

# SAFETY DATA SHEET

INNOVANCE® D-Dimer

**SIEMENS**  
**Healthineers** 


SDS no.:

mrhm0156

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

### 1.1 Product identifier

**Product name** : INNOVANCE® D-Dimer

**Product code** :  OPBP03, 10445979; OPBP07, 10445980; OPBP09, 10445981; OPBP11, 10445982; 10873785, 10873786

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

<b>Identified uses</b>	INNOVANCE® D-Dimer Buffer	Diagnostic agents.
	INNOVANCE® D-Dimer Calibrator	Diagnostic agents.
	INNOVANCE® D-Dimer Sample Diluent	Diagnostic agents.
	INNOVANCE® D-Dimer Reagent	Diagnostic agents.
	INNOVANCE® D-Dimer Supplementary Reagent	Diagnostic agents.

**Restrictions on use**  For professional users only.

**Supplier** : Siemens Healthcare Diagnostics Limited  
Park View,  
Watchmoor Park,  
Camberley,  
Surrey,  
GU15 3YL  
United Kingdom

Phone: +44 (0) 345 600 1955

**e-mail address of person responsible for this SDS** : dx.msds.healthcare@siemens-healthineers.com

### 1.4 Emergency telephone number

CHEMTREC: +44 20 3807 3798

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

<b>Product definition</b>	INNOVANCE® D-Dimer Buffer	Mixture
	INNOVANCE® D-Dimer Calibrator	Mixture
	INNOVANCE® D-Dimer Sample Diluent	Mixture
	INNOVANCE® D-Dimer Reagent	Mixture
	INNOVANCE® D-Dimer Supplementary Reagent	Mixture

#### Classification according to UK CLP/GHS

##### INNOVANCE® D-Dimer Calibrator

Skin Sens. 1, H317

Aquatic Chronic 3, H412

##### INNOVANCE® D-Dimer Sample Diluent

Repr. 1B, H360D

##### INNOVANCE® D-Dimer Reagent

Skin Irrit. 2, H315

Eye Dam. 1, H318

Repr. 1B, H360D

The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

See Section 16 for the full text of the H statements declared above.

## SECTION 2: Hazards identification

See Section 11 for more detailed information on health effects and symptoms.

### 2.2 Label elements

#### Hazard pictograms



#### Signal word

: INNOVANCE® D-Dimer Buffer	No signal word.
INNOVANCE® D-Dimer Calibrator	Warning
INNOVANCE® D-Dimer Sample Diluent	Danger
INNOVANCE® D-Dimer Reagent	Danger
INNOVANCE® D-Dimer Supplementary Reagent	No signal word.

#### Hazard statements

: INNOVANCE® D-Dimer Buffer	No known significant effects or critical hazards.
INNOVANCE® D-Dimer Calibrator	H317 - May cause an allergic skin reaction. H412 - Harmful to aquatic life with long lasting effects.
INNOVANCE® D-Dimer Sample Diluent	H360D - May damage the unborn child.
INNOVANCE® D-Dimer Reagent	H315 - Causes skin irritation. H318 - Causes serious eye damage. H360D - May damage the unborn child.
INNOVANCE® D-Dimer Supplementary Reagent	No known significant effects or critical hazards.

### Precautionary statements

#### Prevention

: INNOVANCE® D-Dimer Buffer	Not applicable.
INNOVANCE® D-Dimer Calibrator	P261 - Avoid breathing dust. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
INNOVANCE® D-Dimer Sample Diluent	P273 - Avoid release to the environment. P201 - Obtain special instructions before use. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
INNOVANCE® D-Dimer Reagent	P264 - Wash hands thoroughly after handling. P201 - Obtain special instructions before use. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
INNOVANCE® D-Dimer Supplementary Reagent	Not applicable.

#### Response

: INNOVANCE® D-Dimer Buffer	Not applicable.
INNOVANCE® D-Dimer Calibrator	P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 - Take off contaminated clothing and wash it before reuse.
INNOVANCE® D-Dimer Sample Diluent	P308 + P313 - IF exposed or concerned: Get medical advice or attention.
INNOVANCE® D-Dimer Reagent	P308 - IF exposed or concerned: P313 - Get medical attention. P305 - IF IN EYES: P351 - Rinse cautiously with water for several minutes. P338 - Remove contact lenses, if present and easy to do. Continue rinsing.

**SECTION 2: Hazards identification**

	INNOVANCE® D-Dimer Supplementary Reagent	P310 - Immediately call a POISON CENTER or physician. Not applicable.
<b>Storage</b>	: INNOVANCE® D-Dimer Buffer INNOVANCE® D-Dimer Calibrator INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
<b>Disposal</b>	: INNOVANCE® D-Dimer Buffer INNOVANCE® D-Dimer Calibrator  INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, and national regulations. Not applicable. Not applicable. Not applicable.
<b>Supplemental label elements</b>	: INNOVANCE® D-Dimer Buffer INNOVANCE® D-Dimer Calibrator INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
<b>Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles</b>	: INNOVANCE® D-Dimer Buffer INNOVANCE® D-Dimer Calibrator INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	Not applicable. Not applicable. Restricted to professional users. Restricted to professional users. Not applicable.
<b>2.3 Other hazards</b>		
<b>Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII</b>	: INNOVANCE® D-Dimer Buffer  INNOVANCE® D-Dimer Calibrator  INNOVANCE® D-Dimer Sample Diluent  INNOVANCE® D-Dimer Reagent  INNOVANCE® D-Dimer Supplementary Reagent	This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
<b>Other hazards which do not result in classification</b>	: INNOVANCE® D-Dimer Buffer INNOVANCE® D-Dimer Calibrator INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	None known. None known. None known. None known. None known.
<b>Additional information</b>	: Potentially biohazardous material.  Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.	

