

Urgent Field Safety Notice – Product Advisory

Avanos* Ballard* Oral Care Swab FCA-2023-001

7 February 2023

«Customer Name»

Dear Valued Customer,

Avanos Medical Inc. is hereby issuing a voluntary Field Safety Corrective Action (FSCA) involving certain lots of the Avanos* Ballard* Oral Care products that were distributed with incorrect expiration dates on the label. The intended use of these products is to apply a mouth moisturizer as well as wiping the lips, mouth, teeth, and soft tissue of patients who require oral hygiene assistance.

There have been **no incidents** of injuries or deaths associated with incorrect expiration dates reported to Avanos Medical, Inc. to date.

The lot numbers and codes with incorrect expiration dates are listed in Appendix 1 (Table 1, Table 2 and Table 3).

REASONS FOR THE VOLUNTARY FSCA

This Field Safety Corrective Action has been initiated due to certain lots labeled with incorrect expiration dates. The labeled expiration dates of impacted products were printed with a 10-year expiration date however, the products have an established shelf life of 5 years.

RISK TO HEALTH

There are currently **no expired products** among the impacted lots, therefore there is no immediate patient risk and all products listed in **Appendix 1** are **safe to use on patients**. However, the impacted products should not be used past their actual expiration dates.

Avanos Medical, Inc. is committed to patient safety and improving patient outcomes, which is why this Field Safety Corrective Action has been initiated.

The hazardous situation with the expired product is the potential for component breaks/detaches. The harm for this situation is the potential for minor choking hazard.

The purpose of this Field Safety Notice is to make sure that you are aware of the correct expiration dates of impacted products so you can ensure that they are safely used on patients prior to expiring. There is no need to return impacted product to Avanos.

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TYPE OF ACTION TAKEN BY AVANOS

Avanos has made applicable corrections to the internal process to correct the incident. The labeling of product manufactured after 03 May 2022 contain the correct expiration date.

ACTIONS TO BE TAKEN BY CUSTOMERS

Our records show that your facility has received one or more lots of the impacted product. This product is safe to use on patients until the correct expiration date shown in Table 1, Table 2, and Table 3 below (Appendix 1). However, Avanos requests that you take the following actions:

- There is no need to return impacted product.
- **COMPLETE** and **RETURN** the attached Acknowledgement Form (**Attachment 1**) to Avanos via email to emeafieldaction@avanos.com.
- **PLEASE FORWARD THE ATTACHED CUSTOMER LETTER** and the **Oral Care Swab List of Impacted Lots – (Appendix 1)** to any of your customers who may have received or will receive impacted product from you.
- If your facility is aware of any adverse events associated with this issue, please contact piq.emea@avanos.com.

Please respond within five (5) business days of receipt of this letter.

If you have questions or require further assistance, please contact Avanos via email at emeafieldaction@avanos.com.

The Competent Authority of your country has been informed about this Field Safety Notice.

Please maintain a copy of this letter for your records.

Thank you for your assistance. We appreciate your prompt attention in this matter and apologize for any disruptions this issue may cause to your facility.

Sincerely,



Klien van Dam
Director, Quality and Regulatory Affairs
Avanos Medical Belgium BV

Attachment 1 – Product Advisory Acknowledgement Form.

Appendix 1 – Oral Care Swab List of Impacted Lots with Incorrect Expiration Date.



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Attachment 1 – Product Advisory Acknowledgement Form

Please complete this form, even if you do not have any affected product, to acknowledge you have received and understand this Field Safety Notice and send it to emeafieldaction@avanos.com.

Our records indicate you have received the following affected product (additionally please check inventory against the complete list of affected products provided in **Appendix 1**).

