Safe Bottle Feeding & Formula Mixing

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Recipe for Formula

“A healthy, full term infant does well on almost any of a great variety of milk mixtures.” (Better Homes and Gardens, 1957).

**Formula**

- 6 oz. Pet Evaporated Milk
- 12 oz. Water
- 2 level Tablespoons Dextri-Maltose #1

Pour 3 oz. into each of 6 bottles. When to offer: After breastfeeding or in place of breastfeeding. Single bottles use ¼ formula recipe.
History of Artificial Breast Milk

- 1700’s “Gentry” used breastmilk substitute with poor outcomes for infants. “Peasant’s” infants were healthier, as they were breastfed. “Wet-nurses” predominately used.
- 1867 Henri Nestle, a Swiss pharmacist developed the world’s first commercial infant food by mixing cows milk, wheat flour and sugar. “It helped save the life of a neighbor’s baby who would not nurse”.
- Formula hype: equal to or even better than human milk…
- In 1960, Nestle Company sought after the International market, including third world countries who did not have a need for a milk substitute.

History of Artificial Breastmilk

- 1974 a request from both the clergy and lay groups demanding to set marketing standards for infant formula
- 1979 a meeting was convened with the WHO and UNICEF regarding infant and young child feeding to develop an International Code of Marketing of infant formula and other related products used as substitutes for human breastmilk
- The purpose of the “Code” is it prohibits direct-to-consumer commercial formula promotion in healthcare facilities
History

- 1984 the recommendations were formalized. Nestle agreed to abide by the “Code”
- The “Code” was quickly ignored by the formula companies. They used creative ways by using older children formula advertising for the ages of 3-6 months
- 1988, the boycott against Nestle was re-instated. Twenty nations now have organized boycotts against Nestle and its subsidiaries

Because milk substitutes require water, places with limited water supply, often the case in most developing countries, are at great health risk for babies, including diarrhea

- 14 times greater risk of death
- Language barriers with labels poses another lethal risk
- Check out packaging
The World Health Organization released a study that showed Filipino mothers who’d been encouraged by advertising or doctor promotions to use infant formula were “two to four times more likely to feed their babies with those products ... despite poverty and extra strain on household income associated with formula use.”

Salon (2014) www.salon.com/2014/03/24/should_baby_formula_ads_be_banned?
By LUCY CARROLL

- **The Pulse Live with Judith Ireland**

Doctors are calling on the federal government to ban the promotion of baby formula, fearing a drop in breastfeeding rates if manufacturers are allowed to oversee their own marketing practices.

The move by the Royal Australasian College of Physicians follows Assistant Health Minister Fiona Nash’s decision to scrap an independent panel that aimed to ensure the proper use of breast milk substitutes.
Background Information: BLOOMBERG TO NEW MOTHERS: “YOU SHOULD BE BREASTFEEDING”

http://www.redstate.com/diao420/2012/07/31/baby-formula-now-on-the-banned-wagon/

Types of formula

- **Term Formula**
  - All brands the same
  - Iron fortified to be used to prevent anemia
  - Protein- cow’s milk protein

- **Preterm and Enriched Formula**
  - Need higher calories
  - Need Higher protein
  - Need Minerals: calcium, magnesium, & Phosphorus
Specialized Term Formulas

- Congenital Lactase Deficiencies
- Galactosemia
- Gastroenteritis in at risk infants
- Milk Protein allergies
- Gastroesophageal reflux

Soy Formula

- 25% of formula used in the U.S. is Soy
- Corn-based carbohydrate and soy protein
- Lactose free
- Cow’s milk free
Designer Formulas

- Lactose free
- Hypo allergenic and Non allergenic formulas
- Anti-reflux Formulas
- Infant Formula and colic
- Toddler Formulas

Supporting the Non Breastfeeding Mother & Baby

- Primary concern- Contamination of Powdered Infant formula (PIF) and human milk fortifier
- PIF- associated with serious illness and death in infants from contamination with Enter sakazakii and Salmonella entrica
Contamination of Powder

- Manufacturing process

- *Pediatrics*, 2008 showed:
  - 55% of mothers did not wash hands prior to preparation of PIF
  - 32% did not adequately wash bottle nipples before each use
  - 35% heated in microwaves
  - 6% did not always discard formula after standing out for over 2 hours

U.S. Training Requirements

- All person who will be mixing formula should be trained in safe preparation of PIF
  - In care settings, including hospitals and child care settings
  - In home settings

- Also advisable to educate on the importance of proper techniques for dilution for each brand of formula.
  - Too concentrated can cause kidney problems and is
  - Too diluted can cause malnutrition and poor weight gain.
Expectation of Hospital

- Parents should be taught by health care provider before leaving the hospital on proper methods of reconstituting formula
- A return demonstration should be mandatory to make sure the parents understand and can provide a return demonstration
- Written instructions should also be part of the discharge materials for parents choosing formula

Expectations for Formula Companies

- Must be simple and easy to read in appropriate languages
- Must contain a statement on the superiority of breastfeeding
- Also should state should only be used after consult with Health professional
- Idealizing with pictures or words such as humanized or materialized should not be used
- Nutrition and Health claims on labels should not be permitted unless allowed by National Legislation
- Warnings need to be displayed about the risk of contamination of powdered formula
- Labels need to conform with WHO guidelines on safe preparation
- All complimentary foods must be labeled as suitable for use by infants from 6 months and not earlier.
WHO Recommendations

- Hospitals and child care settings should use commercially sterile formula

- Written material on safe preparation and handling of formula with a tracking system using the lot numbers

- Cleaning and sterilizing:
  - Hand washing
  - Cleaning equipment with hot soapy water
  - Sterilizing

https://www.google.com/search?num=10&hl
WHO Recommendations

- Prepare feedings fresh each time prior to feedings
- Bottled water is not sterile and needs to be boiled before use, as does tap water
- Boil water for 5 minutes and no longer (WHO, 2010)
- FDA recommends 1 minute
- Cool the water to not less than 158 degrees F before pouring into sterile feeding bottle

- Greatest risk of bacterial growth is when boiled water is allowed to drop to around 122 F degrees and is then used to reconstitute PIF.

