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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 Serie 33
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

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]

Skin sensitisation, Category 1 H317
Hazardous to the aquatic environment – Chronic H411
Hazard, Category 2
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

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

Hazard pictograms (CLP)



Signal word

: Warning

Contains

: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1); Gentamicin, sulfate (salt)

Hazard statements (CLP)

: H317 - May cause an allergic skin reaction.
H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P273 - Avoid release to the environment.
P280 - Wear protective gloves.
P391 - Collect spillage.
P501 - Dispose of contents and container to an approved waste disposal plant.

2.3. Other hazards

Other hazards

: Risk of dust explosion. Results of PBT and vPvB assessment : 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
(lyophilised)

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	< 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Gentamicin, sulfate (salt)	CAS-No.: 1405-41-0 EC-No.: 215-778-9	0,1 - <1	Resp. Sens. 1, H334 Skin Sens. 1, H317

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Substance name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index: 613-167-00-5	0,025 - <0,06	Acute Tox. 2 (Inhalation), H330 (ATE=0,5 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=50 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100)

Specific concentration limits:

Substance name	Product identifier	Specific concentration limits (%)
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index: 613-167-00-5	(0,0015 ≤ C ≤ 100) Skin Sens. 1A, H317 (0,06 ≤ C < 0,6) Eye Irrit. 2, H319 (0,06 ≤ C < 0,6) Skin Irrit. 2, H315 (0,6 ≤ C ≤ 100) Eye Dam. 1, H318 (0,6 ≤ C ≤ 100) Skin Corr. 1C, H314

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.
Inhalation	: May be harmful if inhaled. Inhalation of dust may cause irritation of the respiratory system.
Skin contact	: May cause an allergic skin reaction. Contact with dust may cause mechanical irritation or drying of the skin.
Eyes contact	: Dust may cause painful eye irritation and tearing.
Ingestion	: May be harmful if swallowed. May cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

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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. Risk of dust explosion.
 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. Avoid dust formation. Knock down/dilute dust cloud with water spray.
 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. Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothing. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ensure equipment is adequately earthed. Use explosion-proof equipment. Use only non-sparking tools.

6.1.2. For emergency responders

For emergency responders : Ensure procedures and training for emergency decontamination and disposal are in place. 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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Stop leak if safe to do so. Dam up the solid spill. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Large spills: scoop solid spill into closing containers. This material and its container must be disposed of in a safe way, and as per local legislation. Avoid dust formation. Knock down/dilute dust cloud with water spray.

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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 dust. 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. Contaminated work clothing must not be allowed out of the workplace. Avoid dust formation. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use explosion-proof equipment. Use only non-sparking tools.

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

Storage conditions

: Store in a dry, cool and well-ventilated place. Do not store near or with any of the incompatible materials listed in section 10. Protect from moisture. Recommended storage temperature : 2-8°C.

Packaging materials

: Keep only in the original container.

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Austria - Occupational Exposure Limits	
Local name	5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on und 2-Methyl-2,3-dihydroisothiazol-3-on (Gemisch im Verhältnis 3:1)
MAK (OEL TWA)	0,05 mg/m ³ (5-Chloro-2-methyl-2,3-dihydroisothiazol-3-one and 2-methyl-2,3-dihydroisothiazol-3-one mixture in ratio 3:1)
Remark	Sh
OEL chemical category	Skin sensitizer

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reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Regulatory reference	BGBl. II Nr. 156/2021
Switzerland - Occupational Exposure Limits	
Local name	2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle et 2,3-dihydro-isothiazol-3-one de 2-méthyle [2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle, 2,3-Dihydro-isothiazol-3-one de 2-méthyle] / 5-Chlor-2-methyl-2,3-dihydro-isothiazol-3-on und 2-Methyl-2,3-dihydroisothiazol-3-on [2-Methyl-2,3-dihydroisothiazol-3-on, 5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on]
MAK (OEL TWA)	0,2 mg/m ³ (inhalable dust)
KZGW (OEL STEL)	0,4 mg/m ³ (inhalable dust)
Notation	S, SS _c / S, SS _c
OEL chemical category	Sensitizer
Regulatory reference	www.suva.ch, 01.01.2024

8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	Personal air monitoring. Room air monitoring.

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

Additional information : Recommended monitoring procedures :. Personal air monitoring. Room air monitoring

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. Apply measures to prevent dust explosions. Ensure equipment is adequately earthed.

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.