Impacted Product Code	Product Description	Lot Number	Quantity Sent	Quantity at Facility
12241	BALLARD* ORAL CARE SWAB, Bulk Packed (qty 500)	«Lot Number»	«Quantity»	
12243	BALLARD* ORAL CARE SWAB, Bulk Packed (qty 1000)	«Lot Number»	«Quantity»	
12251	BALLARD* ORAL CARE SWAB, Bulk Packed 15 cm (6 in) Plastic Handle (qty 1000)	«Lot Number»	«Quantity»	

We acknowledge receipt of this Field Safety Notice dated 7 February 2023.

By completing and returning the **Product Advisory Acknowledgement Form** below you are also committing to send a copy of the attached Customer Letter and to follow up as applicable to any customers who received impacted product from you.

Please provide any additional information, if applicable			
Contact Name		Title	
Facility Name			
Email			
Telephone		Date	

Please return a copy of this Acknowledgement Form to Avanos within **5 business** days of receipt of this notice via email to emeafieldaction@avanos.com.

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Appendix 1

Oral Care Swab List of Impacted Lots With Incorrect Expiration Date

Table 1 – AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed (qty 500)

AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed (qty 500)			
Avanos Medical Material Number: 109687003		Avanos product code: 12241	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20067528	12-Jul-21	6-Jul-31	6-Jul-26
20069614	13-Jul-21	13-Jul-31	13-Jul-26
20077132	27-Sep-21	22-Sep-31	22-Sep-26
20079287	10-Nov-21	3-Nov-31	3-Nov-26
20079286	10-Nov-21	10-Nov-31	10-Nov-26
20079285	17-Nov-21	17-Nov-31	17-Nov-26
20079284	23-Nov-21	23-Nov-31	23-Nov-26
20079283	1-Dec-21	1-Dec-31	1-Dec-26
20079282	10-Nov-21	8-Nov-31	8-Nov-26
20082126	27-Dec-21	27-Dec-31	27-Dec-26
20082118	10-Jan-22	10-Jan-32	10-Jan-27
20082119	12-Jan-22	12-Jan-32	12-Jan-27
20082120	19-Jan-22	19-Jan-32	19-Jan-27
20082121	26-Jan-22	26-Jan-32	26-Jan-27
20082122	2-Feb-22	2-Feb-32	2-Feb-27
20086314	23-Mar-22	20-Mar-32	20-Mar-27



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Table 2 – AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed (qty 1000)

AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed (qty 1000)			
Avanos Medical Material Number: 109687204		Avanos Product code: 12243	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20050262	13-Apr-21	13-Apr-31	13-Apr-26
20050263	13-Apr-21	13-Apr-31	13-Apr-26
20050261	13-Apr-21	13-Apr-31	13-Apr-26
20050264	20-Apr-21	20-Apr-31	20-Apr-26
20050265	26-Apr-21	20-Apr-31	20-Apr-26
20058683	27-Apr-21	27-Apr-31	27-Apr-26
20058689	27-Apr-21	27-Apr-31	27-Apr-26
20061145	5-May-21	5-May-31	5-May-26
20061947	11-May-21	11-May-31	11-May-26
20061946	28-May-21	25-Aug-31	25-Aug-26
20062596	18-May-21	18-May-31	18-May-26
20062597	18-May-21	18-May-31	18-May-26
20063681	25-May-21	25-May-31	25-May-26
20063682	1-Jun-21	25-May-31	25-May-26
20064346	1-Jun-21	25-May-31	25-May-26
20064347	25-May-21	30-May-31	30-May-26
20064363	1-Jun-21	1-Jun-31	1-Jun-26
20064364	1-Jun-21	1-Jun-31	1-Jun-26
20064656	8-Jun-21	8-Jun-31	8-Jun-26
20064657	8-Jun-21	8-Jun-31	8-Jun-26
20065662	22-Jun-21	22-Jun-31	22-Jun-26
20065663	22-Jun-21	22-Jun-31	22-Jun-26
20065667	22-Jun-21	22-Jun-31	22-Jun-26
20065668	22-Jun-21	22-Jun-31	22-Jun-26
20067519	28-Jun-21	28-Jun-31	28-Jun-26
20067520	26-Jun-21	26-Jun-31	26-Jun-26
20067478	6-Jul-21	6-Jul-31	6-Jul-26
20069597	13-Jul-21	13-Jul-31	13-Jul-26
20069598	20-Jul-21	20-Jul-31	20-Jul-26
20069601	20-Jul-21	20-Jul-31	20-Jul-26
20072177	28-Jul-21	28-Jul-31	28-Jul-26
20072184	28-Jul-21	28-Jul-31	28-Jul-26



