

Date: 4 December 2023, United Kingdom

Urgent Medical Device Field Safety Notice

Amity Ltd FSCA Reference: 255

To: Distributors and Hospitals

Affected Product: Virusolve+® Concentrate and Virusolve+® Ready To Use



Amity Ltd. is conducting a voluntary medical device Field Safety Corrective Action for the products listed in Annex I.

As Amity is progressing to 2017/745 (EU) Medical Device Regulation we have commissioned tests to support our technical documentation according to updated requirements.

According to these tests, Virusolve+® Concentrate and Virusolve+® Ready To Use do not fulfil the requirements for the HLD (high level disinfection) claim and will therefore be removed from the market.

The Amity Virusolve+ Family is intended as being applicable to the high-level disinfection of medical and surgical instrument surfaces following initial cleaning.

Potential impact:

According to the risks assessment, in case the incorrect concentration of the Virusolve+ family products are used and infection from contaminated instruments or surfaces occur, further need of medical intervention might be indicated when the protection against spores, viruses and mycobacteria are expected.

Potential risks identified	
Immediate health consequences	None
Long range health consequences	Infection that may itself lead to further need of medical intervention.

Our records indicate that you have received one or more of the products from the scope listed in Annex I of this FSN.

Instructions for distributors and hospitals:

1. Please review and familiarize yourself with the content of this notice and inform any relevant stakeholders within your organization.
2. If you have any products listed in Annex I, please quarantine the product(s) and kindly return it to Amity Ltd through its sales representative.

3. Review, complete all fields, sign the Customer Acknowledgement Form **within 5 business days** of receipt of this field safety notice and return it to tech@aihc.co.uk. **Please return the completed and signed customer acknowledgment form also when you do not have any products listed in Annex I at your facility at the time of receipt of this notice.**
4. If any of the products listed in Annex I were sent, stored, consigned, or further distributed to other locations or facilities, please kindly contact that location, and forward this field safety notice.
5. Please retain a copy of this notice for your reference documentation and forward the communication to whom it may concern under your organization or affiliates.
6. In case of any questions, please contact tech@aihc.co.uk.

Please note that this field safety notice has been reported to relevant competent authorities. In case of any questions about this notice, please contact tech@aihc.co.uk

Amity Ltd. regrets the inconvenience caused to you by this action and would like to thank you for your co-operation in this matter.

We are kindly requesting you to acknowledge this notification by sending us back the reply form within 5 business days of receipt.

We thank you for your cooperation in the execution of this field safety corrective action.

Sincerely,



Clare Clark
Technical Manager

Field Safety Notice Customer Acknowledgement Form

Amity Ltd FSCA Reference: 255

Affected Product: Virusolve+® Concentrate and Virusolve+® Ready To Use

By signing this form, I confirm the receipt of this Field Safety Notice and that I read and understood its content.

Customer Details	
Company/Customer Name	
Company Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

Actions taken:

- The information and required actions have been brought to the attention of all relevant users and executed.
- I have returned the affected devices - enter number of devices returned and date of completion. A separate list of returned products may be provided if the space below is not sufficient to list all product concerned.

Qty:	Item Number:	Lot/Batch Number:	Date of return/destruction:

No further actions will be taken, all products in the scope of this field safety notice are consumed.

Completed and signed customer acknowledgment form must be returned to tech@aihc.co.uk within 5 business days of receipt. In case of any questions, you may contact: tech@aihc.co.uk.

IMPORTANT: Please complete, sign and return the form even when no product listed in Annex I of this field safety notice is available at your facility, because this is necessary for internal reporting and avoiding issues in the future.