INNOVANCE® D-Dimer

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

<b>3.1 Substances</b>	:	INNOVANCE® D-Dimer Buffer	Mixture
		INNOVANCE® D-Dimer Calibrator	Mixture
		INNOVANCE® D-Dimer Sample Diluent	Mixture
		INNOVANCE® D-Dimer Reagent	Mixture
		INNOVANCE® D-Dimer Supplementary Reagent	Mixture

Product/ingredient name	Identifiers	%	Classification	Type
<b>INNOVANCE® D-Dimer Calibrator</b> sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	≤1	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	CAS: 55965-84-9 Index: 613-167-00-5	≤0.013	Acute Tox. 3, H301 Acute Tox. 2, H310 Acute Tox. 2, H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071	[1]
<b>INNOVANCE® D-Dimer Sample Diluent</b> imidazole	EC: 206-019-2 CAS: 288-32-4 Index: 613-319-00-0	<1	Acute Tox. 4, H302 Skin Corr. 1C, H314 Eye Dam. 1, H318 Repr. 1B, H360D	[1]
sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	<0.1	Acute Tox. 2, H300 Acute Tox. 1, H310 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
<b>INNOVANCE® D-Dimer Reagent</b> sucrose	REACH #: Annex IV EC: 200-334-9 CAS: 57-50-1	≥90	Not classified.	[2]
imidazole	EC: 206-019-2 CAS: 288-32-4 Index: 613-319-00-0	<5	Acute Tox. 4, H302 Skin Corr. 1C, H314 Eye Dam. 1, H318 Repr. 1B, H360D <b>See Section 16 for the full text of the H statements declared above.</b>	[1]

Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

Occupational exposure limits, if available, are listed in Section 8.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

<b>Eye contact</b>	: INNOVANCE® D-Dimer Buffer	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
	INNOVANCE® D-Dimer Calibrator	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
	INNOVANCE® D-Dimer Sample Diluent	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
	INNOVANCE® D-Dimer Reagent	Get medical attention immediately. Call a poison center or physician. Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Chemical burns must be treated promptly by a physician.
	INNOVANCE® D-Dimer Supplementary Reagent	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
<b>Inhalation</b>	: INNOVANCE® D-Dimer Buffer	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
	INNOVANCE® D-Dimer Calibrator	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
	INNOVANCE® D-Dimer Sample Diluent	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical

**SECTION 4: First aid measures**

	INNOVANCE® D-Dimer Reagent	<p>attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.</p> <p>Get medical attention immediately. Call a poison center or physician. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.</p>
	INNOVANCE® D-Dimer Supplementary Reagent	<p>Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.</p>
<b>Skin contact</b>	: INNOVANCE® D-Dimer Buffer	<p>Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.</p>
	INNOVANCE® D-Dimer Calibrator	<p>Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.</p>
	INNOVANCE® D-Dimer Sample Diluent	<p>Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.</p>
	INNOVANCE® D-Dimer Reagent	<p>Get medical attention immediately. Call a poison center or physician. Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Chemical burns must be treated promptly by a physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.</p>
	INNOVANCE® D-Dimer Supplementary	<p>Flush contaminated skin with plenty of</p>

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	Reagent	water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>Ingestion</b>	: INNOVANCE® D-Dimer Buffer	Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
	INNOVANCE® D-Dimer Calibrator	Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
	INNOVANCE® D-Dimer Sample Diluent	Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
	INNOVANCE® D-Dimer Reagent	Get medical attention immediately. Call a poison center or physician. Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Chemical burns must be treated promptly by a physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open

**SECTION 4: First aid measures**

	INNOVANCE® D-Dimer Supplementary Reagent	<p>airway. Loosen tight clothing such as a collar, tie, belt or waistband.</p> <p>Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.</p>
<b>Protection of first-aiders</b>	: INNOVANCE® D-Dimer Buffer	No action shall be taken involving any personal risk or without suitable training.
	INNOVANCE® D-Dimer Calibrator	No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.
	INNOVANCE® D-Dimer Sample Diluent	No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.
	INNOVANCE® D-Dimer Reagent	No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.
	INNOVANCE® D-Dimer Supplementary Reagent	No action shall be taken involving any personal risk or without suitable training.

**4.2 Most important symptoms and effects, both acute and delayed****Over-exposure signs/symptoms**

<b>Eye contact</b>	: INNOVANCE® D-Dimer Buffer	No specific data.
	INNOVANCE® D-Dimer Calibrator	No specific data.
	INNOVANCE® D-Dimer Sample Diluent	No specific data.
	INNOVANCE® D-Dimer Reagent	Adverse symptoms may include the following: pain watering redness
	INNOVANCE® D-Dimer Supplementary Reagent	No specific data.
<b>Inhalation</b>	: INNOVANCE® D-Dimer Buffer	No specific data.
	INNOVANCE® D-Dimer Calibrator	No specific data.
	INNOVANCE® D-Dimer Sample Diluent	No specific data.
	INNOVANCE® D-Dimer Reagent	No specific data.
	INNOVANCE® D-Dimer Supplementary Reagent	No specific data.



**SECTION 4: First aid measures**

<b>Skin contact</b>	: INNOVANCE® D-Dimer Buffer	No specific data.
	INNOVANCE® D-Dimer Calibrator	Adverse symptoms may include the following: irritation redness
	INNOVANCE® D-Dimer Sample Diluent	No specific data.
	INNOVANCE® D-Dimer Reagent	Adverse symptoms may include the following: pain or irritation redness blistering may occur
	INNOVANCE® D-Dimer Supplementary Reagent	No specific data.
<b>Ingestion</b>	: INNOVANCE® D-Dimer Buffer	No specific data.
	INNOVANCE® D-Dimer Calibrator	No specific data.
	INNOVANCE® D-Dimer Sample Diluent	No specific data.
	INNOVANCE® D-Dimer Reagent	Adverse symptoms may include the following: stomach pains
	INNOVANCE® D-Dimer Supplementary Reagent	No specific data.
<b>4.3 Indication of any immediate medical attention and special treatment needed</b>		
<b>Notes to physician</b>	: INNOVANCE® D-Dimer Buffer	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
	INNOVANCE® D-Dimer Calibrator	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
	INNOVANCE® D-Dimer Sample Diluent	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
	INNOVANCE® D-Dimer Reagent	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
	INNOVANCE® D-Dimer Supplementary Reagent	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
<b>Specific treatments</b>	: INNOVANCE® D-Dimer Buffer	No specific treatment.
	INNOVANCE® D-Dimer Calibrator	No specific treatment.
	INNOVANCE® D-Dimer Sample Diluent	No specific treatment.
	INNOVANCE® D-Dimer Reagent	No specific treatment.
	INNOVANCE® D-Dimer Supplementary Reagent	No specific treatment.
	INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

**Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.

**Unsuitable extinguishing media** : None known.

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

**Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.

**Hazardous combustion products** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides  
halogenated compounds  
metal oxide/oxides

### 5.3 Advice for firefighters

**Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## SECTION 6: Accidental release measures

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

**For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

**For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

### 6.2 Environmental precautions

: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

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

**Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

**Large spill** : Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

**SECTION 6: Accidental release measures**

- 6.4 Reference to other sections** : See Section 1 for emergency contact information.  
See Section 8 for information on appropriate personal protective equipment.  
See Section 13 for additional waste treatment information.

