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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 CEA (with SVHCs)  
Product code : 0020354, 0020554  
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

Substance name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
boric acid substance listed as REACH Candidate	CAS-No.: 10043-35-3 EC-No.: 233-139-2 EC Index: 005-007-00-2	0,1 – < 0,3	Repr. 1B, H360FD
disodium tetraborate, anhydrous substance listed as REACH Candidate	CAS-No.: 1330-43-4 EC-No.: 215-540-4 EC Index: 005-011-00-4	0,1 – < 0,3	Eye Irrit. 2, H319 Repr. 1B, H360FD

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. 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. Do NOT induce vomiting. 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	: The following symptoms may occur: Cough, Sore throat.

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Skin contact : The following symptoms may occur: Redness.

Eyes contact : The following symptoms may occur: Redness, pain.

Ingestion : May cause gastrointestinal irritation, nausea, vomiting and diarrhoea.  
Abdominal pain.

#### **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 (CO<sub>2</sub>), 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 : Carbon oxides (CO, CO<sub>2</sub>).

#### **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. 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 : 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 : Protect from moisture. Recommended storage temperature : 2-8°C.

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. Bund storage facilities to prevent soil and water pollution in the event of spillage.

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**

<b>boric acid (10043-35-3)</b>	
<b>Austria - Occupational Exposure Limits</b>	
Local name	Borsäure (Orthoborsäure)
Remark	Fortpflanzungsgefährdend: F, D

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<b>boric acid (10043-35-3)</b>	
Regulatory reference	BGBI. II Nr. 156/2021
<b>Belgium - Occupational Exposure Limits</b>	
OEL TWA	2 mg/m <sup>3</sup>
OEL STEL	6 mg/m <sup>3</sup>
<b>Bulgaria - Occupational Exposure Limits</b>	
OEL TWA	5 mg/m <sup>3</sup> (Boron and its inorganic compounds)
<b>Germany - Occupational Exposure Limits (TRGS 900)</b>	
Local name	Borsäure und Natriumborate
Occupational exposure limit value (mg/m <sup>3</sup> ) (TRGS900)	0,5 mg/m <sup>3</sup> (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed-inhalable fraction)
Peak exposure limitation factor	2(I)
Remark	AGS - Ausschuss für Gefahrstoffe; Y - Ein Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes (BGW) nicht befürchtet zu werden; 10 - Der Arbeitsplatzgrenzwert bezieht sich auf den Elementgehalt des entsprechenden Metalls
Regulatory reference	TRGS900
<b>Hungary - Occupational Exposure Limits</b>	
OEL chemical category	Repr1B
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Borate compounds inorganic: Boric acid
OEL TWA	2 mg/m <sup>3</sup> (Borate compounds inorganic)
OEL STEL	6 mg/m <sup>3</sup> (calculated (Borate compounds inorganic)
Remark	Repr.1B (Substances which are presumed human reproductive toxicants)
Regulatory reference	Chemical Agents Code of Practice 2021
<b>Latvia - Occupational Exposure Limits</b>	
Local name	Borskābe
OEL TWA	10 mg/m <sup>3</sup>
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325
<b>Lithuania - Occupational Exposure Limits</b>	
Local name	Boro rūgštis
IPRV (OEL TWA)	10 mg/m <sup>3</sup>
Remark	R (reprodukcijai toksiškas poveikis)
OEL chemical category	Reproductive toxin
Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)
<b>Portugal - Occupational Exposure Limits</b>	
Local name	Boratos, compostos inorgânicos
OEL TWA	2 mg/m <sup>3</sup> (inhalable fraction (Borate compounds, inorganic)

