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

· Product identifier

Trade name: AIA-PACK B12 PRETREATMENT SET (020706)

Concerned item: AIA-PACK B12 PRETREATMENT 1
AIA-PACK FOLATE PRETREATMENT SET (020707)

Concerned item: AIA-PACK FOLATE PRETREATMENT 1

- · Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the preparation In Vitro Diagnostics.
- Details of the supplier of the safety data sheet

Manufacturer / Supplier:

TOSOH CORPORATION 3-8-2 Shiba, Minato-ku Tokyo 105 -8623 JAPAN TOSOH BIOSCIENCE, INC. 6000 Shoreline Ct.; Suite 101 South San Francisco, CA94080 USA

· Information department:

QA-RA: susan.koss@tosoh.com www.diagnostics.us.tosohbioscience.com

· Emergency telephone number: Poison Control Center: + 1 800 222 1222

2 Hazards identification

· Classification of the substance or mixture



GHS08 Health hazard

Carc. 2 H351 Suspected of causing cancer.

STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Toxic

Toxic if swallowed. Toxic: danger of serious damage to health by prolonged exposure if swallowed.



Harmful

Limited evidence of a carcinogenic effect.



Dangerous for the environment

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of international guidelines.

Classification system:

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

- · Label elements
- · Labelling according to EU guidelines:

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

· Code letter and hazard designation of product:





Toxic
Dangerous for the environment

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· Hazard-determining components of labelling:

DDT (common name not adopted by ISO) sodium azide

· Risk phrases:

Toxic if swallowed.

Limited evidence of a carcinogenic effect.

Toxic: danger of serious damage to health by prolonged exposure if swallowed.

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

Keep locked up and out of the reach of children.

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

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 3 Fire = 0 Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = *3 Fire = 0 Reactivity = 0

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:		
57-50-1	sucrose, pure	25-50%
	DDT (common name not adopted by ISO)	10-25%
	♦ Acute Tox. 3, H301; ♦ Carc. 2, H351; STOT RE 1, H372	
26628-22-8	sodium azide	≤ 2.5%
	Acute Tox. 2, H300	

4 First aid measures

- Description of first aid measures
- **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

In case of irregular breathing or respiratory arrest provide artificial respiration.

- · After inhalation: In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: Do not induce vomiting; immediately call for medical help.
- Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed No further relevant information available.

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5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

· Precautions for safe handling

Store in cool, dry place in tightly closed receptacles.

Prevent formation of dust.

- Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep receptacle tightly sealed.
- · **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

57-50-1 sucrose, pure

PEL 15* 5** mg/m³

*total dust **respirable fraction

REL 10* 5** mg/m³

*total dust **respirable fraction

TLV 10 mg/m³

50-29-3 DDT (common name not adopted by ISO)

PEL 1 mg/m³

Skin

REL 0.5 mg/m³

See Pocket Guide App. A

TLV 1 mg/m³

26628-22-8 sodium azide

REL Short-term value: C 0.3** mg/m³, C 0.1* ppm

*as HN3; **as NaN3; Skin

TLV Short-term value: C 0.29** mg/m³, C 0.11* ppm

*as HN3 vapor **as NaN3

· Additional information: The lists that were valid during the creation were used as basis.

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- · Exposure controls
- Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Not required.

9 Physical and chemical proper	ties
Information on basic physical and c	hemical properties
General Information	
· Appearance:	
Form:	Spray dried powder
Color:	Whitish
· Odor:	uncharacteristic
· Odour threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	185°C (365 °F)
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Ignition temperature:	
Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
Relative density	Not determined.
· Vapour density	Not applicable.
Evaporation rate	Not applicable.

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· Solubility in / Miscibility with		
Water:	Soluble.	
Segregation coefficient (n-octono	ol/water): Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
· Solvent content:		
Organic solvents:	0.0 %	
Solids content:	100.0 %	
Other information	No further relevant information available.	

10 Stability and reactivity

- Reactivity
- Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- Information on toxicological effects
- · Acute toxicity:

· LD/LC	· LD/LC50 values that are relevant for classification:			
50-29-3	DDT (common name not adopted by ISO)		
		113 mg/kg (rat)		
Dermal	LD50	2510 mg/kg (rat)		
26628-2	2-8 so	dium azide		
		27 mg/kg (rat)		
Dermal	LD50	20 mg/kg (rabbit)		

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations: Toxic

Carcinogenic categories

· IARC (International Agency for Research on Cancer)	
50-29-3 DDT (common name not adopted by ISO)	2B
· NTP (National Toxicology Program)	
50-29-3 DDT (common name not adopted by ISO)	R

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.