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AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed (qty 1000)			
Avanos Medical Material Number: 109687204		Avanos Product code: 12243	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20072181	25-Aug-21	25-Aug-31	25-Aug-26
20072182	31-Aug-21	25-Aug-31	25-Aug-26
20072183	1-Sep-21	1-Sep-31	1-Sep-26
20072189	1-Sep-21	1-Sep-31	1-Sep-26
20075102	8-Sep-21	8-Sep-31	8-Sep-26
20075104	8-Sep-21	8-Sep-31	8-Sep-26
20077212	23-Sep-21	23-Sep-31	23-Sep-26
20075105	22-Sep-21	22-Sep-31	22-Sep-26
20077328	29-Sep-21	29-Sep-31	29-Sep-26
20077391	6-Oct-21	6-Oct-31	6-Oct-26
20077403	17-Nov-21	17-Nov-31	17-Nov-26
20077407	17-Nov-21	17-Nov-31	17-Nov-26
20079296	17-Nov-21	17-Nov-31	17-Nov-26
20079297	17-Nov-21	17-Nov-31	17-Nov-26
20079312	23-Nov-21	23-Nov-31	23-Nov-26
20079313	23-Nov-21	23-Nov-31	23-Nov-26
20079260	1-Dec-21	1-Dec-31	1-Dec-26
20079261	1-Dec-21	1-Dec-31	1-Dec-26
20079299	8-Dec-21	8-Dec-31	8-Dec-26
20079300	8-Dec-21	8-Dec-31	8-Dec-26
20079301	8-Dec-21	8-Dec-31	8-Dec-26
20079315	8-Dec-21	8-Dec-31	8-Dec-26
20084389	19-Jan-22	19-Jan-32	19-Jan-27
20084390	19-Jan-22	19-Jan-32	19-Jan-27
20082130	9-Feb-22	9-Feb-32	9-Feb-27
20082175	9-Feb-22	9-Feb-32	9-Feb-27
20082176	22-Feb-22	22-Feb-32	22-Feb-27
20082177	22-Feb-22	22-Feb-32	22-Feb-27
20086318	22-Feb-22	22-Feb-32	22-Feb-27
20086319	2-Mar-22	2-Mar-32	2-Mar-27
20082179	2-Mar-22	2-Mar-32	2-Mar-27
20086271	8-Mar-22	8-Mar-32	8-Mar-27
20086272	8-Mar-22	8-Mar-32	8-Mar-27



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Avanos Medical Material Number: 109687204		Avanos Product code: 12243	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20088628	9-Apr-22	9-Apr-32	9-Apr-27
20088600	9-Apr-22	9-Apr-32	9-Apr-27
20089012	9-Apr-22	9-Apr-32	9-Apr-27
20089015	9-Apr-22	9-Apr-32	9-Apr-27
20090190	26-Apr-22	23-Apr-32	23-Apr-27
20090206	26-Apr-22	23-Apr-32	23-Apr-27
20090191	26-Apr-22	23-Apr-32	23-Apr-27



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Table 3 – AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed 15 cm (6 in) Plastic Handle (qty 1000)

AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed 15 cm (6 in) Plastic Handle (qty 1000)			
Avanos Medical Material Number: 109687804		Avanos product code: 12251	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20054925	10-Mar-21	10-Mar-31	10-Mar-26
20054926	10-Mar-21	10-Mar-31	10-Mar-26
20056744	26-Mar-21	29-Mar-31	29-Mar-26
20056745	13-Apr-21	13-Apr-31	13-Apr-26
20057662	13-Apr-21	13-Apr-31	13-Apr-26
20057664	13-Apr-21	13-Apr-31	13-Apr-26
20057663	20-Apr-21	20-Apr-31	20-Apr-26
20057665	20-Apr-21	20-Apr-31	20-Apr-26
20058694	27-Apr-21	27-Apr-31	27-Apr-26
20058695	27-Apr-21	27-Apr-31	27-Apr-26
20058696	5-May-21	5-May-31	5-May-26
20058697	5-May-21	5-May-31	5-May-26
20061147	11-May-21	11-May-31	11-May-26
20061148	11-May-21	11-May-31	11-May-26
20061149	11-May-21	11-May-31	11-May-26
20061951	18-May-21	18-May-31	18-May-26
20061952	18-May-21	18-May-31	18-May-26
20061953	25-May-21	25-May-31	25-May-26
20062605	1-Jun-21	1-Jun-31	1-Jun-26
20062608	1-Jun-21	1-Jun-31	1-Jun-26
20062609	1-Jun-21	1-Jun-31	1-Jun-26
20063691	8-Jun-21	8-Jun-31	8-Jun-26
20063692	8-Jun-21	8-Jun-31	8-Jun-26
20063693	8-Jun-21	8-Jun-31	8-Jun-26
20064348	16-Jun-21	16-Jun-31	16-Jun-26
20064349	16-Jun-21	16-Jun-31	16-Jun-26
20064350	16-Jun-21	16-Jun-31	16-Jun-26
20065664	16-Jun-21	16-Jun-31	16-Jun-26
20065665	16-Jun-21	16-Jun-31	16-Jun-26
20065666	22-Jun-21	22-Jun-31	22-Jun-26
20067479	28-Jun-21	28-Jun-31	28-Jun-26



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Avanos Medical Material Number: 109687804		Avanos product code: 12251	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20067501	28-Jun-21	28-Jun-31	28-Jun-26
20067502	28-Jun-21	28-Jun-31	28-Jun-26
20067500	6-Jul-21	6-Jul-31	6-Jul-26
20067503	6-Jul-21	6-Jul-31	6-Jul-26
20067504	6-Jul-21	6-Jul-31	6-Jul-26
20069599	13-Jul-21	13-Jul-31	13-Jul-26
20069602	13-Jul-21	13-Jul-31	13-Jul-26
20069603	13-Jul-21	13-Jul-31	13-Jul-26
20069600	20-Jul-21	20-Jul-31	20-Jul-26
20069604	20-Jul-21	20-Jul-31	20-Jul-26
20069605	20-Jul-21	20-Jul-31	20-Jul-26
20072178	28-Jul-21	28-Jul-31	28-Jul-26
20072188	28-Jul-21	28-Jul-31	28-Jul-26
20072190	28-Jul-21	28-Jul-31	28-Jul-26
20072179	3-Aug-21	3-Aug-31	3-Aug-26
20072191	3-Aug-21	3-Aug-31	3-Aug-26
20072180	10-Aug-21	10-Aug-31	10-Aug-26
20072187	18-Aug-21	18-Aug-31	18-Aug-26
20075101	25-Aug-21	25-Aug-31	25-Aug-26
20075097	1-Sep-21	1-Sep-31	1-Sep-26
20075098	1-Sep-21	1-Sep-31	1-Sep-26
20075099	1-Sep-21	1-Sep-31	1-Sep-26
20075100	1-Sep-21	1-Sep-31	1-Sep-26
20075085	8-Sep-21	8-Sep-31	8-Sep-26
20075086	8-Sep-21	8-Sep-31	8-Sep-26
20075087	8-Sep-21	8-Sep-31	8-Sep-26
20075088	8-Sep-21	8-Sep-31	8-Sep-26
20076648	15-Sep-21	15-Sep-31	15-Sep-26
20075089	15-Sep-21	15-Sep-31	15-Sep-26
20075090	22-Sep-21	22-Sep-31	22-Sep-26
20075094	22-Sep-21	22-Sep-31	22-Sep-26
20077330	29-Sep-21	29-Sep-31	29-Sep-26



