

Formato 1 - Notificación de alerta rápida por defecto de calidad / recall

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

IMPORTANT -- DELIVER IMMEDIATELY

Reference Number: 42/2023

(add letter head of sender):

1. To: (see list attached, if more than one)	
2. Product Recall Clas of Defect:	3. Falsification / Fraud (specify):
4. Product: LIPOVON capsules, dietary supplements.	5. Marketing Authorisation number: N/A For use in humans / animals (Select as required):
6. Brand / Trade name: LIPOVON	7. INN o generic name: N/A
8. Dosage form: Capsules	9. Strength: N/A
10. Batch number (and bulk , if different): All batch number	11. Expiry date: All expiry dates
12. Pack size and Presentation: Bottle with 30 capsules	13. Date manufactured: N/A
14. Marketing Authorisation holder: N/A	
15. Manufacturer: LIPOVON LTD. Mexico Contact person: Telephone:	16. Recalling firm (if different) Contact person: Telephone:
17. Recall number assigned (if available):	
18. Details of defect / Reason for recall: The product is labeled as a dietary supplement; however, the analysis conducted by international agencies has identified the presence of Sibutramine, a substance banned since 2010; on the other hand, the Hoodia Gordonii and Garcinia cambogia was not allowed by this Cofepris for use in the formulation of dietary supplements.	
19. Information on distribution including exports (type of costumers, e.g. hospitals): Unknown information	
20. Action taken by issuing Authority: Sanitary Alert Published on the Cofepris website and notify to the Federal System for the intentional search.	
21. Proposed action:	
22. From (issuing Authority): Federal Commission for the Protection Against Sanitary Risk Comission of Evidence and Risk Management	23. Contact person: alertas@cofepris.gob.mx Telephone: +52 55 5080 5200 ext. 11257
24. Signed	25. Date: 06/12/2023
	26. Time: 14:10

LINK https://www.gob.mx/cms/uploads/attachment/file/873625/Alertas_Sanitarias_Lipovon_29112023.pdf

