

**GOVERNMENT OF MAHARASHTRA**

Office of Commissioner

Food and Drugs Administration (M.S.)

341, Banda-Kurla Complex, Opposite of RBI Buildings,
Bandra (E), Mumbai-400 051

Tel:022-26592362-65

Email: jchq.fda-mah@nic.in

No. D&CA/Cough Syrup/ 549 -2025/10

Date: 07/10/2025

PROHIBITION ORDER

Subject: Prohibition of sale and distribution of cough syrups detected with Diethylene Glycol (DEG) impurities.

As per communication received from FDA, Madhya Pradesh, the following drug formulations have been found containing Diethylene Glycol (DEG) impurity above permissible limits and are declared adulterated and Not of Standard Quality:

Sr. No.	Name of Drug	Batch No.	Expiry Date	Manufacturer
1	Respifresh TR (Bromhexine Hydrochloride, Terbutaline Sulphate, Guaiphenesin & Menthol Syrup)	R01GL2523	12/2026	M/s Rednex Pharmaceuticals Pvt. Ltd., Survey No. 586 & 231, NR SKF Bearing, Bavla, Bagodara, N.H. 8A, Tal. Bavla, Dist. Ahmedabad, Gujarat – 383220
2	Relife (Ambroxol Hydrochloride, Guaiphenesin, Terbutaline Sulphate & Menthol Syrup)	LSL25160	DEC2026	M/s Shape Pharma Pvt. Ltd., Plot No. 4, Sundernagar, Rajkot Highway Road, Shekhpur, Gujarat – 363510

The above-mentioned cough syrup formulations contain Diethylene Glycol (DEG)- a toxic chemical that can cause serious poisoning, including kidney failure, neurological complications, and even death, especially among children. The sale or distribution of these batches is strictly prohibited with immediate effect as per section 18 of Drugs and Cosmetics Act 1940. Retailers, wholesalers, distributors, hospitals, and medical practitioners across Maharashtra are hereby instructed not to sell/distribute or use the above-mentioned batches. Concerned licensees of Maharashtra State are directed to report any stock or supply details to the respective Assistant Commissioner of district office of their jurisdiction immediately.

Issued in Public Interest.

(D.R. Gahane)

Drugs Controller,
Food and Drugs Administration,
Maharashtra State