WHO Recommendations: Water Safety Concerns

- Softened tap water- too high in sodium
- H2o collected as run off from eaves- high in bacterial contamination
- Filtered H2o- may contain silver and bacteria
- Mineral H2O- is too high in sodium and minerals
- Distilled H2O- contains no minerals
- Carbonated H2O- not appropriate for infants
- Soda H2O- too high in sodium
- Contaminated well H2O- may contain harmful minerals, bacteria
- Designer waters for infants- may contain excess minerals
WHO Recommendations for Storage

- Feedings can be stored up to 24 hours in refrigeration
- Large volumes left to cool can promote bacterial growth
- Store in smaller volumes

WHO Recommendations for Storage

- Remove feeds immediately from refrigeration before use and re warm (No more than 15 minutes)
- Longer periods of warming time leads to bacterial growth
- Prepared feedings should be stored on ice or ice pack when traveling. Formula should never be left at room temperature for more than 1 hour
- If feeds are not consumed within 2 hours of being made, then refrigerate and reheat for next feeding
WHO Recommendations

- Any feedings not consumed within 2 hours of preparation (unless refrigerated) should be discarded.
- Prepared foods can be refrigerated up to 24 hours.
- Discard any partially drank bottle due to contamination of saliva on nipple.

LIPIL Additive in Formula

![Image of LIPIL additive in formula]
**DHA and AA**

- **DHA** Docosahexaenoic acid: **AA**: Arachidonic acid
- Two long chain polyunsaturated fatty acid
- Both play a significant role in brain development
- Human DHA and AA important for retinal development, CNS and prostaglandins & leukotriene's

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**AHA and AA: Why?**

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- Two long chain polyunsaturated fatty acid
- Both play a significant role in brain development
- Human DHA and AA important for retinal development, CNS and prostaglandins & leukotriene’s
DHA and AA in Formula

- The ingredient in formula is not derived from human source
- No benefits have been shown in research to support
- Cochrane reviews conclude that supplementation of formula with DHA an AA cannot be recommended
- Based on current evidence cost is 30% more than formula without additives

AAFP (2009)

Does FDA Approve Infant Formula Before They Are Marketed?

- NO

- However, all formulas marketed in the US must meet federal nutrient requirements and infant formula manufactures must notify the FDA prior to marketing a new formula

Guidance for industry: frequently asked questions about FDA’s Regulation of formula, March 1, 2006.
Formula Recalls
Three Classifications

- **Class I Recall:** A product use will cause serious health consequences or death
- **Class II Recall:** A product whose use may cause medically reversible health consequence
- **Class III Recall:** A product whose use is not likely to cause adverse health consequences

FDA Enforcement Report, HFI-20

- Recall I I - 2007 Similac Special Care 24 cal/fl oz. 5000 cases
- **PROBLEM:** Deficient in iron, which is used for longer than one month could result in anemia

- Initiated recall -2005 Similac Advanced and Alimentum 32 oz ready to feed, including hospital discharge bags
- **PROBLEM:** Deficient in Vit C. Complaints about a dark color formula. If consumed for greater than 2 weeks, lead to low Vit C levels
Recalls

- September 2010 Abbott Laboratories recalls 5 million containers of its most popular Similac Advanced Formula Powder due to a contamination of a beetle and larvae
  - This particular product was sold in the US, Caribbean, Guam and Porto Rico

Fury in China over Babies Growing Breasts from Powdered Formula
FDA Enforcement Report, HFI-20

- Firm initiated recall- 2006  Gentlease powdered infant formula. 41, 000 cans
- **PROBLEM** contained metal particles
- **Recall II- 2005**  Similiac Advance with Iron Powder. 82, 986 cans
- **PROBLEM** Contains rigid polyvinyl chloride (Distributed nationwide)
- **Recall I- 2003**  EnfaCare Lipil 505 cases
- **PROBLEM**  E. Sakazakii. Distributed to hospitals, retail stores and WIC nationwide in December 2002

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**BREAKING NEWS**

According to the Associated Press, the U.S. Centers for Disease Control and Prevention discovered that:

“Traces of a chemical used in rocket fuel were found in samples of powdered baby formula.”

Site for parents to check for recalls

- [http://www.fda.gov/Safety/Recalls/ucm295406.htm](http://www.fda.gov/Safety/Recalls/ucm295406.htm)
- Food and Drug Administration US of Health and Human Services Downloaded from: [http://www.fda.gov/Safety/Recalls/ucm295406.htm](http://www.fda.gov/Safety/Recalls/ucm295406.htm)

References

- [Food and Drug A](http://www.fda.gov/Safety/Recalls/ucm295406.htm)
- [Irvine et al 1995](http://www.fda.gov/Safety/Recalls/ucm295406.htm)
- [Setchell K. et al., 1997](http://www.fda.gov/Safety/Recalls/ucm295406.htm)
- [Shell.hug.co.nz/-stu/milk.htm](http://www.fda.gov/Safety/Recalls/ucm295406.htm)
- [WHO, 2012](http://www.fda.gov/Safety/Recalls/ucm295406.htm)
- [www.naba-breastfeeding.org](http://www.naba-breastfeeding.org)
PHOTOS:

- Slide 1 http://www.healthtap.com/topics/docosahexaenoic-acids&docid=KWWLD4pKQ