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- · Ecotoxical effects:
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Water hazard class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agent: Water, if necessary with cleansing agents.

Transport information	
UN-Number DOT, ADR, IMDG, IATA	UN2588
UN proper shipping name	
ADR	2588 PESTICIDE, SOLID, TOXIC, N.O.S. (SODIUM AZIDE, D
IMDG	(common name not adopted by ISO)) PESTICIDE, SOLID, TOXIC, N.O.S. (SODIUM AZIDE, D
	(common name not adopted by ISO)), MARINE POLLUTANT
IATA	PESTICIDE, SOLID, TOXIC, N.O.S. (SODIUM AZIDE, D. (common name not adopted by ISO))
Transport hazard class(es)	
DOT	
TOXIC 8	
Class	6.1 Toxic substances.
Label	6.1
ADR, IMDG	
Class	6.1 Toxic substances
Label	6.1
IATA	
Class	6.1 Toxic substances.



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(Contd. of page 6) · Label 6.1 · Packing group · DOT, ADR, IMDG, IATA Ш · Environmental hazards: Product contains environmentally hazardous substances: DDT (common name not adopted by ISO) · Marine pollutant: Symbol (fish and tree) · Special marking (ADR): Symbol (fish and tree) · Special precautions for user Warning: Toxic substances · Danger code (Kemler): 60 · EMS Number: F-A,S-A · Segregation groups Azides Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable. UN "Model Regulation": UN2588, PESTICIDE, SOLID, TOXIC, N.O.S., 6.1, III

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- Section 355 (extremely hazardous substances):

26628-22-8 sodium azide

Section 313 (Specific toxic chemical listings):

26628-22-8 sodium azide

TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · Proposition 65
- · Chemicals known to cause cancer:

50-29-3 DDT (common name not adopted by ISO)

· Chemicals known to cause reproductive toxicity for females:

50-29-3 DDT (common name not adopted by ISO)

Chemicals known to cause reproductive toxicity for males:

50-29-3 DDT (common name not adopted by ISO)

· Chemicals known to cause developmental toxicity:

50-29-3 DDT (common name not adopted by ISO)

- Carcinogenic categories
- EPA (Environmental Protection Agency)

50-29-3 DDT (common name not adopted by ISO)

B2

TLV (Threshold Limit Value established by ACGIH)

 57-50-1
 sucrose, pure
 A4

 50-29-3
 DDT (common name not adopted by ISO)
 A3

 26628-22-8
 sodium azide
 A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

50-29-3 DDT (common name not adopted by ISO)

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Product related hazard informations:

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

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· Hazard symbols:





Toxic Dangerous for the environment

· Hazard-determining components of labelling:

DDT (common name not adopted by ISO) sodium azide

· Risk phrases:

Toxic if swallowed.

Limited evidence of a carcinogenic effect.

Toxic: danger of serious damage to health by prolonged exposure if swallowed.

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

Keep locked up and out of the reach of children.

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

Wear suitable protective clothing and gloves.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The information contained herein is prepared based on the available information to Tosoh that is believed to be reliable: however the information is provided by Tosoh WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, AS TO ITS COMPLETENESS, COMPREHENSIVENESS AND ACCURACY.

Since the conditions of handling, storage and disposal of this material are beyond our control, it is the responsibility of the user to determine whether the material is fit for a particular purpose and/or suitable for the user's method of use or application, and to determine safe conditions for use of the material, and to assume full responsibility for loss, injury and expense arising out of or in connection with the use of material. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, REGARDING THE MATERIAL DESCRIBED HEREIN SHALL BE CREATED BY OR INFERRED FROM ANY STATEMENT OR OMISSION FROM THIS MSDS.

Various government agencies and local authorities may have general or specific regulations applicable to the material which may not be covered in this MSDS. It is sole responsibility of the user to examine and confirm for its full compliance with any such regulations.

When the revision of this MSDS is received, please dispose of the old one.

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organization

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods

by Road)
IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent