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*subject to change*

## **Testing Standards for Prenatal Vitamins**

The FORUM has established initial testing protocols in line with the stringent requirements of California Proposition 65, the standards set by the United States Pharmacopeia, as well as the regulatory frameworks of the European Union and the U.S. Food and Drug Administration. These standards also follow the FIGO list of heavy metals and toxins and the standard of de minimis levels of the hazardous metals and the listed testing detection levels of each metal contained in the October 2023 Paris document

Only laboratories with ISO 17025 certification and a minimum of three years' accreditation in testing are to conduct these evaluations. Furthermore, Purity Laboratories has been designated by the FORUM, through a formal agreement, as the exclusive testing body for P2i products.

Standards for Each Lot (depending on the size of the lot one or more samples will need to be tested based on FDA guidelines):

1. **Chemical and Pesticide Testing:** The testing regimen is designed to identify approximately 120 distinct chemicals and pesticides. The sensitivity of the tests is

calibrated to detect minuscule concentrations, specifically in parts per billion (ppb). This rigorous screening is focused on isolating harmful substances, often referred to as 'bad actors', from the products. Additionally, there's a specialized panel for analyzing 24 different metals. The FORUM is charting a course to expand this panel to encompass around 190 toxic substances or more, with incremental additions each year as advised by a FIGO representative. Advanced mass spectrometry techniques, including Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS), Gas Chromatography Mass Spectrometry (GC-MS), and Inductively Coupled Plasma Mass Spectrometry (ICP-MS), will be utilized for this testing.

2. **Label Claims Verification:** For the representation of folate or folic acid on product labels, the testing will align with general FDA's guidelines, permitting a margin of accuracy. Other prenatal formula ingredients must also exhibit a reasonable degree of accuracy and adhere to current Good Manufacturing Practice (cGMP) standards. In general, the major and critical ingredients such as folic acid or folate should exceed 90% of label claim and have sufficient overage to accommodate normal deterioration.
3. **Microbial Testing:** Each product batch will undergo a comprehensive microbial panel test. Any detection of microbes that exceed laboratory standards will result in a failing grade for the batch. The micro tests for final products will include checks for Aerobic Plate Count, Yeasts, Molds, Total Coliforms/*Escherichia coli* (TC/EC), *Pseudomonas*, *Staphylococcus*, Bile Tolerant Gram-negative bacteria, *E. coli*, *Salmonella*, and *Listeria*.
4. **Allergen Detection:** The materials will be scrutinized for the presence of seven common allergens. Detection of any of these allergens more than a de minimis level will be grounds for failure. The allergens currently identified for testing include:
  - Egg
  - Gluten
  - Peanut
  - Shellfish
  - Tree Nuts (including coconut, hazelnut, and almonds)
  - Fish
  - Wheat
  - Milk

5. **Ingredient Safety Review:** It is imperative that all ingredients (vitamins and minerals listed on product labels are confirmed to be safe beyond reasonable doubt. This includes verifying that the stated amounts are safe for consumption. The ingredient review process is distinct from laboratory testing—it serves as a certification of the company’s formula to ensure compliance with safety standards.

**6. 24 metals Test**

Beryllium
Aluminium
Vanadium
Chromium
Manganese
Cobalt
Nickel
Copper
Zinc
Arsenic
Selenium
Molybdenum
Palladium
Silver
Cadmium
Tin
Antimony
Barium
Tungsten
Platinum
Thallium
Lead
Uranium
Mercury

The analysis of heavy metals constitutes a crucial aspect of the prenatal vitamin testing procedure, and it poses a substantial risk of potential toxicity. To safeguard the well-being of the developing fetus, we will conduct an assessment of 24 selected heavy metals. Among these 24 metals, 7 fall within the category of hazardous materials as defined by Proposition 65 guidelines, while additional heavy metals are of concern to various government and private testing agencies.

We will follow the FIGO list of heavy metals and the standard of de minimis levels of the hazardous metals and the listed testing detection levels of each metal contained in the October 2023 Paris document.

It is important to acknowledge that achieving low measurements of heavy metals in parts per billion (ppb) can be challenging, especially when prenatal formulas contain minerals such as calcium and magnesium. Nevertheless, maintaining these levels at a minimum and within safe thresholds is essential to ensure the safety of the unborn child.

Our standards will entail a thorough comparison of the actual test results for a batch of products against the benchmarks set by California Proposition 65, the United States Pharmacopeia Standard, the European Union, and FDA regulations for daily exposures, with a focus on ppb measurements. Our goal is to consistently maintain levels significantly below the safety thresholds established by all relevant standards and for all actionable heavy metals. (Actionable heavy metals are those that are specifically measured in accordance with California Proposition 65, the European Union, and FDA guidelines.)

