

INNOVANCE D-Dimer Controls –

missing hazards and precautionary statements on product labeling



Urgent Field Safety Notice

PH-22-005-A-C OUS

April 2022

**INNOVANCE® D-Dimer Controls –
missing hazards and precautionary statements on product labeling**

Our records indicate that your facility may have received the following product:

Table 1. INNOVANCE D-Dimer Controls Affected Product(s)

Consumable	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Expiration Date	Manufacturing / 1 st Distribution Date
INNOVANCE D-Dimer Control 1	10446005	0405686900175V7	562293	All lots in shelf-life up to	
INNOVANCE D-Dimer Control 2			562193	2024-03-07	2022-03-08

Reason for Correction

The purpose of this communication is to inform you about the potential risk of allergic skin reactions in case of direct skin contact with the products listed in Table1 above, and to provide instructions on actions that your laboratory must take to avoid this risk.

Siemens Healthineers has initiated an update of the Safety Data Sheets and product labeling elements to comply with European REACH Regulation Article 31 and EU REGULATION 2018/1480 regarding this risk, and first lots with updated labeling are expected to be available in summer 2022.

For immediate risk mitigation, we would like to provide you with the hazards and precautionary statements which should be considered when using INNOVANCE D-Dimer Controls:

Hazard pictogram



Signal Word

Warning

Hazard Statements

H317 – May cause an allergic skin reaction.

H412 – Harmful to aquatic life with long lasting effects.

Prevention Statements

Prevention

P261 – Avoid breathing dust.

P280 – Wear protective gloves / protective clothing/eye protection/face protection.

P273 – Avoid release to the environment.

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Response	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.
Disposal	P501 – Dispose of contents and container in accordance with all local, regional and national regulations.
Hazardous ingredients	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) (also known as Chlormethylisothiazolinon (CMIT or CMI) or methylisothiazolinon (MIT or MI))

Risk to Health

A low health risk is given as a priming sensitization could be triggered by the INNOVANCE D-Dimer Controls. Nevertheless, the possible allergic reaction is reversible.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Independent of the labeling, please consider the provided prevention and response hazards when using INNOVANCE D-Dimer Controls:
 - Prevention P261 – Avoid breathing dust.

P280 – Wear protective gloves / protective clothing/eye protection/face protection.

P273 – Avoid release to the environment.
 - Response 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.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

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We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

This letter was created electronically and is valid without signature

XXX

XXX

INNOVANCE is a trademark of Siemens Healthcare Diagnostics.

**INNOVANCE D-Dimer Controls –
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FIELD CORRECTION EFFECTIVENESS CHECK**

INNOVANCE D-Dimer Controls – missing hazards and precautionary statements on product labeling]

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice PH-22-005-A-C OUS Number dated April 2022 regarding INNOVANCE D-Dimer Controls – missing hazards and precautionary statements on product labeling. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided Yes No
in this letter.

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to XXXX@XXX (for the OUS letter the information will be filled in by the region).

Or to fax this completed form to the Customer Care Center at XXXXXX (for the OUS letter the information will be filled in by the region) delete the Not Applicable text in yellow prior to sending.

If you have any questions, contact your local Siemens Healthineers technical support representative.