

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 01.02.2016

Revision: 01.02.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **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: 0020490
AIA-PACK TPOAb CONJUGATE: 0020708
AIA-PACK TgAb CONJUGATE: 0020709
AIA-PACK RBC FOLATE HEMOLYZING REAGENT (0020711): concerned item:
AIA-PACK RBC FOLATE HEMOLYZING REAGENT 2
ST AIA-PACK hSE2 (0025225): concerned item: ST AIA-PACK hSE2
CONJUGATE
AIA-PACK Cystatin C CONTROL SET: 0025417
AIA-PACK Homocysteine CONTROL SET: 0025426
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** In Vitro Diagnostics.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer** / **SDS Supplier:**
TOSOH CORPORATION
2-2-1 Yaesu, Chuo-ku
104-0028 Tokyo Japan
Tel. : + 81 3 5427 5181
Fax: + 81 3 5427 5220
TOSOH EUROPE NV
Transportstraat 4
B-3980 Tessenderlo
BELGIUM
Tel. : + 32 (0) 13 66 88 30
Fax: + 32 (0) 13 66 47 49
- **Further information obtainable from:** QA-RA : info.raqa.eu@tosoh.com
- **1.4 Emergency telephone number:** The UK National Poisons Emergency number: + 44 (0) 870 600 6266

SECTION 2: Hazards 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
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 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.

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- **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.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, 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.

SECTION 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.

SECTION 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 fire - and explosion protection:** 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.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients 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 valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** 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

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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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	Solution
Colour:	Colourless
Odour:	Odourless
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.

Self-igniting: Product is not selfigniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

Vapour 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.

Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

Solvent content:

Organic solvents: 0.0 %

9.2 Other information

No further relevant information available.

SECTION 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.

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- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **LD/LC50 values relevant for classification:**
- | | | |
|-------------------------|------|-------------------|
| 26628-22-8 sodium azide | | |
| Oral | LD50 | 27 mg/kg (rat) |
| Dermal | LD50 | 20 mg/kg (rabbit) |
- **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 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.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Void
- **14.2 UN proper shipping name**
- **ADR, ADN, IMDG, IATA** Void

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· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Labelling according to Regulation (EC) No 1272/2008 Void
- Hazard pictograms Void
- Signal word Void
- Hazard statements Void
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

ANNEX I:

AIA-PACK CALIBRATOR SET Series 1:

Revision:

1/02/2016

Catalogue Number	Description	
0020352	AIA-PACK AFP CALIBRATOR SET	
0020353	AIA-PACK FER CALIBRATOR SET	
0020354	AIA-PACK CEA CALIBRATOR SET	
0020356	AIA-PACK HCG CALIBRATOR SET	
0020358	AIA-PACK T4 CALIBRATOR SET	
0020361	AIA-PACK β HCG CALIBRATOR SET	
0020365	AIA-PACK FSH CALIBRATOR SET	
0020381	AIA-PACK PROG CALIBRATOR SET	
0020382	AIA-PACK TT3 CALIBRATOR SET	
0020390	AIA-PACK TPOAb CALIBRATOR SET	
0020394	AIA-PACK TSH 3rd-Gen CALIBRATOR SET	
0020395	AIA-PACK IgEII CALIBRATOR SET	
0025304	ST AIA-PACK Testosterone CALIBRATOR SET	
0025311	ST AIA-PACK free PSA CALIBRATOR SET	
0025312	ST AIA-PACK PSA II CALIBRATOR SET	
0025317	ST AIA-PACK Cystatin C CALIBRATOR SET	
0025322	ST AIA-PACK DHEA-S CALIBRATOR SET	
0025324	ST AIA-PACK iE2 CALIBRATOR SET	
0025325	ST AIA-PACK hsE2 CALIBRATOR SET	
0025326	ST AIA-PACK Homocysteine CALIBRATOR SET	
0025339	ST AIA-PACK PROGII CALIBRATOR SET	
0025340	ST AIA-PACK PROGIII CALIBRATOR SET	
0025374	ST AIA-PACK E2 CALIBRATOR SET	
	Description (on outer packaging)	Description concerned item(as on label)
	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 cTnI 3rd-Gen CALIBRATOR SET (0025315)	ST AIA-PACK cTnI 3rd-Gen CALIBRATOR (1)
	ST AIA-PACK HCGII CALIBRATOR SET (0025319)	ST AIA-PACK HCGII CALIBRATOR (1)
	ST AIA-PACK β HCGII CALIBRATOR SET (0025320)	ST AIA-PACK β HCGII 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**

Catalogue Number	Description
0020552	AIA-PACK AFP SAMPLE DILUTING SOLUTION
0020553	AIA-PACK FER SAMPLE DILUTING SOLUTION
0020554	AIA-PACK CEA SAMPLE DILUTING SOLUTION
0020555	AIA-PACK PRL SAMPLE DILUTING SOLUTION
0020556	AIA-PACK HCG SAMPLE DILUTING SOLUTION
0020560	AIA-PACK IRI SAMPLE DILUTING SOLUTION
0020561	AIA-PACK β HCG SAMPLE DILUTING SOLUTION
0020562	AIA-PACK PAP SAMPLE DILUTING SOLUTION
0020565	AIA-PACK FSH SAMPLE DILUTING SOLUTION
0020569	AIA-PACK CK-MB SAMPLE DILUTING SOLUTION
0020574	AIA-PACK E2 SAMPLE DILUTING SOLUTION
0020581	AIA-PACK PROG SAMPLE DILUTING SOLUTION
0020582	AIA-PACK TT3 SAMPLE DILUTING SOLUTION
0020584	AIA-PACK C-Peptide SAMPLE DILUTING SOLUTION
0020585	AIA-PACK SLA SAMPLE DILUTING SOLUTION
0020587	AIA-PACK CORT SAMPLE DILUTING SOLUTION
0020589	AIA-PACK OVCA SAMPLE DILUTING SOLUTION
0020590	AIA-PACK TPOAb/TgAb SAMPLE DILUTING SOLUTION
0020593	AIA-PACK B12 SAMPLE DILUTING SOLUTION
0020594	AIA-PACK TSH 3rd-Gen SAMPLE DILUTING SOLUTION
0020595	AIA-PACK IgEII SAMPLE DILUTING SOLUTION
0020596	AIA-PACK LH II SAMPLE DILUTING SOLUTION
0025504	ST AIA-PACK Testosterone SAMPLE DILUTING SOLUTION
0025511	ST AIA-PACK free PSA SAMPLE DILUTING SOLUTION
0025512	ST AIA-PACK PSA II SAMPLE DILUTING SOLUTION
0025513	ST AIA-PACK Intact PTH SAMPLE DILUTING SOLUTION
0025515	ST AIA-PACK cTnI 3rd-Gen SAMPLE DILUTING SOLUTION
0025517	ST AIA-PACK Cystcin C SAMPLE DILUTING SOLUTION
0025519	ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION
0025520	ST AIA-PACK β HCGII SAMPLE DILUTING SOLUTION
0025521	ST AIA-PACK ACTH SAMPLE DILUTING SOLUTION
0025522	ST AIA-PACK DHEA-S SAMPLE DILUTING SOLUTION
0025524	ST AIA-PACK iE2 SAMPLE DILUTING SOLUTION
0025525	ST AIA-PACK hsE2 SAMPLE DILUTING SOLUTION
0025526	ST AIA-PACK Homocysteine SAMPLE DILUTING SOLUTION
0025527	ST AIA-PACK Thyroglobulin SAMPLE DILUTING SOLUTION
0025530	ST AIA-PACK Whole PTH SAMPLE DILUTING SOLUTION
0025532	ST AIA-PACK D-Dimer SAMPLE DILUTING SOLUTION
0025536	ST AIA-PACK Osteocalcin SAMPLE DILUTING SOLUTION
0025537	ST AIA-PACK SCC SAMPLE DILUTING SOLUTION
0025538	ST AIA-PACK SHBG SAMPLE DILUTING SOLUTION
0025539	ST AIA-PACK PROGII SAMPLE DILUTING SOLUTION
0025540	ST AIA-PACK PROGIII SAMPLE DILUTING SOLUTION
0025583	ST AIA-PACK C-Peptidell SAMPLE DILUTING SOLUTION