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

### 1.1. Product identifier

Product form : Mixture  
Trade name : AIA-PACK SOLUTION  
with MOPSO  
Product group : IN VITRO DIAGNOSTIC USE ONLY  
Document no. : See annex

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Main use category : Professional uses  
Use of the substance/mixture : Laboratory use

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

#### Supplier

Tosoh Europe NV  
Transportstraat 4  
3980 Tessenderlo  
Belgium  
T +32 13 66 88 30, F +32 13 66 47 49  
[info.raqa.eu@tosoh.com](mailto:info.raqa.eu@tosoh.com)

#### Manufacturer

Tosoh Corporation  
2-2-1 Yaesu, Chuo-ku  
104-0028 Tokyo  
Japan

### 1.4. Emergency telephone number

Country/Area	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

#### Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Extra phrases : EUH210 - Safety data sheet available on request.

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### **2.3. Other hazards**

Other hazards : Results of PBT and vPvB assessment : Not applicable.

Contains no PBT and/or vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## **SECTION 3: Composition/information on ingredients**

### **3.1. Substances**

Not applicable

### **3.2. Mixtures**

Comments : Reagent

Substance name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-hydroxy-4-morpholinepropanesulphonic acid	CAS-No.: 68399-77-9 EC-No.: 269-989-6	1 – 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H- and EUH-statements: see section 16

## **SECTION 4: First aid measures**

### **4.1. Description of first aid measures**

Additional advice : First aider: Pay attention to self-protection!. Concerning personal protective equipment to use, see section 8. Never give anything by mouth to an unconscious person. In case of doubt or persistent symptoms, consult always a physician. Show this safety data sheet to the doctor in attendance. Treat symptomatically.

Inhalation : Remove casualty to fresh air and keep warm and at rest. Give oxygen or artificial respiration if necessary. In case of doubt or persistent symptoms, consult always a physician.

Skin contact : Remove contaminated clothing and shoes. Gently wash with plenty of soap and water. In case of doubt or persistent symptoms, consult always a physician.

Eyes contact : Rinse immediately carefully and thoroughly with eye-bath or water. In case of doubt or persistent symptoms, consult always a physician.

Ingestion : Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get medical advice/attention.

### **4.2. Most important symptoms and effects, both acute and delayed**

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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Inhalation : May be harmful if inhaled. May cause respiratory irritation.  
Skin contact : May be harmful if absorbed through skin. May cause skin irritation.  
Eyes contact : May cause eye irritation.  
Ingestion : May be harmful if swallowed.

#### **4.3. Indication of any immediate medical attention and special treatment needed**

No data available.

### **SECTION 5: Firefighting measures**

#### **5.1. Extinguishing media**

Suitable extinguishing media : carbon dioxide (CO2), powder, alcohol-resistant foam, water spray.  
Unsuitable extinguishing media : Strong water jet.

#### **5.2. Special hazards arising from the substance or mixture**

Specific hazards : Not flammable. Heating will cause a rise in pressure with a risk of bursting.  
Hazardous decomposition products in case of fire : Unknown.

#### **5.3. Advice for firefighters**

Firefighting instructions : Evacuate area. Use water spray or fog for cooling exposed containers. Contain the extinguishing fluids by bunding. Prevent fire fighting water from entering the environment.  
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus.  
Other information : Do not allow run-off from fire-fighting to enter drains or water courses. Dispose of waste in accordance with environmental legislation.

### **SECTION 6: Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

##### **6.1.1. For non-emergency personnel**

For non-emergency personnel : Evacuate unnecessary personnel. Keep upwind. Provide adequate ventilation. Wear recommended personal protective equipment. Concerning personal protective equipment to use, see section 8. Do not breathe vapours. Avoid contact with skin, eyes and clothing.

##### **6.1.2. For emergency responders**

For emergency responders : Ensure procedures and training for emergency decontamination and disposal are in place. Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8.

#### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains. Notify authorities if product enters sewers or public waters.

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### **6.3. Methods and material for containment and cleaning up**

Methods for cleaning up : Provide adequate ventilation. Stop leak if safe to do so. Dam up the liquid spill. Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container for disposal. Recover large spills by pumping (use an explosion proof or hand pump). Place in a suitable container for disposal in accordance with the waste regulations (see Section 13). This material and its container must be disposed of in a safe way, and as per local legislation.

