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March, 2024

Introduction of PVC-free (DEHP-free) bag material for ACP®215 red cell wash and deglycerolization solutions manufactured by our supplier S.A.L.F. S.p.A.

Affected product codes:

SOL.FIS.2000M; Glucose 0.2% Sodium Chloride 0.9%; 2000ml
SOL.IPERT.100M1 and SOL.IPERT.100M2; Sodium Chloride 12%; 100 ml

Dear valued customer,

The purpose of this customer letter is to inform you of the introduction of PVC-free (DEHP-free) bag film used for Glucose 0,2% Sodium Chloride 0,9% (SOL.FIS.2000M), and Sodium Chloride 12% (SOL.IPERT.100M1 and SOL.IPERT.100M2) solutions manufactured by S.A.L.F S.p.A Laboratorio Farmacologico ("SALF").

In anticipation to compliance with the REACH regulations issued by the European Chemicals Agency (ECHA), our supplier has implemented a change of the bag film used in production of the above-mentioned solution bags, from the current PVC film material to a PVC-free (DEHP-free) bag film.

The new bag film material is polypropylene (PP) which complies with the current European Pharmacopoeia. PP solution bag film is widely used in the industry and shows excellent compatibility for storing many different types of solutions. The material of the solution bag overwrap today is already DEHP-free and is not going to change.

With the introduction of the new PP bag film material, the product codes for those solutions will change:

Product description	**Current Product Code**	**New product code PVC-free**
Glucose 0.2% Sodium Chloride 0.9%; 2000ml	SOL.FIS.2000M	TMIN0220GOO
Sodium Chloride 12%; 100ml	SOL.IPERT.100M1 SOL.IPERT.100M2	TSCN1201GOO-1 TSCN1201GOO-2

As shown in the examples provided on the last page of this letter, the label artwork will change slightly to remove the DEHP symbol and to indicate the use of PVC free bag material.

There is no change to the form, fit or function of those solutions. The shelf life as well as the product packaging configuration (units per box) will remain unchanged.

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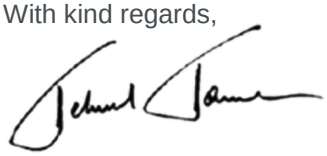
Implementation timing

Timing of the introduction of those solutions in the new PVC-free bag material will depend on the available inventory levels of the current product, as well as on regulatory approvals for this product update in different countries.

Product description	Product code PVC-free	Estimated availability on Haemonetics inventory	Expected first shipment to customers
Glucose 0.2% Sodium Chloride 0.9%; 2000ml	TMIN0220GOO	Q1 2024	With next shipment after regulatory approval
Sodium Chloride 12%; 100ml	TSCN1201GOO-1 TSCN1201GOO-2	Q1 2025	Q1 2025

For further questions or information, please contact your local account manager.

With kind regards,



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Example: Label changes for Glucose 0.2% Sodium Chloride 0.9%; 2000ml (TMIN0220GOO)

New carton label



New bag label

