

## 1 Identification of substance

· **Product details**

· **Trade name:** AIA-PACK CALIBRATOR SET SERIES 4: Please refer to ANNEX 1  
AIA-PACK TgAb CONTROL SET :025491

· **Application of the substance / the preparation** *In Vitro* Diagnostics.

· **Manufacturer**

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

/ **Supplier:**

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· **Information department:**

QA-RA: [susan.koss@tosoh.com](mailto:susan.koss@tosoh.com) [www.diagnostics.us.tosohbioscience.com](http://www.diagnostics.us.tosohbioscience.com)

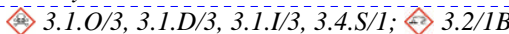

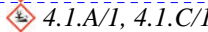
· **Emergency information:** Poison Control Center: + 1 800 222 1222

## 2 Composition/Data on components

· **Chemical characterization**

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

· **Dangerous components:**

26172-55-4	5-chloro-2-methyl-2H-isothiazol-3-one	≤ 2.5%
	Danger:  3.1.O/3, 3.1.D/3, 3.1.I/3, 3.4.S/1;  3.2/1B	
	Warning:  4.1.A/1, 4.1.C/1	

## 3 Hazards identification

· **Hazard description:**



Irritant

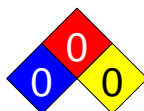
· **Information pertaining to particular dangers for man and environment:**

The product has to be labelled due to the calculation procedure of international guidelines.  
May cause sensitisation by skin contact.

· **Classification system:**

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

· **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

· **GHS label elements**



Warning

3.4/1 - May cause an allergic skin reaction.

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 08/31/2010

Reviewed on 08/30/2010

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- **Prevention:**  
 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 Wear protective gloves/protective clothing/eye protection/face protection.
- **Response:**  
 Specific treatment (see on this label).  
 Wash contaminated clothing before reuse.  
 If skin irritation or rash occurs: Get medical advice/attention.
- **Disposal:**  
 Dispose of contents/container in accordance with local/regional/national/international regulations.

## 4 First aid measures

- **After inhalation:**  
 Supply fresh air and to be sure call for a doctor.  
 In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.

## 5 Fire fighting measures

- **Suitable extinguishing agents:**  
 CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

## 6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:**  
 Do not allow product to reach sewage system or any water course.  
 Inform respective authorities in case of seepage into water course or sewage system.  
 Do not allow to enter sewers/ surface or ground water.
- **Measures for cleaning/collecting:** Pick up mechanically.

## 7 Handling and storage

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

## 8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **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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- **Personal protective equipment:**
- **General protective and hygienic measures:**  
 Immediately remove all soiled and contaminated clothing.  
 Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

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:** Not required.

## 9 Physical and chemical properties

**General Information**

<b>Form:</b>	Spray dried powder
<b>Color:</b>	Light beige
<b>Odor:</b>	Odorless

**Change in condition**

**Melting point/Melting range:** Undetermined.  
**Boiling point/Boiling range:** Undetermined.

- |  |   |
|--|---|
| <b>Flash point:</b>                            | Not applicable.                               |
| <b>Auto igniting:</b>                          | Product is not selfigniting.                  |
| <b>Danger of explosion:</b>                    | Product does not present an explosion hazard. |
| <b>Density:</b>                                | Not determined.                               |
| <b>Solubility in / Miscibility with Water:</b> | Soluble.                                      |
| <b>Solvent content:</b>                        |   |
| <b>Organic solvents:</b>                       | 0.0 %   |
| <b>Solids content:</b>                         | 100.0 %                                       |

## 10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Materials to be avoided:**
- **Dangerous reactions** No dangerous reactions known.

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· **Dangerous products of decomposition:** No dangerous decomposition products known.

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## 11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
 The product shows the following dangers according to internally approved calculation methods for preparations:  
 Irritant

## 12 Ecological information

- **Additional ecological information:**
- **General notes:**  
 Water hazard class 1 (Self-assessment): slightly hazardous for water  
 Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

## 13 Disposal considerations

- **Product:**
- **Recommendation:**  
 Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **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:** -
- **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":** -

## 15 Regulations

- **Sara**
- **Section 355 (extremely hazardous substances):**  
 None of the ingredients is listed.

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· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is 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)**

None of the ingredients is listed.

· **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:**

The product has been classified and marked in accordance with directives on hazardous materials.

· **Hazard symbols:**



Irritant

· **Hazard-determining components of labelling:**

5-chloro-2-methyl-2H-isothiazol-3-one

· **Risk phrases:**

May cause sensitisation by skin contact.

· **Safety phrases:**

Keep out of the reach of children.

Avoid contact with skin.

Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

Wear suitable gloves.

If swallowed, seek medical advice immediately and show this container or label.

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## 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)*

*GHS: Globally Harmonized System of Classification and Labelling of Chemicals*

*ACGIH: American Conference of Governmental Industrial Hygienists*

*NFPA: National Fire Protection Association (USA)*

*HMIS: Hazardous Materials Identification System (USA)*

USA



**TOSOH BIOSCIENCE**

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## AIA-PACK CALIBRATOR SET Series 4:

### ANNEX I:

Revision: 21/06/2010

Catalogue Number	Description	
	Description ( on outer packaging)	Description concerned item( as on label)
	ST AIA-PACK Intact PTH CALIBRATOR SET (025313)	ST AIA-PACK Intact PTH CALIBRATOR (2) ~ (6)
	AIA-PACK RBC FOLATE CALIBRATOR SET (020314)	AIA-PACK RBC FOLATE CALIBRATOR (2) ~ (6)
	AIA-PACK TgAb CALIBRATOR SET(020391)	AIA-PACK TgAb CALIBRATOR (2) ~ (6)
	ST AIA-PACK Intact PTH Control 025413	ST AIA-PACK Intact PTH