

SAFETY DATA SHEET

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

1.1. Product identifier

Product name: Diaphorase (DI II)
Product code: T-227

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

Identified uses: Enzyme for clinical diagnosis reagent
Uses advised against: No information

1.3. Details of the supplier of the safety data sheet

Name of supplier (importer): Sekisui Diagnostics (UK) Ltd.
Department in Charge Technical Services
Address Liphook Way, Allington, Maidstone, Kent, ME16 0LQ, UK
Telephone number +44 (0) 1622 607800
Fax number +44 (0) 01622 607801
e-mail address info@sekisuidiagnostics.com

Name of manufacturer in Japan: Asahi Kasei Pharma Corporation
Department in Charge Diagnostics Department
Address 1-1-2 Yurakucho Chiyoda-ku, Tokyo 100-0006 JAPAN
Telephone number +81-3-6699-3617
Fax number +81-3-6699-3688
e-mail address diagnostics@om.asahi-kasei.co.jp

1.4. Emergency telephone number

+44 (0) 1622 607800

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008:
Resp. Sens. 1: H334

2.2. Label elements

In accordance with EC No 1272/2008:

Pictogram



Signal word

Danger

Hazard Statements

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements

[Prevention]	P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P284: Wear respiratory protection.
[Emergency response]	P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
[Disposal]	P501: Dispose of contents/ container in accordance with related laws and local/ regional regulations.

2.3. Other hazards

Contact or inhalation of dust may cause irritation to eyes, skin and respiratory organs or slight allergic reaction.

SECTION 3: Composition/information on ingredients

3.1. Substances Not applicable

3.2. Mixtures

Product Name: Diaphorase (DI II)

Information on ingredients:

Chemical name	CAS No.	EC No.	Index No.	REACH Registration No.*	Concentration (wt %)	Classification
Enzyme protein	9032-20-6	-	-	-	70 - 100	Resp. Sens. 1: H334
Tris(hydroxymethyl) aminomethane	77-86-1	201-064-4	-	-	0.4 – 4.0	-
Flavin adenine dinucleotide sodium	84366-81-4	282-733-8	-	-	0.1 – 1.0	-

* Registration numbers of ingredients which shall be in compliance with Regulation (EC) No 1907/2006 will be filled in later.

SECTION 4: First aid measures

4.1. Description of first aid measures

IF INHALED	If inhaled large amount and symptoms occur, remove victim to fresh air and keep at rest. Get medical advice as appropriate.
IF ON SKIN	Rinse with plenty of water and soap. If allergic reactions occur, get medical advice as appropriate.
IF IN EYES	Immediately rinse cautiously with clean water. If symptoms occur, immediately get medical advice/attention.
IF SWALLOWED	Rinse mouth. If symptoms occur, immediately get medical advice/attention.

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

Contact or inhalation of dust may cause irritation to eyes, skin and respiratory organs or slight allergic reaction.

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

No information

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Use water mist, dry chemical powder, carbon dioxide or dry sand.

Unsuitable extinguishing media

Applying direct water may be dangerous because fire may expand to surroundings.

5.2. Special hazards arising from the substance or mixture

In case of fire, toxic decomposition products may be generated.

5.3. Advice for firefighters

Take action from windward.

Use respiratory protective equipment.

Move container to a safe area if it can be done without risk. If it is not possible to move, cool the container and surrounding area with water.

Keep out except responsible personnel.

Cut off any ignition sources and extinguish with an appropriate agent.

Cool the surrounding tank and the buildings with direct water jet to avoid risk of fire spreading.

In first-aid fire fighting, use water mist and fire foam. In case of a large fire, quickly extinguish using alcohol-resistant foams.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Wear suitable protective equipment (see SECTION 8) e.g., safety gloves, protective mask and/or protective glasses to prevent exposure.

For emergency responders:

If scattering of large amounts of dust is expected during the procedures, wear protective glasses, protective mask and/or safety gloves to prevent contact to the body.

6.2. Environmental precautions

Be careful not to get large amounts of this product scattered or release into the environment.

Take care not to release large amounts of spilled material into the environment avoiding causing local effects.

6.3. Methods and material for containment and cleaning up

In case of a large amount, sweep up scattered materials or vacuum them using a vacuum cleaner then collect them into an empty container.

In case of a small amount, wash out with a plenty of water

6.4. Reference to other sections

Refer to “SECTION 8: Exposure controls/personal protection” and “SECTION 13: Disposal considerations” as appropriate.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures:

After taking out from cool and dark place (- 20 to - 80 °C), ensure that the product in the container become room temperature before open it to prevent moisture absorption.