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<b>boric acid (10043-35-3)</b>	
OEL STEL	6 mg/m <sup>3</sup> (inhalable fraction)
OEL chemical category	A4 - Not Classifiable as a Human Carcinogen
Remark	A4 (Agente não classificável como carcinogénico no Homem)
Regulatory reference	Norma Portuguesa NP 1796:2014
<b>Slovenia - Occupational Exposure Limits</b>	
Local name	borova kislina in natrijev borat
OEL TWA	0,5 mg/m <sup>3</sup> (inhalable fraction (Boric acid and sodium borate)
OEL STEL	1 mg/m <sup>3</sup> (inhalable fraction)
Remark	Y (Snovi, pri katerih ni nevarnosti za zarodek ob upoštevanju mejnih vrednosti in bat vrednosti)
OEL chemical category	Category 1B
Regulatory reference	Uradni list RS, št. 72/2021 z dne 11.5.2021
<b>Spain - Occupational Exposure Limits</b>	
Local name	Ácido bórico
VLA-ED (OEL TWA)	2 mg/m <sup>3</sup> (partial or complete commercialization or use of this substance as a phytosanitary or biocide compound is prohibited)
VLA-EC (OEL STEL)	6 mg/m <sup>3</sup>
Remark	TR1B (Cuando las pruebas utilizadas para la clasificación procedan principalmente de datos en animales), s (Esta sustancia tiene prohibida total o parcialmente su comercialización y uso como fitosanitario y/o como biocida. Para una información detallada acerca de las prohibiciones consúltese: Base de datos de productos biocidas: <a href="http://www.msssi.gob.es/ciudadanos/productos.do?tipo=plaguicidas">http://www.msssi.gob.es/ciudadanos/productos.do?tipo=plaguicidas</a> Base de datos de productos fitosanitarios <a href="http://www.magrama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/Lista_sa.pdf">http://www.magrama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/Lista_sa.pdf</a> ), r (Esta sustancia tiene establecidas restricciones a la fabricación, la comercialización o el uso en los términos especificados en el "Reglamento (CE) nº 1907/2006 sobre Registro, Evaluación, Autorización y Restricción de sustancias y preparados químicos" (REACH) de 18 de diciembre de 2006 (DOUE L 369 de 30 de diciembre de 2006). Las restricciones de una sustancia pueden aplicarse a todos los usos o sólo a usos concretos. El anexo XVII del Reglamento REACH contiene la lista de todas las sustancias restringidas y especifica los usos que se han restringido).
OEL chemical category	TR1B
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2024. INSHT
<b>Switzerland - Occupational Exposure Limits</b>	
Local name	Acide borique / Borsäure
MAK (OEL TWA)	1,8 mg/m <sup>3</sup> (inhalable dust)
KZGW (OEL STEL)	1,8 mg/m <sup>3</sup> (inhalable dust)
Notation	R1B, SS <sub>B</sub> / R1B, SS <sub>B</sub>
Remark	NIOSH

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<b>boric acid (10043-35-3)</b>	
OEL chemical category	Category 1B reproductive toxin
Regulatory reference	www.suva.ch, 01.01.2024
<b>USA - ACGIH - Occupational Exposure Limits</b>	
Local name	Boric acid
ACGIH OEL TWA	2 mg/m <sup>3</sup> (inhalable particulate matter (Borate compounds, inorganic))
ACGIH OEL STEL	6 mg/m <sup>3</sup> (inhalable particulate matter (Borate compounds, inorganic))
Remark (ACGIH)	TLV <sup>®</sup> Basis: URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
ACGIH chemical category	Not Classifiable as a Human Carcinogen
Regulatory reference	ACGIH 2024

<b>disodium tetraborate, anhydrous (1330-43-4)</b>	
<b>Austria - Occupational Exposure Limits</b>	
Local name	Dinatriumtetraborate (wasserfrei)
Remark	Fortpflanzungsgefährdend: F, D
Regulatory reference	BGBl. II Nr. 156/2021
<b>Belgium - Occupational Exposure Limits</b>	
Local name	Borate, composés inorganiques de # Boraat, anorganische verbindingen van
OEL TWA	2 mg/m <sup>3</sup>
OEL STEL	6 mg/m <sup>3</sup>
Regulatory reference	Koninklijk besluit/Arrêté royal 16/11/2023
<b>Croatia - Occupational Exposure Limits</b>	
Local name	Dinatrijev tetraborat, bezvodni; borna kiselina, dinatrijeva sol
GVI (OEL TWA)	1 mg/m <sup>3</sup>
Remark	Repr 1B
OEL chemical category	Reproductive Toxin Category 1B
Regulatory reference	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 148/2023)
<b>Denmark - Occupational Exposure Limits</b>	
Local name	Natriumtetraborat, vandfri
OEL TWA	1 mg/m <sup>3</sup>
OEL STEL	2 mg/m <sup>3</sup>
Regulatory reference	BEK nr 202 af 21/02/2023
<b>France - Occupational Exposure Limits</b>	
Local name	Sodium (tétraborate de, anhydre) (Tétraborate de sodium anhydre)
VME (OEL TWA)	1 mg/m <sup>3</sup>