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

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

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

**7.3 Specific end use(s)**

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational exposure limits**

Product/ingredient name	Exposure limit values
<b>INNOVANCE® D-Dimer Calibrator</b> sodium azide	<b>EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin.</b> STEL: 0.3 mg/m <sup>3</sup> , (as NaN <sub>3</sub> ) 15 minutes. TWA: 0.1 mg/m <sup>3</sup> , (as NaN <sub>3</sub> ) 8 hours.
<b>INNOVANCE® D-Dimer Sample Diluent</b> sodium azide	<b>EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin.</b> STEL: 0.3 mg/m <sup>3</sup> , (as NaN <sub>3</sub> ) 15 minutes. TWA: 0.1 mg/m <sup>3</sup> , (as NaN <sub>3</sub> ) 8 hours.
<b>INNOVANCE® D-Dimer Reagent</b> sucrose	<b>EH40/2005 WELs (United Kingdom (UK), 1/2020).</b> STEL: 20 mg/m <sup>3</sup> 15 minutes. TWA: 10 mg/m <sup>3</sup> 8 hours.

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

**Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

**DNELs/DMELs**

Product/ingredient name	Type	Exposure	Value	Population	Effects
<b>INNOVANCE® D-Dimer Calibrator</b> sodium azide  reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	DNEL	Long term Oral	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	29 µg/m³	General population	Systemic
	DNEL	Long term Dermal	46.7 µg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	0.164 mg/m³	Workers	Systemic
	DNEL	Long term Inhalation	0.02 mg/m³	General population	Local
	DNEL	Long term Inhalation	0.02 mg/m³	Workers	Local
	DNEL	Short term Inhalation	0.04 mg/m³	General population	Local
	DNEL	Short term Inhalation	0.04 mg/m³	Workers	Local
	DNEL	Long term Oral	0.09 mg/kg bw/day	General population	Systemic
	DNEL	Short term Oral	0.11 mg/kg bw/day	General population	Systemic
<b>INNOVANCE® D-Dimer Sample Diluent</b> imidazole  sodium azide	DNEL	Long term Dermal	1.5 mg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	10.6 mg/m³	Workers	Systemic
	DNEL	Long term Oral	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	16.7 µg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	29 µg/m³	General population	Systemic
	DNEL	Long term Dermal	46.7 µg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	0.164 mg/m³	Workers	Systemic
<b>INNOVANCE® D-Dimer Reagent</b> imidazole	DNEL	Long term Dermal	1.5 mg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	10.6 mg/m³	Workers	Systemic

**PNECs**

No PNECs available

## SECTION 8: Exposure controls/personal protection

### 8.2 Exposure controls

**Appropriate engineering controls** : If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

### Individual protection measures

**Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

### Skin protection

**Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

**Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

**Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

## SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

### 9.1 Information on basic physical and chemical properties

#### Appearance

<b>Physical state</b>	: INNOVANCE® D-Dimer Buffer	Liquid.
	INNOVANCE® D-Dimer Calibrator	Solid.
	INNOVANCE® D-Dimer Sample Diluent	Liquid.
	INNOVANCE® D-Dimer Reagent	Solid.
	INNOVANCE® D-Dimer Supplementary Reagent	Liquid.
<b>Colour</b>	: INNOVANCE® D-Dimer Buffer	Colourless.
	INNOVANCE® D-Dimer Calibrator	White to light yellow.
	INNOVANCE® D-Dimer Sample Diluent	Colourless.
	INNOVANCE® D-Dimer Reagent	White.
	INNOVANCE® D-Dimer Supplementary Reagent	Colourless.

**SECTION 9: Physical and chemical properties**

<b>Odour</b>	: INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Odourless.
	INNOVANCE® D-Dimer Sample	Not available.
	Diluent	
	INNOVANCE® D-Dimer Reagent	Odourless.
	INNOVANCE® D-Dimer	Odourless.
	Supplementary Reagent	
<b>Odour threshold</b>	: Not relevant/applicable due to nature of the product.	
<b>Melting point/freezing point</b>	: Not relevant/applicable due to nature of the product.	
<b>Softening point</b>	: Not relevant/applicable due to nature of the product.	
<b>Sublimation temperature</b>	: Not relevant/applicable due to nature of the product.	
<b>Initial boiling point and boiling range</b>	: INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample	Not available.
	Diluent	
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Flammability (solid, gas)</b>	: INNOVANCE® D-Dimer Buffer	Not relevant/applicable due to nature of the product.
	INNOVANCE® D-Dimer Calibrator	Not relevant/applicable due to nature of the product.
	INNOVANCE® D-Dimer Sample	Not relevant/applicable due to nature of the product.
	Diluent	Not relevant/applicable due to nature of the product.
	INNOVANCE® D-Dimer Reagent	Not relevant/applicable due to nature of the product.
	INNOVANCE® D-Dimer Supplementary Reagent	Not relevant/applicable due to nature of the product.
<b>Upper/lower flammability or explosive limits</b>	: INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not applicable.
	INNOVANCE® D-Dimer Sample	Not available.
	Diluent	
	INNOVANCE® D-Dimer Reagent	Not applicable.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Flash point</b>	: INNOVANCE® D-Dimer Buffer	[Product does not sustain combustion.]
	INNOVANCE® D-Dimer Calibrator	[Product does not sustain combustion.]
	INNOVANCE® D-Dimer Sample	[Product does not sustain combustion.]
	Diluent	
	INNOVANCE® D-Dimer Reagent	[Product does not sustain combustion.]
	INNOVANCE® D-Dimer Supplementary Reagent	[Product does not sustain combustion.]