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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
Respiratory protection	: Not required for normal conditions of use. Provide appropriate exhaust ventilation at places where dust is formed. Effective dust mask (EN 149). When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. full face mask (DIN EN 136). Half-face mask (DIN EN 140). In case of dust formation use respirator with filter: P1 (EN 143)
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	: Solid
Colour	: Light beige.
Appearance	: Powder. (lyophilised).
Odour	: odourless.
Odour threshold	: Not applicable
Melting / freezing point	: Not applicable
Freezing point	: Not available
Initial boiling point and boiling range	: Not applicable
Flammability	: Not applicable
Explosive properties	: Not applicable.
Oxidising properties	: Not applicable.
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not determined
pH	: Not applicable
pH solution	: Not available
Kinematic viscosity	: Not applicable
Dynamic viscosity	: Not applicable
Solubility	: Water: Not determined
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water	: Not applicable
Vapour pressure	: Not applicable
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not determined
Vapour density	: Not applicable

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Particle size : Not available

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) : Not applicable

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 conditions.

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.

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)

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LD50/oral/rat	53 mg/kg (Source: NLM_CIP)
LD50/dermal/rabbit	87,12 mg/kg (Source: ECHA_API)

Gentamicin, sulfate (salt) (1405-41-0)	
LD50/oral/rat	> 5 g/kg (Source: NLM_CIP)

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Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: Not applicable
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: Not applicable
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
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 Serie 33	
Kinematic viscosity	Not applicable

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	: Toxic to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Toxic to aquatic life with long lasting effects.

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12.2. Persistence and degradability

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Persistence and degradability	No additional information available.

12.3. Bioaccumulative potential

AIA-PACK Serie 33	
Partition coefficient n-octanol/water	Not applicable
Bioaccumulative potential	No additional information available.

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
BCF - Fish [1]	(54 dimensionless (whole body w.w.))
Partition coefficient n-octanol/water	-0,32 – 0,7 (at 20 °C (at pH >=5-<=9))

12.4. Mobility in soil

AIA-PACK Serie 33	
Mobility in soil	No data available

12.5. Results of PBT and vPvB assessment

AIA-PACK Serie 33	
Results of PBT assessment	Contains no PBT and/or vPvB substances ≥ 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 %.

12.7. Other adverse effects

Other adverse effects : No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods






Product/Packaging disposal recommendations : Avoid release to the environment. Dispose of empty containers and wastes safely. See Section 7 for information on safe handling. Refer to manufacturer/supplier for information on recovery/recycling. Recycling is preferred to disposal or incineration. If recycling is not possible, eliminate in accordance with local valid waste disposal regulations. Handle contaminated packages in the same way as the substance itself. Dispose of contaminated materials in accordance with current regulations.

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European waste catalogue (2001/573/EC, 75/442/EEC, 91/689/EEC) : This material and its container must be disposed of as hazardous waste
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
14.1. UN number or ID number				
3077	3077	3077	3077	3077
14.2. UN proper shipping name				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))	Environmentally hazardous substance, solid, n.o.s. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))
Transport document description				
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)), 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)), 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)), 9, III	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)), 9, III	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)), 9, III
14.3. Transport hazard class(es)				
9	9	9	9	9
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment : Yes	Dangerous for the environment : Yes Marine pollutant : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available				

14.6. Special precautions for user

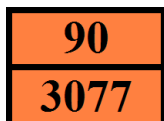
Special precautions for user : No data available

- Overland transport

Classification code (ADR) : M7
Special provisions : 274, 335, 375, 601
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1

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Packing instructions (ADR) : P002, IBC08, LP02, R001
 Special packing provisions (ADR) : PP12, B3
 Mixed packing provisions (ADR) : MP10
 Portable tank and bulk container instructions (ADR) : T1, BK1, BK2, BK3
 Portable tank and bulk container special provisions (ADR) : TP33
 Tank code (ADR) : SGAV, LGBV
 Vehicle for tank carriage : AT
 Transport category (ADR) : 3
 Special provisions for carriage - Packages (ADR) : V13
 Special provisions for carriage - Bulk (ADR) : VC1, VC2
 Special provisions for carriage - Loading, unloading and handling (ADR) : CV13
 Hazard identification number (Kemler No.) : 90
 Orange plates :