Install appropriate equipment and wear suitable protective apparatus to prevent inhaling or contact with eyes, skin or clothes.

Install eye washer and hand washer around the handling area.

Use only at well-ventilated area without moisture.

Avoid making impacts on container or handling violently.

Advice on general occupational hygiene:

Wash hands thoroughly after handling.

Do not eat, drink or smoke when using this product.

Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures:

Keep fire away.

Incompatible materials:

No information

Conditions for safe storage:

Avoid sunlight. Store in a cool, dry and dark place (- 20 to - 80 °C) with desiccants.

Packing material:

No information

7.3. Specific end use(s)

Enzyme for clinical diagnosis reagent

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Acceptable concentration (exposure limit, biological exposure index)

ACGIH TLV-TWA (2016)	3 mg/m ³ (Respirable particles)
	10 mg/m ³ (Inhalable particles)

8.2. Exposure controls

Appropriate engineering controls:

Because the powder is light and easy to scatter, handle only in a calm place. Use sealed instrument or local ventilation as necessary.

Personal protective equipment:

Respiratory protection	Wear dust mask as necessary.
Hand protection	Wear protective gloves as necessary.
Eye protection	Wear safety glasses or goggles as necessary.
Skin and body protection	Wear protective clothing and boots as necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance (physical state, form and colour)	Yellow to yellow brownish lyophilized powder
Odour	Slight characteristic odour
Odour threshold	No information
pH	No information
Melting point/freezing point	No information
Initial boiling point and boiling range	No information
Flash point	No information
Evaporation rate	No information
Flammability (solid, gas)	No information
Upper/lower flammability or explosive limits	No information
Vapour pressure	No information
Vapour density	No information
Relative density	No information
Solubility (ies)	Soluble in water. Insoluble in organic solvents.
Partition coefficient: <i>n</i> -octanol/water	No information
Auto-ignition temperature	No information
Decomposition temperature	No information
Viscosity	No information
Explosive properties	No information
Oxidising properties	No information

9.2. Other information

No information

SECTION 10: Stability and reactivity

10.1. Reactivity

No self-reactivity.

10.2. Chemical stability

Stable for one year under a cool and dark place (- 20 °C).

10.3. Possibility of hazardous reactions

No hazardous reaction expected under normal handling.

10.4. Conditions to avoid

High temperature, high humidity and moisture absorption can stop enzyme activity.

10.5. Incompatible materials

No information

10.6. Hazardous decomposition products

No information

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Information on product: Contact or inhalation of dust may cause irritation to eyes, skin and respiratory organs or slight allergic reaction.

SECTION 12: Ecological information

12.1. Toxicity:

Information on product: Toxicity to fish is expected to be low.

12.2. Persistence and degradability:

This product is readily biodegradable.

12.3. Bioaccumulative potential:

Bioaccumulative potential is expected to be low.

12.4. Mobility in soil:

No information

12.5. Results of PBT and vPvB assessment:

The product does not meet the PBT and vPvB criteria.

12.6. Other adverse effects:

No information

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of waste in accordance with applicable local, regional and international regulations and standards.

Containers should completely be cleaned up before disposal.

SECTION 14: Transport information

14.1. UN number	Not applicable
14.2. UN proper shipping name	Not applicable
14.3. Transport hazard class(es)	Not applicable
14.4. Packing group	Not applicable
14.5. Environmental hazards	Not applicable

14.6. Special precautions for user

When transporting, avoid direct sunlight. Confirm no leakage to containers. When loading, prevent containers from falling, dropping off or damaging. Take preventive measures of collapse.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and IBC code

Not applicable

SECTION 15: Regulatory information

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

The product and its ingredients are not regulated by specific provisions related to protection of human health or the environment at EU level, e.g. not considered as SVHCs or POPs.

15.2. Chemical safety assessment

Not conducted

SECTION 16: Other information

Update history:

Date of issue: 10th Dec, 2018

References:

Information of Asahi Kasei Pharma Corporation.
ACGIH, American Conference of Governmental Industrial Hygienists (2016) TLVs and BEIs.

Abbreviations

PBT: Persistent, Bioaccumulative and Toxic substance
POPs: Persistent Organic Pollutants
STOT: Specific Target Organ Toxicity
SVHC: Substances of Very High Concern
vPvB: Very Persistent and Very Bioaccumulative

[Disclaimer]

This SDS has been prepared based on the best available information however, it may not be sufficient in some cases. It is user's responsibility to modify or update any contents in this SDS regarding information on hazardous properties and/or instruction for safe handling of the product when they become available. Precautionary measures in this SDS are only applicable for normal handling conditions and it is necessary to take appropriate additional measures to ensure safe handling which depend on your specific use conditions or situations.