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
INNOVANCE® D-Dimer Buffer imidazole	>135	>275				
INNOVANCE® D-Dimer Sample Diluent imidazole	>135	>275				

Auto-ignition temperature :

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**SECTION 9: Physical and chemical properties**

Ingredient name	°C	°F	Method
<b>INNOVANCE® D-Dimer Buffer</b>			
sodium azide	309	588.2	EU A.16
<b>INNOVANCE® D-Dimer Sample Diluent</b>			
sodium azide	309	588.2	EU A.16
<b>INNOVANCE® D-Dimer Supplementary Reagent</b>			
sodium azide	309	588.2	EU A.16

**Decomposition temperature** : Not relevant/applicable due to nature of the product.

**pH** : INNOVANCE® D-Dimer Buffer 7  
 INNOVANCE® D-Dimer Calibrator Not applicable.  
 INNOVANCE® D-Dimer Sample Diluent 7  
 INNOVANCE® D-Dimer Reagent Not applicable.  
 INNOVANCE® D-Dimer Supplementary Reagent 7.1

**Viscosity** : INNOVANCE® D-Dimer Buffer Not available.  
 INNOVANCE® D-Dimer Calibrator Not applicable.  
 INNOVANCE® D-Dimer Sample Diluent Not available.  
 INNOVANCE® D-Dimer Reagent Not applicable.  
 INNOVANCE® D-Dimer Supplementary Reagent Not available.

**Solubility(ies)** :  
 Not available.

**Solubility in water** : Not relevant/applicable due to nature of the product.**Miscible with water** : Not relevant/applicable due to nature of the product.**Partition coefficient: n-octanol/ water** : Not relevant/applicable due to nature of the product.**Vapour pressure** :

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
<b>INNOVANCE® D-Dimer Buffer</b>						
water	23.8	3.2				
<b>INNOVANCE® D-Dimer Sample Diluent</b>						
water	23.8	3.2				
<b>INNOVANCE® D-Dimer Supplementary Reagent</b>						
water	23.8	3.2				

**Evaporation rate** : Not relevant/applicable due to nature of the product.

**Relative density** : INNOVANCE® D-Dimer Buffer 1.017  
 INNOVANCE® D-Dimer Calibrator Not available.  
 INNOVANCE® D-Dimer Sample Diluent 1.025  
 INNOVANCE® D-Dimer Reagent Not available.  
 INNOVANCE® D-Dimer Supplementary Reagent 1.026

**SECTION 9: Physical and chemical properties**

<b>Density</b>	: INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Vapour density</b>	: INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not applicable.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Not applicable.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Explosive properties</b>	: INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Non-explosive in the presence of the following materials or conditions: open flames, sparks and static discharge and oxidising materials.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Explosive in the presence of the following materials or conditions: oxidising materials.
		Non-explosive in the presence of the following materials or conditions: open flames, sparks and static discharge.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Oxidising properties</b>	: INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b><u>Particle characteristics</u></b>		
<b>Median particle size</b>	: Not applicable.	
<b>Shape</b>	: INNOVANCE® D-Dimer Buffer	Not applicable.
	INNOVANCE® D-Dimer Calibrator	
	INNOVANCE® D-Dimer Sample Diluent	Not applicable.
	INNOVANCE® D-Dimer Reagent	
	INNOVANCE® D-Dimer Supplementary Reagent	Not applicable.
<b>Crystallinity</b>	: INNOVANCE® D-Dimer Buffer	Not applicable.
	INNOVANCE® D-Dimer Calibrator	
	INNOVANCE® D-Dimer Sample Diluent	Not applicable.
	INNOVANCE® D-Dimer Reagent	
	INNOVANCE® D-Dimer Supplementary Reagent	Not applicable.
<b>Additional information</b>	: INNOVANCE® D-Dimer Buffer	Not applicable.
	INNOVANCE® D-Dimer Calibrator	
	INNOVANCE® D-Dimer Sample Diluent	Not applicable.
	INNOVANCE® D-Dimer Reagent	
	INNOVANCE® D-Dimer Supplementary Reagent	Not applicable.

**9.2 Other information**



**SECTION 9: Physical and chemical properties**

<b>Fire point</b>	: INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample	Not available.
	Diluent	
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer	Not available.
	Supplementary Reagent	
<b>Burning time</b>	: Not relevant/applicable due to nature of the product.	
<b>Fundamental burning velocity</b>	: Not relevant/applicable due to nature of the product.	
<b>Burning rate</b>	: Not relevant/applicable due to nature of the product.	
<b>SADT</b>	: Not relevant/applicable due to nature of the product.	
<b>SAPT</b>	: Not relevant/applicable due to nature of the product.	
<b>Heat of reaction</b>	: Not relevant/applicable due to nature of the product.	
<b>Heat of combustion</b>	: Not relevant/applicable due to nature of the product.	
<b>Flow time (ISO 2431)</b>	: Not relevant/applicable due to nature of the product.	
<b>Molecular weight</b>	: Not relevant/applicable due to nature of the product.	

**SECTION 10: Stability and reactivity**

<b>10.1 Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>10.2 Chemical stability</b>	: The product is stable.
<b>10.3 Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>10.4 Conditions to avoid</b>	: No specific data.
<b>10.5 Incompatible materials</b>	: No specific data.
<b>10.6 Hazardous decomposition products</b>	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

**SECTION 11: Toxicological information****11.1 Information on toxicological effects****Acute toxicity**

Product/ingredient name	Result	Species	Dose	Exposure
<b>INNOVANCE® D-Dimer Calibrator</b> sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-
	LD50 Oral	Rat	53 mg/kg	-
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)				
<b>INNOVANCE® D-Dimer Sample Diluent</b> imidazole	LD50 Oral	Rat	220 mg/kg	-
sodium azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-

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<b>INNOVANCE® D-Dimer Reagent</b> sucrose imidazole	LD50 Oral LD50 Oral	Rat Rat	29700 mg/kg 220 mg/kg	- -
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**Conclusion/Summary** : INNOVANCE® D-Dimer Buffer Not available.  
 INNOVANCE® D-Dimer Calibrator Not available.  
 INNOVANCE® D-Dimer Sample Diluent Not available.  
 INNOVANCE® D-Dimer Reagent Not available.  
 INNOVANCE® D-Dimer Supplementary Reagent Not available.