### **6.4. Reference to other sections**

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

Precautions for safe handling : Provide adequate ventilation. Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8. Do not breathe vapours. Avoid contact with skin, eyes and clothing. Take any precaution to avoid mixing with Incompatible materials, Refer to Section 10 on Incompatible Materials. Ensure proper process control to avoid excess waste discharge (temperature, concentration, pH, time). Avoid release to the environment.

Hygiene measures : Keep good industrial hygiene. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feedingstuffs. Remove contaminated clothes. Separate working clothes from town clothes. Launder separately. Wash contaminated clothing before reuse.

### **7.2. Conditions for safe storage, including any incompatibilities**

Technical measures : Keep container tightly closed in a cool, well-ventilated place. Keep only in the original container. Protect from moisture. Do not store near or with any of the incompatible materials listed in section 10. Recommended storage temperature : 2-8°C.

### **7.3. Specific end use(s)**

No data available.

## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

#### **8.1.1 National occupational exposure and biological limit values**

No additional information available

#### **8.1.2. Recommended monitoring procedures**

<b>Monitoring methods</b>	
Monitoring methods	Concentration measurement in air. Personal air monitoring .

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#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

Additional information : Contains no substances with occupational exposure limit values.

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

Engineering measure(s)	: Provide adequate ventilation. Organisational measures to prevent/limit releases, dispersion and exposure. See Section 7 for information on safe handling .
Personal protective equipment	: The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Hand protection	: Wear chemically resistant gloves (tested to EN374) . Suitable material: Not determined. Thickness : Not determined. Breakthrough time : Not determined. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.
Eye protection	: Use suitable eye protection (EN166): Safety glasses with side shields
Body protection	: Wear suitable protective clothing. Lab coat
Respiratory protection	: Not required for normal conditions of use. In case of insufficient ventilation, wear suitable respiratory equipment. Half-face mask (DIN EN 140). full face mask (DIN EN 136). Filter type: ABEK (EN14387). The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. (EN 137)
Thermal hazard protection	: Not required for normal conditions of use. Use dedicated equipment.
Environmental exposure controls	: Avoid release to the environment. Comply with applicable Community environmental protection legislation.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: No additional information available.
Appearance	: Liquid.
Odour	: No additional information available.
Odour threshold	: No data available
Melting / freezing point	: No data available
Freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flammability	: Not applicable
Explosive properties	: Not applicable.
Oxidising properties	: Not applicable.

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Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: Not determined
pH	: 7,4
Kinematic viscosity	: No data available
Dynamic viscosity	: No data available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water	: No data available
Vapour pressure	: No data available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not determined
Vapour density	: No data available
Particle characteristics	: Not applicable

## **9.2. Other information**

### **9.2.1. Information with regard to physical hazard classes**

No additional information available

### **9.2.2. Other safety characteristics**

Relative evaporation rate (butylacetate=1) : No data available

Additional information : No data available

## **SECTION 10: Stability and reactivity**

### **10.1. Reactivity**

Stable at ambient temperature and under normal conditions of use. Reference to other sections: 10.4 & 10.5.

### **10.2. Chemical stability**

Stable under recommended storage conditions. (2-8°C). Observe the expiry date.

### **10.3. Possibility of hazardous reactions**

None under normal processing.

### **10.4. Conditions to avoid**

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from moisture. See Section 7 for information on safe handling.

### **10.5. Incompatible materials**

Strong oxidizing agents. See Section 7 for information on safe handling.

### **10.6. Hazardous decomposition products**

Reference to other sections 5.2.

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## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7,4
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7,4
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)

### 2-hydroxy-4-morpholinepropanesulphonic acid (68399-77-9)

STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### AIA-PACK SOLUTION with MOPSO

Kinematic viscosity	No data available
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### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %
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#### 11.2.2. Other information

Other information	: Symptoms related to the physical, chemical and toxicological characteristics, For further information see section 4
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## SECTION 12: Ecological information

### 12.1. Toxicity

Environmental properties	: Ecological problems are not known or expected under normal use.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

### 12.2. Persistence and degradability

AIA-PACK SOLUTION with MOPSO	
Persistence and degradability	No additional information available.

### 12.3. Bioaccumulative potential

AIA-PACK SOLUTION with MOPSO	
Partition coefficient n-octanol/water	No data available
Bioaccumulative potential	No additional information available.