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<b>disodium tetraborate, anhydrous (1330-43-4)</b>	
Remark	Valeurs recommandées/admises. Toxique pour la reproduction de catégorie 1B
OEL chemical category	Reproductive Toxin category 1B
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 6443, 2022; Outil65)
<b>Greece - Occupational Exposure Limits</b>	
Local name	Βόρακας (άνυδρος)
OEL TWA	10 mg/m <sup>3</sup>
Regulatory reference	Π.Δ. 90/1999 - Προστασία της υγείας των εργαζομένων που εκτίθενται σε ορισμένους χημικούς παράγοντες κατά τη διάρκεια της εργασίας τους
<b>Hungary - Occupational Exposure Limits</b>	
OEL chemical category	Repr1B
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Borate compounds inorganic: Borates, tetra, sodium, anhydrous [Disodium tetraborate, anhydrous]
OEL TWA	1 mg/m <sup>3</sup> (Borates)
OEL STEL	6 mg/m <sup>3</sup> (calculated)
Remark	Repr.1B (Substances which are presumed human reproductive toxicants)
Regulatory reference	Chemical Agents Code of Practice 2021
<b>Portugal - Occupational Exposure Limits</b>	
Local name	Boratos, compostos inorgânicos
OEL TWA	2 mg/m <sup>3</sup> (inhalable fraction (Borate compounds, inorganic))
OEL STEL	6 mg/m <sup>3</sup> (inhalable fraction)
OEL chemical category	A4 - Not Classifiable as a Human Carcinogen
Remark	A4 (Agente não classificável como carcinogénico no Homem)
Regulatory reference	Norma Portuguesa NP 1796:2014
<b>Spain - Occupational Exposure Limits</b>	
Local name	Borato de sodio, anhidro (Tetraborato de sodio, anhidro)
VLA-ED (OEL TWA)	2 mg/m <sup>3</sup>
VLA-EC (OEL STEL)	6 mg/m <sup>3</sup>
Remark	TR1B (Cuando las pruebas utilizadas para la clasificación procedan principalmente de datos en animales), r (Esta sustancia tiene establecidas restricciones a la fabricación, la comercialización o el uso en los términos especificados en el "Reglamento (CE) nº 1907/2006 sobre Registro, Evaluación, Autorización y Restricción de sustancias y preparados químicos" (REACH) de 18 de diciembre de 2006 (DOUE L 369 de 30 de diciembre de 2006). Las restricciones de una sustancia pueden aplicarse a todos los usos o sólo a usos concretos. El anexo XVII del Reglamento REACH contiene la lista de todas las sustancias restringidas y especifica los usos que se han restringido).
OEL chemical category	TR1B



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<b>disodium tetraborate, anhydrous (1330-43-4)</b>	
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2024. INSHT
<b>United Kingdom - Occupational Exposure Limits</b>	
Local name	Disodium tetraborate, anhydrous
WEL TWA (OEL TWA)	1 mg/m³
WEL STEL (OEL STEL)	3 mg/m³ (calculated)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
<b>Iceland - Occupational Exposure Limits</b>	
Local name	Natriúmtetrabórat, vatnsfrítt
OEL TWA	1 mg/m³
Regulatory reference	Reglugerð um mengunarmörk og aðgerðir til að draga úr mengun á vinnustöðum (Nr. 390/2009)
<b>Norway - Occupational Exposure Limits</b>	
Local name	Natriumtetraborater: Vannfritt
Grenseverdi (OEL TWA)	1 mg/m³
Korttidsverdi (OEL STEL)	3 mg/m³ (value calculated)
Regulatory reference	FOR-2023-12-18-2278
<b>USA - ACGIH - Occupational Exposure Limits</b>	
Local name	Sodium tetraborate, anhydrate
ACGIH OEL TWA	2 mg/m³ (inhalable particulate matter (Borate compounds, inorganic)
ACGIH OEL STEL	6 mg/m³ (inhalable particulate matter (Borate compounds, inorganic)
Remark (ACGIH)	TLV® Basis: URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
ACGIH chemical category	Not Classifiable as a Human Carcinogen
Regulatory reference	ACGIH 2024

8.1.2. Recommended monitoring procedures

<b>Monitoring methods</b>	
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

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## 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	: In case of insufficient ventilation, wear suitable respiratory equipment. Half-face mask (DIN EN 140). full face mask (DIN EN 136). Filter type: A (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	: Not available
Initial boiling point and boiling range	: No data available
Flammability	: Not flammable
Explosive properties	: Not applicable.
Oxidising properties	: Not applicable.
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Kinematic viscosity	: No data available
Solubility	: Water: No data available
Partition coefficient n-octanol/water (Log Kow)	: Not available

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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 : No data available  
 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**

No additional information 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**

No dangerous reactions known under normal conditions of use.