**Acute toxicity estimates**

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
<b>INNOVANCE® D-Dimer Calibrator</b> INNOVANCE® D-Dimer Calibrator sodium azide reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	3350 27 53	2481.5 20 50	N/A N/A N/A	N/A N/A 0.5	N/A N/A N/A
<b>INNOVANCE® D-Dimer Sample Diluent</b> imidazole sodium azide	500 27	N/A 20	N/A N/A	N/A N/A	N/A N/A
<b>INNOVANCE® D-Dimer Reagent</b> INNOVANCE® D-Dimer Reagent sucrose imidazole	10395 29700 500	N/A N/A N/A	N/A N/A N/A	N/A N/A N/A	N/A N/A N/A

**Irritation/Corrosion**

Product/ingredient name	Result	Species	Score	Exposure	Observation
<b>INNOVANCE® D-Dimer Calibrator</b> reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	Skin - Severe irritant	Human	-	0.01 %	-
<b>INNOVANCE® D-Dimer Sample Diluent</b> imidazole	Eyes - Moderate irritant	Rabbit	-	168 hours 105 mg	-
<b>INNOVANCE® D-Dimer Reagent</b> imidazole	Eyes - Moderate irritant	Rabbit	-	168 hours 105 mg	-

**Conclusion/Summary**

**Skin** : INNOVANCE® D-Dimer Buffer Not available.  
 INNOVANCE® D-Dimer Calibrator Not available.  
 INNOVANCE® D-Dimer Sample Diluent Not available.  
 INNOVANCE® D-Dimer Reagent Not available.  
 INNOVANCE® D-Dimer Supplementary Reagent Not available.

**SECTION 11: Toxicological information**

<b>Eyes</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
		INNOVANCE® D-Dimer Calibrator	Not available.
		INNOVANCE® D-Dimer Sample Diluent	Not available.
		INNOVANCE® D-Dimer Reagent	Not available.
		INNOVANCE® D-Dimer Supplementary Reagent	Not available.

<b>Respiratory</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
		INNOVANCE® D-Dimer Calibrator	Not available.
		INNOVANCE® D-Dimer Sample Diluent	Not available.
		INNOVANCE® D-Dimer Reagent	Not available.
		INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**Sensitisation****Conclusion/Summary**

<b>Skin</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
		INNOVANCE® D-Dimer Calibrator	Not available.
		INNOVANCE® D-Dimer Sample Diluent	Not available.
		INNOVANCE® D-Dimer Reagent	Not available.
		INNOVANCE® D-Dimer Supplementary Reagent	Not available.

<b>Respiratory</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
		INNOVANCE® D-Dimer Calibrator	Not available.
		INNOVANCE® D-Dimer Sample Diluent	Not available.
		INNOVANCE® D-Dimer Reagent	Not available.
		INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**Mutagenicity****Conclusion/Summary**

:	INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**Carcinogenicity****Conclusion/Summary**

:	INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**Reproductive toxicity****Conclusion/Summary**

:	INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**Teratogenicity****Conclusion/Summary**

:	INNOVANCE® D-Dimer Buffer	Not available.
	INNOVANCE® D-Dimer Calibrator	Not available.
	INNOVANCE® D-Dimer Sample Diluent	Not available.
	INNOVANCE® D-Dimer Reagent	Not available.
	INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**Specific target organ toxicity (single exposure)**

Not available.

**Specific target organ toxicity (repeated exposure)**

Not available.

**SECTION 11: Toxicological information****Aspiration hazard**

Not available.

**Information on likely routes of exposure** : INNOVANCE® D-Dimer Buffer Not available.  
 INNOVANCE® D-Dimer Calibrator Not available.  
 INNOVANCE® D-Dimer Sample Diluent Not available.  
 INNOVANCE® D-Dimer Reagent Not available.  
 INNOVANCE® D-Dimer Supplementary Reagent Not available.

**Potential acute health effects**

**Eye contact** : INNOVANCE® D-Dimer Buffer No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Calibrator No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Sample Diluent No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Reagent Causes serious eye damage.  
 INNOVANCE® D-Dimer Supplementary Reagent No known significant effects or critical hazards.

**Inhalation** : INNOVANCE® D-Dimer Buffer No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Calibrator No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Sample Diluent No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Reagent No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Supplementary Reagent No known significant effects or critical hazards.

**Skin contact** : INNOVANCE® D-Dimer Buffer No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Calibrator May cause an allergic skin reaction.  
 INNOVANCE® D-Dimer Sample Diluent No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Reagent Causes skin irritation.  
 INNOVANCE® D-Dimer Supplementary Reagent No known significant effects or critical hazards.

**Ingestion** : INNOVANCE® D-Dimer Buffer No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Calibrator No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Sample Diluent No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Reagent No known significant effects or critical hazards.  
 INNOVANCE® D-Dimer Supplementary Reagent No known significant effects or critical hazards.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Eye contact** : INNOVANCE® D-Dimer Buffer No specific data.  
 INNOVANCE® D-Dimer Calibrator No specific data.  
 INNOVANCE® D-Dimer Sample Diluent No specific data.  
 INNOVANCE® D-Dimer Reagent Adverse symptoms may include the following:  
 pain  
 watering  
 redness  
 INNOVANCE® D-Dimer Supplementary Reagent No specific data.

