

SUBJECT : Change of supplier for P0390

1- INFORMATION ON PRODUCT CONCERNED BY THE NOTIFICATION :

Catalogue Number : P0390 - L0210

Batch Number : All batches produced since 19/09/2023

Production date : NA

Request Number : NA

2- DESCRIPTION OF THE NOTIFICATION :

Description : Our current supplier of P0390 is discontinuing production of the McCoy's 5A with L-Glutamine and without Sodium Bicarbonate. As a result, we have had to change our supplier for this item.

The composition and specification of the new supplier's P0390 differs slightly from the previous product but those changes are not significant and have no impact on the quality or efficiency of the product.

The P0390 is sell as it (as powder media) or used for production of L0210 (liquid media).

We have updated our documentation related to those 2 products.

The changes are:

- Slight changes in the composition of P0390 and L0210 (see old and new compositions attached)
- Change of the quantity of P0390 needed to reconstitute 1 litre of media : 11.96 g/L => 11.92 g/L (see new technical data sheet FT.P0390an)
- Modification of the endotoxin specification of P0390 : < 1 EU/ml => < 10 EU/ml (see new technical data sheet FT.P0390an)
- The L0210 and P0390 become Animal Component Free (ACF)

Documents linked :

Old and new composition for P0390

Old and new composition for L0210

New Technical Data Sheet for P0390 (FT.P0390an 19/09/2023)

Material Safety Data Sheet for P0390 (updated on 19/09/2023 - version 4)

Material Safety Data Sheet for L0210 (updated on 19/09/2023 - version 5)

3- PREVENTIVE / CORRECTIVE ACTION TO REALISE :

Description : NA

Written by : S. Niama

Position : Quality and EHS
Assistant

Date : 25/09/2023

Signature :


NIAMA.S

DOMINIQUE DUTSCHER SAS