### **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)

<b>boric acid (10043-35-3)</b>	
LD50/oral/rat	2660 mg/kg

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<b>boric acid (10043-35-3)</b>	
LD50/dermal/rabbit	> 2000 mg/kg (Source: NLM_HSDB)
LC50/inhalation/4h/rat	> 2,12 mg/l/4h

<b>disodium tetraborate, anhydrous (1330-43-4)</b>	
LD50/oral/rat	2660 mg/kg (Source: JAPAN_GHS)
LD50 oral	2660 mg/kg
LD50/dermal/rabbit	> 2000 mg/kg (Source: ECHA_API)
LD50 dermal	> 2000 mg/kg
LC50/inhalation/4h/rat	> 2 mg/m <sup>3</sup> (Exposure time: 4 h Source: NLM_HSDB)

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: No data available
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: No data available
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)
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)

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Kinematic viscosity	No data available

## **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	: According to the criteria of the European classification and labelling system, the substance/the product has not to be labelled as "dangerous for the environment".
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

#### boric acid (10043-35-3)

EC50 - Crustacea [1]	658 - 875 mg/l (Daphnia Magna)
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#### disodium tetraborate, anhydrous (1330-43-4)

LC50 - Fish [1]	340 mg/l (Exposure time: 96 h - Species: Limanda limanda Source: IUCLID)
EC50 - Crustacea [1]	1085 – 1402 mg/l (Exposure time: 48 h - Species: Daphnia magna)
EC50 96h - Algae [1]	158 mg/l (Species: Desmodesmus subspicatus)
EC50 96h - Algae [2]	2,6 – 21,8 mg/l (Species: Pseudokirchneriella subcapitata [static])

### 12.2. Persistence and degradability

#### AIA-PACK CEA (with SVHCs)

Persistence and degradability	No additional information available.
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### 12.3. Bioaccumulative potential

#### AIA-PACK CEA (with SVHCs)

Partition coefficient n-octanol/water	No data available
Bioaccumulative potential	No additional information available.

#### boric acid (10043-35-3)

BCF - Fish [1]	(0 dimensionless)
Partition coefficient n-octanol/water	-1,09 (at 22 °C (at pH 7.5)

#### disodium tetraborate, anhydrous (1330-43-4)

BCF - Fish [1]	(no evidence of bioaccumulation)
Partition coefficient n-octanol/water	-1,53 (at 22 °C (at pH 7.5)

### 12.4. Mobility in soil

#### AIA-PACK CEA (with SVHCs)

Mobility in soil	No data available
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#### 12.5. Results of PBT and vPvB assessment

AIA-PACK CEA (with SVHCs)	
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 %.

#### 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.

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				

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#### 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.

### 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
30.	boric acid ; disodium tetraborate, anhydrous	Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.

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

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

##### REACH Candidate List (SVHC)

Contains substance(s) listed on the REACH Candidate List in concentrations  $\geq 0.1\%$  or SCL: Boric acid (EC 233-139-2, CAS 10043-35-3), Disodium tetraborate, anhydrous (EC 215-540-4, CAS 1330-43-4)

##### 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)

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#### 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

##### 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 nwg, Non-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 : boric acid, disodium tetraborate, anhydrous are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : boric acid, disodium tetraborate, anhydrous 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

#### SECTION 16: Other information

Indication of changes:

1.3	Details of the supplier of the safety data	Modified	
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	sheet		
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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
	EWC = 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 : Supplier. ECHA (European Chemicals Agency), Ioli, Inchem.

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
H319	Causes serious eye irritation.
H360FD	May damage fertility. May damage the unborn child.
Repr. 1B	Reproductive toxicity, Category 1B

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878  
Classification according to Regulation (EC) No. 1272/2008 [CLP]

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

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## **ANNEX: AIA-PACK CEA (with SVHCs), Tosoh-57**

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

EN

<b>Product code</b>	<b>Designation</b>
0020354	AIA-PACK CEA CALIBRATOR SET
0020554	AIA-PACK CEA SAMPLE DILUTING SOLUTION