**SECTION 11: Toxicological information**

<b>Inhalation</b>	:	INNOVANCE® D-Dimer Buffer	No specific data.
	:	INNOVANCE® D-Dimer Calibrator	No specific data.
	:	INNOVANCE® D-Dimer Sample Diluent	No specific data.
	:	INNOVANCE® D-Dimer Reagent	No specific data.
	:	INNOVANCE® D-Dimer Supplementary Reagent	No specific data.
<b>Skin contact</b>	:	INNOVANCE® D-Dimer Buffer	No specific data.
	:	INNOVANCE® D-Dimer Calibrator	Adverse symptoms may include the following: irritation redness
	:	INNOVANCE® D-Dimer Sample Diluent	No specific data.
	:	INNOVANCE® D-Dimer Reagent	Adverse symptoms may include the following: pain or irritation redness blistering may occur
	:	INNOVANCE® D-Dimer Supplementary Reagent	No specific data.
<b>Ingestion</b>	:	INNOVANCE® D-Dimer Buffer	No specific data.
	:	INNOVANCE® D-Dimer Calibrator	No specific data.
	:	INNOVANCE® D-Dimer Sample Diluent	No specific data.
	:	INNOVANCE® D-Dimer Reagent	Adverse symptoms may include the following: stomach pains
	:	INNOVANCE® D-Dimer Supplementary Reagent	No specific data.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Short term exposure**

<b>Potential immediate effects</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
	:	INNOVANCE® D-Dimer Calibrator	Not available.
	:	INNOVANCE® D-Dimer Sample Diluent	Not available.
	:	INNOVANCE® D-Dimer Reagent	Not available.
	:	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Potential delayed effects</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
	:	INNOVANCE® D-Dimer Calibrator	Not available.
	:	INNOVANCE® D-Dimer Sample Diluent	Not available.
	:	INNOVANCE® D-Dimer Reagent	Not available.
	:	INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**Long term exposure**

<b>Potential immediate effects</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
	:	INNOVANCE® D-Dimer Calibrator	Not available.
	:	INNOVANCE® D-Dimer Sample Diluent	Not available.
	:	INNOVANCE® D-Dimer Reagent	Not available.
	:	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Potential delayed effects</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
	:	INNOVANCE® D-Dimer Calibrator	Not available.
	:	INNOVANCE® D-Dimer Sample Diluent	Not available.
	:	INNOVANCE® D-Dimer Reagent	Not available.
	:	INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**Potential chronic health effects**

Not available.

**SECTION 11: Toxicological information**

<b>Conclusion/Summary</b>	: INNOVANCE® D-Dimer Buffer INNOVANCE® D-Dimer Calibrator INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	Not available. Not available. Not available. Not available. Not available.
<b>General</b>	: INNOVANCE® D-Dimer Buffer  INNOVANCE® D-Dimer Calibrator  INNOVANCE® D-Dimer Sample Diluent  INNOVANCE® D-Dimer Reagent  INNOVANCE® D-Dimer Supplementary Reagent	No known significant effects or critical hazards. Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
<b>Carcinogenicity</b>	: INNOVANCE® D-Dimer Buffer  INNOVANCE® D-Dimer Calibrator  INNOVANCE® D-Dimer Sample Diluent  INNOVANCE® D-Dimer Reagent  INNOVANCE® D-Dimer Supplementary Reagent	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
<b>Mutagenicity</b>	: INNOVANCE® D-Dimer Buffer  INNOVANCE® D-Dimer Calibrator  INNOVANCE® D-Dimer Sample Diluent  INNOVANCE® D-Dimer Reagent  INNOVANCE® D-Dimer Supplementary Reagent	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
<b>Reproductive toxicity</b>	: INNOVANCE® D-Dimer Buffer  INNOVANCE® D-Dimer Calibrator  INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	No known significant effects or critical hazards. No known significant effects or critical hazards. May damage the unborn child. May damage the unborn child. No known significant effects or critical hazards.
<b>Interactive effects</b>	: INNOVANCE® D-Dimer Buffer INNOVANCE® D-Dimer Calibrator INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	Not available. Not available. Not available. Not available. Not available.
<b><u>Toxicokinetics</u></b>		
<b>Absorption</b>	: INNOVANCE® D-Dimer Buffer INNOVANCE® D-Dimer Calibrator INNOVANCE® D-Dimer Sample Diluent INNOVANCE® D-Dimer Reagent INNOVANCE® D-Dimer Supplementary Reagent	Not available. Not available. Not available. Not available. Not available.

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**SECTION 11: Toxicological information**

<b>Distribution</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
	:	INNOVANCE® D-Dimer Calibrator	Not available.
	:	INNOVANCE® D-Dimer Sample Diluent	Not available.
	:	INNOVANCE® D-Dimer Reagent	Not available.
	:	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Metabolism</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
	:	INNOVANCE® D-Dimer Calibrator	Not available.
	:	INNOVANCE® D-Dimer Sample Diluent	Not available.
	:	INNOVANCE® D-Dimer Reagent	Not available.
	:	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Elimination</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
	:	INNOVANCE® D-Dimer Calibrator	Not available.
	:	INNOVANCE® D-Dimer Sample Diluent	Not available.
	:	INNOVANCE® D-Dimer Reagent	Not available.
	:	INNOVANCE® D-Dimer Supplementary Reagent	Not available.
<b>Other information</b>	:	INNOVANCE® D-Dimer Buffer	Not available.
	:	INNOVANCE® D-Dimer Calibrator	Not available.
	:	INNOVANCE® D-Dimer Sample Diluent	Not available.
	:	INNOVANCE® D-Dimer Reagent	Not available.
	:	INNOVANCE® D-Dimer Supplementary Reagent	Not available.

**SECTION 12: Ecological information****12.1 Toxicity**

Product/ingredient name	Result	Species	Exposure
<b>INNOVANCE® D-Dimer Calibrator</b> sodium azide	Acute EC50 9200 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours
	Acute EC50 6.4 mg/l Fresh water	Crustaceans - Water flea - Simocephalus serrulatus - Larvae	48 hours
	Acute EC50 4.2 mg/l Fresh water	Daphnia - Water flea - Daphnia pulex - Larvae	48 hours
	Acute LC50 0.68 mg/l Fresh water	Fish - Bluegill - Lepomis macrochirus	96 hours
	Chronic NOEC 5600 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours
<b>INNOVANCE® D-Dimer Sample Diluent</b> sodium azide	Acute EC50 9200 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours
	Acute EC50 6.4 mg/l Fresh water	Crustaceans - Water flea - Simocephalus serrulatus - Larvae	48 hours
	Acute EC50 4.2 mg/l Fresh water	Daphnia - Water flea - Daphnia pulex - Larvae	48 hours
	Acute LC50 0.68 mg/l Fresh water	Fish - Bluegill - Lepomis macrochirus	96 hours
	Chronic NOEC 5600 µg/l Marine water	Algae - Giant kelp - Macrocystis pyrifera	96 hours

INNOVANCE® D-Dimer

**SECTION 12: Ecological information**

**Conclusion/Summary** : INNOVANCE® D-Dimer Buffer Not available.  
 INNOVANCE® D-Dimer Calibrator Not available.  
 INNOVANCE® D-Dimer Sample Diluent Not available.  
 INNOVANCE® D-Dimer Reagent Not available.  
 INNOVANCE® D-Dimer Supplementary Reagent Not available.