Name, Surname: _____

Position, Title: _____

Date, Signature: _____

Annex I

1.1 Scope of FSCA 255

Amity Product	Amity Code	Pack Size	Batch Codes	
Virusolve+ Concentrate Dyed violet	J29CV	4 x 5L	OK040923	OK240523
			OK230622	OK270723
			OK240123	OK280722
Virusolve+ Concentrate Orchid	J29BDO	10 x 1L	OO080623	OO131022
	J29CO	4 x 5L	OO091222	OO270123
	J29EO	1 x 210L	OO100823	--
Virusolve+Lemon	J29ALE	4 x 2.5L	OR080623	OR111022
	J29CLE	4 x 5L	OR031022	OR250722
			OR080623	OR251022
			OR100823	OR260523
			OR171122	OR270123
			OR220323	OR290622
	J29FLE	1 x 1000L	OR100823	OR290622
Virusolve+ Concentrate Lavender	J29BDL	10 x 1L	OY021023	OY200723
			OY170223	OY230922
			OY180823	--
	J29AL	4 x 2.5L	OY071022	OY111022
			OY100623	OY171122
	J29CL	4 x 5L	OY021023	OY240622
			OY071022	OY250722
			OY100823	--
	J29FL	1000L	OY100623	OY130622
			OY100823	OY271023
Virusolve+ Concentrate	J29A	4 x 2.5L	OU041023	OU160923
			OU080922	OU170823
			OU090223	OU171122
			OU091222	OU200723
			OU100822	OU210323
			OU100123	OU230622
			OU120523	OU280623
			OU130623	--
	J29C	4 x 5L	OU041023	OU200723
			OU091222	OU230622
			OU120722	OU240622
			OU170223	OU251022
			OU170823	OU301122
	J29D	20/25L	OU041023	OU180823
			OU060623	OU200723
			OU100123	OU200922
			OU014591	OU210723
			OU170523	OU280823

Amity Product	Amity Code	Pack Size	Batch Codes	
Virusolve+ Ready to Use	J30TP	12 x 750ml	OV010823	OV151122
			OV020223	OV160523
			OV030323	OV160523
			OV050923	OV160623
			OV071022	OV191222
			OV100123	OV220523
			OV100123	OV220722
			OV120723	OV230323
			OV120822	--
	J30C	4 x 5L	OV100323	OV220923
			OV210922	OV240822
			OV220523	OV280623

1.2 UDI References

Basic UDI-DI	Amity Product Name	Amity Code	GMDN	EMDN	UDI-DI (GTIN 13)	UDI-DI (GTIN 14)
506072225AAA0008JY	Virusolve+ Concentrate	J29AAA	47631	D99	5060722250034	15060722250031
		J29A	47631	D99	5060722250058	15060722250055
		J29BD	47631	D99	5060722250041	15060722250048
		J29C	47631	D99	5060722250065	15060722250062
		J29D	47631	D99	5060722250089	
		J29E	47631	D99	5060722250096	
		J29F	47631	D99	5060722252267	
	Virusolve+ concentrate Dyed violet	J29CV	47631	D99	5060722250072	15060722250079
	Virusolve+ Concentrate Lavendar	J29AAL	47631	D99	5060722250102	15060722250109
		J29AL	47631	D99	5060722250126	15060722250123
		J29BDL	47631	D99	5060722250119	15060722250116
		J29CL	47631	D99	5060722250133	15060722250130
		J29DL	47631	D99	5060722250140	
		J29EL	47631	D99	5060722252571	
		J29FL	47631	D99	5060722252274	
	Virusolve+ Concentrate Lemon	J29ALE	47631	D99	5060722250164	15060722250161
		J29BDLE	47631	D99	5060722250157	15060722250154
		J29CLE	47631	D99	5060722250171	15060722250178
		J29DLE	47631	D99	5060722250188	
		J29ELE	47631	D99	5060722252366	
		J29FLE	47631	D99	5060722252397	
	Virusolve+ Conc. Orchid	J29BDO	47631	D99	5060722250195	15060722250192
		J29CO	47631	D99	5060722250201	15060722250208
		J29EO	47631	D99	5060722252588	
		J29FO	47631	D99	5060722252373	
		J29OA	47631	D99	5060722250218	15060722250215
	Virusolve+ RTU and Trigger Pack	J30A	47631	D99	5060722252595	15060722252592
		J30C	47631	D99	5060722250003	15060722250000
		J30D	47631	D99	5060722250010	
		J30E	47631	D99	5060722252502	
		J30F	47631	D99	5060722252519	
		J30TP500	47631	D99	5060722252335	15060722252332
		J30TP	47631	D99	5060722250027	15060722250024