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AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed 15 cm (6 in) Plastic Handle (qty 1000)			
Avanos Medical Material Number: 109687804		Avanos product code: 12251	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20075095	22-Sep-21	22-Sep-31	22-Sep-26
20077384	29-Sep-21	29-Sep-31	29-Sep-26
20077383	6-Oct-21	6-Oct-31	6-Oct-26
20077385	6-Oct-21	6-Oct-31	6-Oct-26
20077375	13-Oct-21	13-Oct-31	13-Oct-26
20077376	13-Oct-21	13-Oct-31	13-Oct-26
20077397	13-Oct-21	13-Oct-31	13-Oct-26
20077377	20-Oct-21	20-Oct-31	20-Oct-26
20077378	20-Oct-21	20-Oct-31	20-Oct-26
20077398	20-Oct-21	20-Oct-31	20-Oct-26
20077379	28-Oct-21	28-Oct-31	28-Oct-26
20077380	28-Oct-21	28-Oct-31	28-Oct-26
20077381	28-Oct-21	28-Oct-31	28-Oct-26
20077382	28-Oct-21	28-Oct-31	28-Oct-26
20079226	3-Nov-21	3-Nov-31	3-Nov-26
20079227	3-Nov-21	3-Nov-31	3-Nov-26
20079228	3-Nov-21	3-Nov-31	3-Nov-26
20079229	3-Nov-21	3-Nov-31	3-Nov-26
20079243	10-Nov-21	10-Nov-31	10-Nov-26
20079250	10-Nov-21	10-Nov-31	10-Nov-26
20079252	17-Nov-21	17-Nov-31	17-Nov-26
20079253	17-Nov-21	17-Nov-31	17-Nov-26
20079255	23-Nov-21	23-Nov-31	23-Nov-26
20079256	23-Nov-21	23-Nov-31	23-Nov-26
20079235	1-Dec-21	1-Dec-31	1-Dec-26
20079236	1-Dec-21	1-Dec-31	1-Dec-26
20079237	1-Dec-21	1-Dec-31	1-Dec-26
20079239	8-Dec-21	8-Dec-31	8-Dec-26
20079240	8-Dec-21	8-Dec-31	8-Dec-26
20079241	8-Dec-21	8-Dec-31	8-Dec-26
20079242	8-Dec-21	8-Dec-31	8-Dec-26
20082076	23-Dec-21	23-Dec-31	23-Dec-26