Tunnel restriction code : -
 EAC code : 2Z

- Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969
 Limited quantities (IMDG) : 5 kg
 Excepted quantities (IMDG) : E1
 Packing instructions (IMDG) : LP02, P002
 Special packing provisions (IMDG) : PP12
 IBC packing instructions (IMDG) : IBC08
 IBC special provisions (IMDG) : B3
 Tank instructions (IMDG) : BK1, BK2, BK3, T1
 Tank special provisions (IMDG) : TP33
 EmS-No. (Fire) : F-A
 EmS-No. (Spillage) : S-F
 Stowage category (IMDG) : A
 Stowage and handling (IMDG) : SW23

- Air transport

PCA Excepted quantities (IATA) : E1
 PCA Limited quantities (IATA) : Y956
 PCA limited quantity max net quantity (IATA) : 30kgG
 PCA packing instructions (IATA) : 956
 PCA max net quantity (IATA) : 400kg
 CAO packing instructions (IATA) : 956

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CAO max net quantity (IATA) : 400kg
Special provisions (IATA) : A97, A158, A179, A197, A215
ERG code (IATA) : 9L

- Inland waterway transport

Classification code (ADN) : M7
Special provisions (ADN) : 274, 335, 375, 601
Limited quantities (ADN) : 5 kg
Excepted quantities (ADN) : E1
Carriage permitted (ADN) : T* B**
Equipment required (ADN) : PP, A***
Number of blue cones/lights (ADN) : 0
Additional requirements/Remarks (ADN) : * Only in the molten state. ** For carriage in bulk see also 7.1.4.1. *** Only in the case of transport in bulk.

- Rail transport

Classification code (RID) : M7
Special provisions (RID) : 274, 335, 375, 601
Limited quantities (RID) : 5kg
Excepted quantities (RID) : E1
Packing instructions (RID) : P002, IBC08, LP02, R001
Special packing provisions (RID) : PP12, B3
Mixed packing provisions (RID) : MP10
Portable tank and bulk container instructions (RID) : T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (RID) : TP33
Tank codes for RID tanks (RID) : SGAV, LGBV
Transport category (RID) : 3
Special provisions for carriage – Packages (RID) : W13
Special provisions for carriage – Bulk (RID) : VC1, VC2
Special provisions for carriage - Loading, unloading and handling (RID) : CW13, CW31
Colis express (express parcels) (RID) : CE11
Hazard identification number (RID) : 90

14.7. Maritime transport in bulk according to IMO instruments

Code: IBC : No data available.

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

This safety datasheet has been prepared according to Polish legislation. :Not applicable.

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REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)		
Reference code	Applicable on	Entry title or description
3(b)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) ; 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
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	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 class 4.1

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

Occupational diseases			
Code	Description		
RG 31	Occupational diseases caused by aminoglycosides, including streptomycin, neomycin and their salts		
Installations classées			
No ICPE	Désignation de la rubrique	Code Régime	Rayon
4511.text	Dangereux pour l'environnement aquatique de catégorie chronique 2.		
4511.1	La quantité totale susceptible d'être présente dans l'installation étant : 1. Supérieure ou égale à 200 t Quantité seuil bas au sens de l'article R. 511-10 : 200 t. Quantité seuil haut au sens de l'article R. 511-10 : 500 t.	A	1
4511.2	La quantité totale susceptible d'être présente dans l'installation étant : 2. Supérieure ou égale à 100 t mais inférieure à 200 t Quantité seuil bas au sens de l'article R. 511-10 : 200 t. Quantité seuil haut au sens de l'article R. 511-10 : 500 t.	DC	

No ICPE

No ICPE

No ICPE

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).

Hazardous Incident Ordinance (12. BImSchV) : Listed in the 12. BImSchV (Annex I) under: 1.3.2
- Quantity threshold for operational area under § 1 para. 1
- Sentence 1 :200000 kg
- Sentence 2 :500000 kg

Netherlands

Waterbezwaarlijkheid : A (2) - Vergiftig voor in water levende organismen kan in het aquatische milieu op lange termijn schadelijke effecten veroorzaken

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

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

Not applicable

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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 Explosion Limit/Upper Explosive 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
	EWG = European waste catalogue
	LC50 = Median lethal concentration
	LD50 = Median lethal dose
	LL50 = Median lethal level
	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 datasheet : Additional information : Manufacturer/Supplier. ECHA (European Chemicals Agency), LOLI.

Training advice : Training staff on good practice. Manipulations are to be done only by qualified and authorised persons.

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

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3

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Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A
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 Serie 33, Tosoh-73

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EN

Product code	Designation
0025327	ST AIA-PACK Thyroglobulin CALIBRATOR SET
0025427	AIA-PACK Thyroglobulin CONTROL SET