**12.2 Persistence and degradability**

**Conclusion/Summary** : INNOVANCE® D-Dimer Buffer Not available.  
 INNOVANCE® D-Dimer Calibrator Not available.  
 INNOVANCE® D-Dimer Sample Diluent Not available.  
 INNOVANCE® D-Dimer Reagent Not available.  
 INNOVANCE® D-Dimer Supplementary Reagent Not available.

**12.3 Bioaccumulative potential**

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
<b>INNOVANCE® D-Dimer Sample Diluent</b> imidazole	-0.02	-	low
<b>INNOVANCE® D-Dimer Reagent</b> imidazole	-0.02	-	low

**12.4 Mobility in soil**

**Soil/water partition coefficient (K<sub>oc</sub>)** : INNOVANCE® D-Dimer Buffer Not available.  
 INNOVANCE® D-Dimer Calibrator Not available.  
 INNOVANCE® D-Dimer Sample Diluent Not available.  
 INNOVANCE® D-Dimer Reagent Not available.  
 INNOVANCE® D-Dimer Supplementary Reagent Not available.

**Mobility** : INNOVANCE® D-Dimer Buffer Not available.  
 INNOVANCE® D-Dimer Calibrator Not available.  
 INNOVANCE® D-Dimer Sample Diluent Not available.  
 INNOVANCE® D-Dimer Reagent Not available.  
 INNOVANCE® D-Dimer Supplementary Reagent Not available.

**12.5 Results of PBT and vPvB assessment**

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

**12.6 Other adverse effects** : No known significant effects or critical hazards.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods****Product**

**Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

**Hazardous waste** : The classification of the product may meet the criteria for a hazardous waste.



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**SECTION 13: Disposal considerations**

Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

**Packaging**

- Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.
- Special precautions** : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

**SECTION 14: Transport information****ADR/RID**

<b>14.1 UN number</b>	INNOVANCE® D-Dimer Buffer	Not regulated.
	INNOVANCE® D-Dimer Calibrator	Not regulated.
	INNOVANCE® D-Dimer Sample Diluent	Not regulated.
	INNOVANCE® D-Dimer Reagent	Not regulated.
	INNOVANCE® D-Dimer Supplementary Reagent	Not regulated.
<b>14.2 UN proper shipping name</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.3 Transport hazard class(es)</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.4 Packing group</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.5 Environmental hazards</b>	INNOVANCE® D-Dimer Buffer	No.
	INNOVANCE® D-Dimer Calibrator	No.
	INNOVANCE® D-Dimer Sample Diluent	No.
	INNOVANCE® D-Dimer Reagent	No.
	INNOVANCE® D-Dimer Supplementary Reagent	No.
<b>Additional information</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-

**ADN****14.1 UN number**

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**SECTION 14: Transport information**

	INNOVANCE® D-Dimer Buffer	Not regulated.
	INNOVANCE® D-Dimer Calibrator	Not regulated.
	INNOVANCE® D-Dimer Sample Diluent	Not regulated.
	INNOVANCE® D-Dimer Reagent	Not regulated.
	INNOVANCE® D-Dimer Supplementary Reagent	Not regulated.
<b>14.2 UN proper shipping name</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.3 Transport hazard class(es)</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.4 Packing group</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.5 Environmental hazards</b>	INNOVANCE® D-Dimer Buffer	No.
	INNOVANCE® D-Dimer Calibrator	No.
	INNOVANCE® D-Dimer Sample Diluent	No.
	INNOVANCE® D-Dimer Reagent	No.
	INNOVANCE® D-Dimer Supplementary Reagent	No.
<b>Additional information</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>IMDG</b>		
<b>14.1 UN number</b>	INNOVANCE® D-Dimer Buffer	Not regulated.
	INNOVANCE® D-Dimer Calibrator	Not regulated.
	INNOVANCE® D-Dimer Sample Diluent	Not regulated.
	INNOVANCE® D-Dimer Reagent	Not regulated.
	INNOVANCE® D-Dimer Supplementary Reagent	Not regulated.
<b>14.2 UN proper shipping name</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.3 Transport hazard class(es)</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-

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**SECTION 14: Transport information**

<b>14.4 Packing group</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.5 Environmental hazards</b>	INNOVANCE® D-Dimer Buffer	No.
	INNOVANCE® D-Dimer Calibrator	No.
	INNOVANCE® D-Dimer Sample Diluent	No.
	INNOVANCE® D-Dimer Reagent	No.
	INNOVANCE® D-Dimer Supplementary Reagent	No.
<b>Additional information</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-

**IATA**

<b>14.1 UN number</b>	INNOVANCE® D-Dimer Buffer	Not regulated.
	INNOVANCE® D-Dimer Calibrator	Not regulated.
	INNOVANCE® D-Dimer Sample Diluent	Not regulated.
	INNOVANCE® D-Dimer Reagent	Not regulated.
	INNOVANCE® D-Dimer Supplementary Reagent	Not regulated.
<b>14.2 UN proper shipping name</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.3 Transport hazard class(es)</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.4 Packing group</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-
<b>14.5 Environmental hazards</b>	INNOVANCE® D-Dimer Buffer	No.
	INNOVANCE® D-Dimer Calibrator	No.
	INNOVANCE® D-Dimer Sample Diluent	No.
	INNOVANCE® D-Dimer Reagent	No.
	INNOVANCE® D-Dimer Supplementary Reagent	No.