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AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed 15 cm (6 in) Plastic Handle (qty 1000)			
Avanos Medical Material Number: 109687804		Avanos product code: 12251	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20082077	23-Dec-21	23-Dec-31	23-Dec-26
20082078	4-Jan-22	4-Jan-32	4-Jan-27
20082079	4-Jan-22	4-Jan-32	4-Jan-27
20082080	4-Jan-22	4-Jan-32	4-Jan-27
20082082	12-Jan-22	12-Jan-32	12-Jan-27
20082083	12-Jan-22	12-Jan-32	12-Jan-27
20082084	12-Jan-22	12-Jan-32	12-Jan-27
20082086	19-Jan-22	19-Jan-32	19-Jan-27
20082087	19-Jan-22	19-Jan-32	19-Jan-27
20082090	26-Jan-22	26-Jan-32	26-Jan-27
20082091	26-Jan-22	26-Jan-32	26-Jan-27
20082092	26-Jan-22	26-Jan-32	26-Jan-27
20082103	26-Jan-22	26-Jan-32	26-Jan-27
20082093	2-Feb-22	2-Feb-32	2-Feb-27
20082094	2-Feb-22	2-Feb-32	2-Feb-27
20082095	2-Feb-22	2-Feb-32	2-Feb-27
20082073	16-Feb-22	16-Feb-32	16-Feb-27
20082074	16-Feb-22	16-Feb-32	16-Feb-27
20082075	16-Feb-22	16-Feb-32	16-Feb-27
20082098	16-Feb-22	16-Feb-32	16-Feb-27
20082070	22-Feb-22	22-Feb-32	22-Feb-27
20082071	22-Feb-22	22-Feb-32	22-Feb-27
20082072	22-Feb-22	22-Feb-32	22-Feb-27
20086306	2-Mar-22	2-Mar-32	2-Mar-27
20086309	2-Mar-22	2-Mar-32	2-Mar-27
20086310	2-Mar-22	2-Mar-32	2-Mar-27
20086305	8-Mar-22	5-Mar-32	5-Mar-27
20086307	8-Mar-22	5-Mar-32	5-Mar-27
20086308	8-Mar-22	8-Mar-32	8-Mar-27
20086275	15-Mar-22	12-Mar-32	12-Mar-27
20086276	15-Mar-22	12-Mar-32	12-Mar-27
20086277	15-Mar-22	12-Mar-32	12-Mar-27



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AVANOS* BALLARD* ORAL CARE SWAB, Bulk Packed 15 cm (6 in) Plastic Handle (qty 1000)			
Avanos Medical Material Number: 109687804		Avanos product code: 12251	
Lot Number	Manufacture Date (DD-MM-YYYY)	Labeled Expiration Date (DD-MM-YYYY)	Correct Expiration Date (DD-MM-YYYY)
20086278	15-Mar-22	12-Mar-32	12-Mar-27
20086279	15-Mar-22	12-Mar-32	12-Mar-27
20086300	15-Mar-22	12-Mar-32	12-Mar-27
20086301	23-Mar-22	20-Mar-32	20-Mar-27
20086302	23-Mar-22	20-Mar-32	20-Mar-27
20086303	23-Mar-22	20-Mar-32	20-Mar-27
20086304	23-Mar-22	20-Mar-32	20-Mar-27
20088253	23-Mar-22	20-Mar-32	20-Mar-27
20088256	23-Mar-22	20-Mar-32	20-Mar-27
20088254	28-Mar-22	25-Mar-32	25-Mar-27
20088257	28-Mar-22	25-Mar-32	25-Mar-27
20088258	28-Mar-22	25-Mar-32	25-Mar-27
20088259	28-Mar-22	25-Mar-32	25-Mar-27
20088260	28-Mar-22	25-Mar-32	25-Mar-27
20088261	28-Mar-22	25-Mar-32	25-Mar-27
20088255	5-Apr-22	2-Apr-32	2-Apr-27
20088262	5-Apr-22	2-Apr-32	2-Apr-27
20088263	5-Apr-22	2-Apr-32	2-Apr-27
20088264	5-Apr-22	2-Apr-32	2-Apr-27
20088265	5-Apr-22	2-Apr-32	2-Apr-27
20088266	5-Apr-22	2-Apr-32	2-Apr-27
20088619	12-Apr-22	9-Apr-32	9-Apr-27
20088620	12-Apr-22	9-Apr-32	9-Apr-27
20088621	12-Apr-22	9-Apr-32	9-Apr-27
20088622	12-Apr-22	9-Apr-32	9-Apr-27
20088623	12-Apr-22	9-Apr-32	9-Apr-27
20089019	19-Apr-22	16-Apr-32	16-Apr-27
20089080	19-Apr-22	16-Apr-32	16-Apr-27
20089081	19-Apr-22	16-Apr-32	16-Apr-27
20089082	19-Apr-22	16-Apr-32	16-Apr-27