What is Claimed Is:

1. Crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide or crystalline (S)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide comprising Form III, characterized as having a powder x-ray diffraction pattern with peaks at 8.14, 8.52, 9.62, 11.02, 11.90, 12.16, 14.02, 14.62, 17.00, 17.88, 18.56, 19.02, 19.24, 20.51, 20.93, 22.19, 22.73, 23.22, 24.31, 24.53, 25.91, 26.22, 27.36, 27.73, 28.70, 30.84, 31.52, 32.30, 33.19, and 34.39 degrees 2Θ.

2. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 1, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is pure Form III.

3. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claims 1 or 2 having an average particle size distribution of 10 μm or less.

4. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 3 having an average particle size distribution of 1 μm or less.

5. A composition comprising the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of any one of claims 1-4 and one or more excipients.

6. The composition of claim 5, wherein said one or more excipients comprise one or more pharmaceutically acceptable excipients.

7. The composition of claim 6, wherein said one or more pharmaceutically acceptable excipients comprise Miglyol 812, phospholipon 90G, or tocopheryl polyethylene glycol 1000 succinate, or a mixture thereof.

8. A method of making a composition, the method comprising admixing the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of any one of claims 1-4 and an excipient.

9. A method of regulating gene expression of a gene of interest in an isolated host cell, the method comprising contacting said host cell with the composition of claim 5, wherein the host cell comprises a polynucleotide encoding a gene switch that comprises a ligand binding domain that binds (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide.

10. Use of the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of any one of claims 1-4 for the manufacture of a medicament for treating cancer in a subject.

11. The use of claim 10, wherein a host cell within said subject comprises a polynucleotide encoding a gene switch that comprises a ligand binding domain that binds (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide.

12. The use of claim 11, wherein said gene switch comprises an ecdysone receptor ligand binding domain.

13. The use of claim 12, wherein said host cell further comprises a polynucleotide encoding a peptide, protein or polypeptide whose expression is regulated by said gene switch.

14. The use of claim 13, wherein said polynucleotide encodes IL-12 or a subunit thereof.

15. A method of controlling insects, the method comprising contacting said insects or their habitat with an insecticidally effective amount of the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide or (S)-3,5-dimethyl-benzoic acid N-

(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 1, or a composition thereof.

16. A method of producing pure crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of claim 1, the method comprising: (a) equilibrating a suspension of crystalline or amorphous (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide for at least 0.5 hour in one or more non-solvate forming solvents at 26°C or less; and (b) isolating said pure crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III.

17. A kit comprising the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of any one of claims 1-4.

CLAIMS

1. Crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III, characterized as having a powder x-ray diffraction pattern with peaks at 8.14, 8.52, 9.62, 11.02, 11.90, 12.16, 14.02, 14.62, 17.00, 17.88, 18.56, 19.02, 19.24, 20.51, 20.93, 22.19, 22.73, 23.22, 24.31, 24.53, 25.91, 26.22, 27.36, 27.73, 28.70, 30.84, 31.52, 32.30, 33.19, and 34.39 degrees 2Θ.

2. The crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of claim 1, further characterized as being pure.

3. The crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of claims 1 or 2 having an average particle size distribution of 10 μm or less.

4. The crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of claim 3 having an average particle size distribution of 1 μm or less.

5. A composition comprising the crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of any one of claims 1-4 and one or more excipients.

6. The composition of claim 5, wherein said one or more excipients comprise one or more pharmaceutically acceptable excipients.

7. The composition of claim 6, wherein said one or more pharmaceutically acceptable excipients comprise Miglyol 812, phospholipon 90G, or tocopheryl polyethylene glycol 1000 succinate, or a mixture thereof.

8. A method of making a composition, the method comprising admixing the crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of any one of claims 1-4 and an excipient.

9. A method of regulating gene expression of a gene of interest in an isolated host cell, the method comprising contacting said host cell with the composition of claim 5, wherein the host cell comprises a polynucleotide encoding a gene switch that comprises a ligand binding domain that binds (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide.

10. Use of the crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of any one of claims 1-4 for the manufacture of a medicament for treating cancer in a subject.

11. The use of claim 10, wherein a host cell within said subject comprises a polynucleotide encoding a gene switch that comprises a ligand binding domain that binds (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide.

12. The use of claim 11, wherein said gene switch comprises an ecdysone receptor ligand binding domain.

13. The use of claim 12, wherein said host cell further comprises a polynucleotide encoding a peptide, protein or polypeptide whose expression is regulated by said gene switch.

14. The use of claim 13, wherein said polynucleotide encodes IL-12 or a subunit thereof.

15. A method of controlling insects, the method comprising contacting said insects or their habitat with an insecticidally effective amount of the crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of claim 1, or a composition thereof.

16. A method of producing pure crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of claim 1, the method comprising: (a) equilibrating a suspension of crystalline or amorphous (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide for at least 0.5 hour in one or more non-solvate forming solvents at 26°C or less; and (b) isolating said pure crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III.

17. A kit comprising the crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III of any one of claims 1-4.