As a general guideline for certification the 7 hazardous metals in California Prop 65 have to average 20% of the "safe level" with no metal exceeding 50% of the safe level. Any prenatal lot exceeding this level would have to be reviewed by the FORUM for approval. This general guideline for metals would be considered de minimis under the FIGO October 2023 Paris document. All 24 metals must be measured to the detection levels of the FIGO October 2023 Paris document and be "safe" with the stringent requirements of California Proposition 65, the standards set by the United States Pharmacopeia, as well as the regulatory frameworks of the European Union and the U.S. Food and Drug Administration

**Achieving cGMP Certification.** Every manufacturing facility employed by the vendor to produce certified products is required to possess a valid and up-to-date cGMP certification that is in good standing. These facilities may also be subjected to additional Standard Operating Procedures (SOPs) to ensure adherence to "clean manufacturing" standards.

**Future Changes** – The FORUM's Board of Directors' Executive Committee is expected to periodically review these standards. Moreover, FORUM will constitute a committee, with a member from FIGO, to evaluate and suggest any further inclusions of chemicals and toxins.



## PESTICIDES AND PREGNANCY

### Appendix 1 – 120 Pesticides

- |                         |                   |                           |                            |
|-------------------------|-------------------|---------------------------|----------------------------|
| 1. Acephate             | 31. Diflubenzuron | 61. Kresoxim-Methyl       | 91. Propiconazole          |
| 2. Acetamiprid          | 32. Dimethoate    | 62. Linuron               | 92. Propoxur               |
| 3. Aldicarb             | 33. Dimethomorph  | 63. Lufenuron             | 93. Proquinazid            |
| 4. Amidosulfuron        | 34. Dimoxystrobin | 64. Malathion             | 94. Pymetrozine            |
| 5. Azinphos-ethyl       | 35. Diniconazole  | 65. Mandipropamid         | 95. Pyraclostrobin         |
| 6. Azoxystrobin         | 36. Dinotefuran   | 66. Mepanipyrim           | 96. Pyridaben              |
| 7. Bifenazate           | 37. Ethion        | 67. Metaflumizone         | 97. Pyrimethanil           |
| 8. Bifenthrin           | 38. Ethirimol     | 68. Metalaxyl             | 98. Rimsulfuron            |
| 9. Bitertanol           | 39. Ethofumasate  | 69. Metamitron            | 99. Rotenone               |
| 10. Boscalid            | 40. Ethoprophos   | 70. Methamidophos         | 100. Spinosad              |
| 11. Buprofezin          | 41. Ethoxyquin    | 71. Methiocarb            | 101. Spirodiclofen         |
| 12. Butocarboxim        | 42. Etofenprox    | 72. Methomyl              | 102. Spiromesifen          |
| 13. Carbaryl            | 43. Fenazaquin    | 73. Methoxyfenozine       | 103. Spirotetramat         |
| 14. Carbendazim         | 44. Fenhexamid    | 74. Metrafenone           | 104. Spiroxamine I         |
| 15. Carbofuran          | 45. Fenobucarb    | 75. Mevinphos I           | 105. Spiroxamine II        |
| 16. Carbosulfan         | 46. Fenoxycarb    | 76. Monocrotophos         | 106. Tebufenozide          |
| 17. Chlorantraniliprole | 47. Fenpyroximate | 77. Myclobutanil          | 107. Tebufenpyrad          |
| 18. Chloridazon         | 48. Fipronil      | 78. Novaluron             | 108. Tebuthiuron           |
| 19. Chlorpyrifos        | 49. Flonicamid    | 79. Omethoate             | 109. Teflubenzuron         |
| 20. Chlorsulfuron       | 50. Fludioxonil   | 80. Oxamyl                | 110. Tetraconazole         |
| 21. Clofentezine        | 51. Fluopicolide  | 81. Paclobutrazol         | 111. Thiabendazole         |
| 22. Clomazone           | 52. Fluoxastrobin | 82. Phenmedipham          | 112. Thiacloprid           |
| 23. Coumaphos           | 53. Flutriafol    | 83. Phosalone             | 113. Thiamethoxam          |
| 24. Cymoxanil           | 54. Fuberidazole  | 84. Phosmet               | 114. Thifensulfuron-methyl |
| 25. Cyprodinil          | 55. Hexaconazole  | 85. Phosphamidon          | 115. Tralkoxydim           |
| 26. DEET                | 56. Hexythiazox   | 86. Pirimicarb            | 116. Trichlorfon           |
| 27. Desmedipham         | 57. Imazalil      | 87. Pirimiphos-methyl     | 117. Tricyclazole          |
| 28. Diazinon            | 58. Imidacloprid  | 88. Propamocarb           | 118. Trifloxystrobin       |
| 29. Dichlorvos          | 59. Indoxacarb    | 89. Propargite            | 119. Triticonazole         |
| 30. Difenoconazole      | 60. Ipconazole    | 90. Propfos (Ethoprophos) | 120. Zoxamide              |

## The Following are the two Trademarks authorized to use on the Certified Products.

This is the approved logo for P2i™ to be used in the United States



This is the Certification from Purity Laboratories (the round seal in the center of the image) as it may be applied on a nutraceutical label.



The new version will include the word "Laboratory" under Purity to avoid consumer confusion with just the use of the word Purity.