

**Urgent Field Safety Notice
N. 07/2020**

Product Name	List Number (LN)	Lot Number	Expiration Date
Zinc	17640H	90227	2021/08

Date: October 29th, 2020

Details on affected devices:

This letter contains important information regarding the ZINC product REF 17640H lot 90227. Please review the information carefully and follow the necessary actions.

Description of the problem:

Internal investigations performed have highlighted an issue with the standard (component lot H0207), included in the Zinc product, that can induce a drift down of lot 90227 results versus other lots, resulting in an underestimation up to approximately 15%.

Patient Impact:

The use of the affected lot could generate falsely low zinc results (-15%) in patient samples that can incorrectly lead to a suspected zinc deficiency. This incorrect evaluation could lead to an unnecessary zinc supplementation. This medical treatment can be considered however as low risk for the patient's health.

Actions to be taken:

1. Discontinue the use of the impacted lot immediately and destroy any remaining inventory of impacted lot;
2. If you have an alternate reagent lot available in inventory, switch to this alternate lot according to your laboratory procedures;
3. Follow the instruction reported on the attached form "Receipt of the Safety Notice" and fill all the required fields;
4. Review the content of this communication with your Medical Director and retain this letter for any future reference.

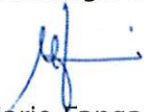
Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization/individuals where the potentially affected devices have been transferred.

Reference person:

If you or any of your customers have any questions regarding this information, please contact your local area Customer Service.

Best Regards,



Mario Fangareggi
Head of Marketing



Patricia Dupé
Head of Quality System

Please, send this document to customerservice@sentinel.it or via fax to no. + 39 02 3455146.

Field Safety Notice Receipt

Field Safety Notice N.: 07/2020 Date:	Product(s): Zinc Code(s): 17640H Lot(s): 90227
---	---

- I acknowledge that I have read and understood the Field Safety Notice.
- I declare that the following product(s) has/have been destroyed and disposed of according to local regulations regarding chemical waste management.

Code	Lot	Number of received kits	Number of used kits	Number of disposed kits

Name	
Title	
Company/Institute	
Address	
Phone	
Fax n	
E-mail	

Notes/Comments:

Date, signature and company stamp