### 12.4. Mobility in soil

AIA-PACK SOLUTION with MOPSO	
Mobility in soil	No additional information available
Ecology - soil	No data available.

### 12.5. Results of PBT and vPvB assessment

AIA-PACK SOLUTION with MOPSO	
Results of PBT assessment	Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.
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### 12.7. Other adverse effects

Other adverse effects	: No data available.
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## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Handle with care. See Section 7 for information on safe handling . Do not allow to enter into surface water or drains. Dispose of contaminated materials in accordance with current regulations.
Additional information	: Delivery to an approved waste disposal company.
European waste catalogue (2001/573/EC, 75/442/EEC, 91/689/EEC)	: Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

### 14.6. Special precautions for user

Special precautions for user : No data available

#### - Overland transport

Not applicable

#### - Transport by sea

Not applicable

#### - Air transport

Not applicable

#### - Inland waterway transport

Not applicable

#### - Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Code: IBC : No data available.

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## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

##### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)		
Reference code	Applicable on	Entry title or description
3(b)	2-hydroxy-4-morpholinepropanes ulphonic acid	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

##### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

##### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

##### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

##### Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

##### Detergent Regulation (648/2004/EC): Labelling of contents

#### 15.1.2. National regulations

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## France

Installations classées			
No ICPE	Désignation de la rubrique	Code Régime	Rayon
na	Not Applicable	na	na

No ICPE

## Germany

Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject to the Hazardous Incident Ordinance (12. BImSchV)

## Netherlands

Waterbezwaarlijkheid : B (4) - Weinig schadelijk voor in het water levende organismen

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

## 15.2. Chemical safety assessment

Not applicable

## SECTION 16: Other information

Indication of changes:

1.3	Details of the supplier of the safety data sheet	Modified	
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Abbreviations and acronyms:

	ABM = Algemene beoordelingsmethodiek
	ADN = Accord Européen relatif au Transport International des Marchandises Dangereuses par voie de Navigation du Rhin
	ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
	CLP = Classification, Labelling and Packaging Regulation according to 1272/2008/EC
	IATA = International Air Transport Association
	IMDG = International Maritime Dangerous Goods Code
	LEL = Lower Explosive Limit/Lower Explosion Limit
	UEL = Upper Explosive Limit/Upper Explosion Limit
	REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals
	BTT = Breakthrough time (maximum wearing time)
	DMEL = Derived Minimal Effect level
	DNEL = Derived No Effect Level
	EC50 = Median Effective Concentration
	EL50 = Median effective level
	ErC50 = EC50 in terms of reduction of growth rate
	ErL50 = EL50 in terms of reduction of growth rate
	EWC = European waste catalogue
	LC50 = Median lethal concentration
	LD50 = Median lethal dose
	LL50 = Median lethal level

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	NA = Not applicable
	NOEC = No observed effect concentration
	NOEL: no-observed-effect level
	NOELR = No observed effect loading rate
	NOAEC = No observed adverse effect concentration
	NOAEL = No observed adverse effect level
	N.O.S. = Not Otherwise Specified
	OEL = Occupational Exposure Limits - Short Term Exposure Limits (STELs)
	PNEC = Predicted No Effect Concentration
	Quantitative structure-activity relationship (QSAR)
	STOT = Specific Target Organ Toxicity
	TWA = time weighted average
	VOC = Volatile organic compounds
	WGK = Wassergefährdungsklasse (Water Hazard Class under German Federal Water Management Act)

Sources of key data used to compile the : Additional information : Manufacturer/Supplier. ECHA (European Chemicals datasheet Agency), LOLI.

Training advice : Training staff on good practice.

Other information : Classification - Assessment method: CLP Calculation method (Article 9).

Full text of H- and EUH-statements:

EUH210	Safety data sheet available on request.
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

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## **ANNEX: AIA-PACK SOLUTION with MOPSO, Tosoh-45**

**Revision Nr:** 20/04/2024

EN

<b>Product code</b>	<b>Designation</b>
0020593	AIA-PACK B12 SAMPLE DILUTING SOLUTION
0025317	ST AIA-PACK Cystatin C CALIBRATOR SET
0025417	AIA-PACK Cystatin C CONTROL SET
0020399	AIA-PACK HBsAb CALIBRATOR SET
0020599	AIA-PACK HBsAb SAMPLE DILUTING SOLUTION