



# Clifton Health Department Food Recall Notification



## Food/Drug/Pet Recall: Able Groupe

Able Groupe announced it is recalling certain products used as infant formulas.

The recalled products are infant formulas (i.e., products intended as a complete or partial substitute for human milk for children 12 months old and younger), but the required pre-market notifications for these new infant formulas have not been submitted to the FDA. In addition, the HiPP Comfort Milk Formula, HiPP Dutch Stage 1 Combiotic Infant Milk Formula, HiPP HA Germany Hypoallergenic Stage PRE Combiotic Infant Milk Formula, HiPP German Stage 1 Combiotic Infant Milk Formula, Holle Bio Stage 1 Organic Infant Milk Formula, Holle Bio Stage PRE Organic Infant Milk Formula, Lebenswert Anfangsmilch Stage 1 Organic Infant Milk Formula, and HiPP UK Stage 1 Combiotic First Infant Milk Formula products contain less than 1 milligram of iron per 100 Calories and may not provide adequate iron for some infants, particularly infants born prematurely or with a low birth weight, those who had low iron levels at birth, or those who are at risk for becoming iron deficient due to illness.

Inadequate intake of iron during infancy may lead to iron deficiency anemia, which, if untreated, has irreversible cognitive and functional development outcomes. Infant formula products that contain less than 1 milligram of iron per 100 Calories are required to include a statement on the label indicating that additional iron may be necessary.

These 8 infant formula product labels do not include the required statement.

Furthermore, all of the infant formulas distributed by Able Group are not labeled as required by 21 CFR 107.10 and 107.20 and do not bear mandatory labeling statements in English.

The products were imported from Europe and distributed to consumers in the U.S. via mail services. The products were purchased through the littlebundle website ([www.littlebundle.com](http://www.littlebundle.com)[External](#) Link Disclaimer). The products were not available at any retail store. The company began distributing the products on May 20, 2021. Approximately 76,000 units were distributed.

The company identified the products as follows: (iron levels provided after each product name, milligrams per 100 Calories) All lots codes are being recalled.

Product Age Iron mg per 100 Calories  
HiPP Anti-Reflux Milk Formula From birth 1.06  
HiPP Comfort Milk Formula From birth 0.91  
HiPP Dutch Stage 1 Combiotic Infant Milk Formula 0-6 months 0.76  
HiPP Dutch Stage 2 Combiotic Follow-on Milk Formula 6+ months 1.47  
HiPP HA Germany Hypoallergenic Stage PRE Combiotic Infant Milk Formula 0-6



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months 0.76

HiPP HA Germany Hypoallergenic Stage 1 Combiotic Infant Milk Formula 6+ months 1.01

HiPP HA Germany Hypoallergenic Stage 2 Combiotic Follow-on Milk Formula 6+ months 1.43

HiPP German Stage 1 Combiotic Infant Milk Formula 0-6

months 0.90

HiPP German Stage 2 Combiotic Follow-on Infant Milk Formula 6+ months 1.47

Holle Bio Stage PRE Organic Infant Milk Formula 0-6

months 0.81

Holle Bio Stage 1 Organic Infant Milk Formula 0-6

months 0.81

Holle Bio Stage 2 Organic Follow-on Milk Formula 6+ months 1.18

Holle Goat Stage 1 Organic Infant Milk Formula 0-6

months 0.99

Holle Goat Stage 2 Organic Follow-On Infant Milk Formula 6+ months 1.47

Holle Goat Stage 3 Organic Toddler Formula 10+

months 1.52

Lebenswert Anfangsmilch Stage 1 Organic Infant Milk Formula 0-6

months 0.88

Lebenswert Anfangsmilch Stage 2 Organic Follow-on Milk Formula 6+ months 1.43

HiPP UK Stage 1 Combiotic First Infant Milk Formula 0-6

months 0.76

HiPP UK Stage 2 Combiotic Follow-on Infant Milk Formula 6+ months 1.47

Kendamil Organic Stage 1 First Infant Milk Formula From birth 1.10

Kendamil Organic Stage 2 Follow on Milk Formula 6+ months 1.06

Consumers who have these products at home should not use them as infant formula and should safely dispose of them immediately. Images of the recalled product labels are attached.

The recall is being coordinated with the U.S. Food and Drug Administration.

Consumers of the product who have questions can email them to:

[recallquestions@ablegroupe.com](mailto:recallquestions@ablegroupe.com)

Media questions: [mediainquiries@ablegroupe.com](mailto:mediainquiries@ablegroupe.com)