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**SECTION 14: Transport information**

<b>Additional information</b>	INNOVANCE® D-Dimer Buffer	-
	INNOVANCE® D-Dimer Calibrator	-
	INNOVANCE® D-Dimer Sample Diluent	-
	INNOVANCE® D-Dimer Reagent	-
	INNOVANCE® D-Dimer Supplementary Reagent	-

**14.6 Special precautions for user** : INNOVANCE® D-Dimer Buffer

INNOVANCE® D-Dimer Calibrator

INNOVANCE® D-Dimer Sample Diluent

INNOVANCE® D-Dimer Reagent

INNOVANCE® D-Dimer Supplementary Reagent

**Transport within user's premises:**

always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport within user's premises:**

always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport within user's premises:**

always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport within user's premises:**

always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport within user's premises:**

always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**14.7 Transport in bulk according to IMO instruments** : Not applicable.

**SECTION 15: Regulatory information**

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

**UK (GB) /REACH****Annex XIV - List of substances subject to authorisation****Annex XIV**

None of the components are listed.

**Substances of very high concern**

None of the components are listed.

**Ozone depleting substances**

Not listed.

**Prior Informed Consent (PIC)**

Not listed.

**Persistent Organic Pollutants**

INNOVANCE® D-Dimer

**SECTION 15: Regulatory information**

Not listed.

<b>Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles</b>	: INNOVANCE® D-Dimer Buffer	Not applicable.
	INNOVANCE® D-Dimer Calibrator	Not applicable.
	INNOVANCE® D-Dimer Sample Diluent	Restricted to professional users.
	INNOVANCE® D-Dimer Reagent	Restricted to professional users.
	INNOVANCE® D-Dimer Supplementary Reagent	Not applicable.

**Seveso Directive**

This product is not controlled under the Seveso Directive.

**National regulations****EU regulations**

<b>Industrial emissions (integrated pollution prevention and control) - Air</b>	: INNOVANCE® D-Dimer Buffer	Not listed
	INNOVANCE® D-Dimer Calibrator	Not listed
	INNOVANCE® D-Dimer Sample Diluent	Not listed
	INNOVANCE® D-Dimer Reagent	Not listed
	INNOVANCE® D-Dimer Supplementary Reagent	Not listed
<b>Industrial emissions (integrated pollution prevention and control) - Water</b>	: INNOVANCE® D-Dimer Buffer	Not listed
	INNOVANCE® D-Dimer Calibrator	Not listed
	INNOVANCE® D-Dimer Sample Diluent	Not listed
	INNOVANCE® D-Dimer Reagent	Not listed
	INNOVANCE® D-Dimer Supplementary Reagent	Not listed

**International regulations****Montreal Protocol**

Not listed.

**Stockholm Convention on Persistent Organic Pollutants**

Not listed.

**Rotterdam Convention on Prior Informed Consent (PIC)**

Not listed.

**UNECE Aarhus Protocol on POPs and Heavy Metals**

Not listed.

**15.2 Chemical safety assessment** : Not applicable.

**SECTION 16: Other information**

Indicates information that has changed from previously issued version.

<b>Abbreviations and acronyms</b>	: ATE = Acute Toxicity Estimate
	GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
	DMEL = Derived Minimal Effect Level
	DNEL = Derived No Effect Level
	EUH statement = GB CLP-specific Hazard statement
	N/A = Not available
	PBT = Persistent, Bioaccumulative and Toxic
	PNEC = Predicted No Effect Concentration
	RRN = REACH Registration Number
	SGG = Segregation Group
	vPvB = Very Persistent and Very Bioaccumulative

**Procedure used to derive the classification**

INNOVANCE® D-Dimer

**SECTION 16: Other information**

Classification	Justification
<b>INNOVANCE® D-Dimer Calibrator</b> Skin Sens. 1, H317 Aquatic Chronic 3, H412	Calculation method Calculation method
<b>INNOVANCE® D-Dimer Sample Diluent</b> Repr. 1B, H360D	Calculation method
<b>INNOVANCE® D-Dimer Reagent</b> Skin Irrit. 2, H315 Eye Dam. 1, H318 Repr. 1B, H360D	Calculation method Calculation method Calculation method

**Full text of abbreviated H statements**

<b>INNOVANCE®</b> <b>D-Dimer</b> <b>Calibrator</b> H300 Fatal if swallowed. H301 Toxic if swallowed. H310 Fatal in contact with skin. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H330 Fatal if inhaled. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects. EUH032 Contact with acids liberates very toxic gas. EUH071 Corrosive to the respiratory tract.	
<b>INNOVANCE®</b> <b>D-Dimer</b> <b>Sample</b> <b>Diluent</b> H300 Fatal if swallowed. H302 Harmful if swallowed. H310 Fatal in contact with skin. H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage. H360D May damage the unborn child. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. EUH032 Contact with acids liberates very toxic gas.	
<b>INNOVANCE®</b> <b>D-Dimer</b> <b>Reagent</b> H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H318 Causes serious eye damage. H360D May damage the unborn child.	

**Full text of classifications**

**SECTION 16: Other information****INNOVANCE® D-Dimer Calibrator**

Acute Tox. 1	ACUTE TOXICITY - Category 1
Acute Tox. 2	ACUTE TOXICITY - Category 2
Acute Tox. 3	ACUTE TOXICITY - Category 3
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 3	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Skin Corr. 1C	SKIN CORROSION/IRRITATION - Category 1C
Skin Sens. 1	SKIN SENSITISATION - Category 1
Skin Sens. 1A	SKIN SENSITISATION - Category 1A

**INNOVANCE® D-Dimer Sample Diluent**

Acute Tox. 1	ACUTE TOXICITY - Category 1
Acute Tox. 2	ACUTE TOXICITY - Category 2
Acute Tox. 4	ACUTE TOXICITY - Category 4
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Repr. 1B	REPRODUCTIVE TOXICITY - Category 1B
Skin Corr. 1C	SKIN CORROSION/IRRITATION - Category 1C

**INNOVANCE® D-Dimer Reagent**

Acute Tox. 4	ACUTE TOXICITY - Category 4
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Repr. 1B	REPRODUCTIVE TOXICITY - Category 1B
Skin Corr. 1C	SKIN CORROSION/IRRITATION - Category 1C
Skin Irrit. 2	SKIN CORROSION/IRRITATION - Category 2

**Date of printing** : 2/20/2023**Date of issue/ Date of revision** : 2/20/2023**Date of previous issue** : 12/13/2022**Version** : 1.01**Notice to reader**

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

