data Sheet
acc. to ISO/DIS 11014

Trade name: AIA-PACK CALIBRATOR SET SERIES 1
AIA-PACK SAMPLE DILUTING SOLUTION Series : Please refer to ANNEX I
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ST AIA-PACK Cystatin C CONTROL SET : 025417

- HMIS-ratings (scale 0 - 4)
  - Health = 0
  - Fire = 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.
Trade name: AIA-PACK CALIBRATOR SET SERIES I  Please refer to ANNEX I  
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AIA-PACK RBC FOLATE HEMOLYZING REAGENT 2: 020711  
ST AIA-PACK Cystatin C CONTROL SET : 025417

- 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.

(Contd. of page 2)

(Contd. on page 4)
Trade name: AIA-PACK CALIBRATOR SET SERIES I : 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
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AIA-PACK RBC FOLATE HEMOLYZING REAGENT 2: 020711
ST AIA-PACK Cystatin C CONTROL SET: 025417

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<tr>
<td>Auto igniting</td>
<td>Product is not selfigniting</td>
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<td>Danger of explosion</td>
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<td>Explosion limits</td>
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<tr>
<td>Upper</td>
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<td>Other information</td>
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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.

12 Ecological information

- Toxicity
- Aquatic 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: -
Trade name: AIA-PACK CALIBRATOR SET SERIES 1  :  Please refer to ANNEX I
AIA-PACK SAMPLE DILUTING SOLUTION Series  :  Please refer to ANNEX II
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ST AIA-PACK Cystatin C CONTROL SET : 025417

- 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.
Material Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 06/23/2011
Reviewed on 06/23/2011

Trade name: AIA-PACK CALIBRATOR SET SERIES 1 : Please refer to ANNEX I
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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: Reglement 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)
ACGH: 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

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