Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION**



GIRASOLE BRODIFACOUM 0.005%

Product type 14

Brodifacoum

Case Number in R4BP: BC-WA026220-62

Competent Authority: IT

Date: 11 January 2023

**CONFIDENTIAL ANNEX**

PAR

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# Product composition and formulation

NB: This information is confidential and should not be disclosed to third parties.

**Formulation process**

The formulation process consists mainly in 4 steps as follows:

1. Aroma and calcium dihydroxide are added to the sunflower seeds and mixed for 5 minutes.
2. Pigment, sorbic acid, bronopol, repxid and polyethylene glycol are added to the mixture resulting from step 1 and mixed for 10 minutes.
3. TEA, brodifacoum technical and oil are added to the mixture resulting from step 2 and mixed.
4. At the end, the food ingredient pappa E, milk and glutamate are added to obtain the final product.

## Qualitative and quantitative information on the full composition of the biocidal product

Table 1.1 Qualitative and quantitative information on the full composition of the biocidal product

|  | **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content** **(% w/w)** |
| --- | --- | --- | --- | --- | --- | --- |
| **1** | Brodifacoum 0.25%(premix, see table 1.2 further down this document) |   |  |  |  | 2.000 |
| Brodifacoum | 3-[(1*RS*,3*RS*;1*RS*,3*SR*)-3-(4′-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin | Active substance | 56073-10-0 | 259-980-5 | 0.005 |
| Denatonium benzoate | *N*-benzyl-2-[(2,6-dimethylphenyl)amino]-N,N-diethyl-2-oxoethanaminium benzoate | Human tastedeterrent | 3734-33-6  | 223-095-2  | 0.001 |
| Triethanolamine | 2,2’,2’’-nitrilotriethanol | Emulsifier | 102-71-6 | 203-049-8 | 0.2 |
| Propylene glycol | propane-1,2-diol | Solvent | 57-55-6 | 200-338-0 | 1.8 |
| **2** | Triethanolamine (TEA) | 2,2',2''-nitrilotriethanol  | Emulsifier  | 102-71-6  | 203-049-8  | 0.209 |
| **3** | Polyethylene glycol 200 (PEG 200) | - | Solvent  | 25322-68-3 | 500-038-2 | 1.047 |
| **4** | Oil seeds | - | Attractant | - | - | 0.366 |
| **5** | Milk powder | - | Attractant | - | - | 0.250 |
| **6** | Calcium dihydroxide | calcium dihydroxide | Stabilizer | 1305-62-0 | 215-137-3 | 0.375 |
| **7** | Sorbic acid | (2E,4E)-hexa-2,4-dienoic acid  | Preservative | 110-44-1  | 203-768-7  | 0.100 |
| **8** | Bronopol  | 2-bromo-2-nitropropane-1,3-diol  | Preservative | 52-51-7  | 200-143-0  | 0.050 |
| **9** | Pigment red 48.2 | calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate | Dye | 7023-61-2 | 230-303-5 | 0.226 |
| **10** | Aroma Biscotto Superior 11054/SB (LIPO) | mixture, see table 1.3.a below | Fragrance | - | - | 0.100 |
| **11** | Repxid BHN | mixture, see table 1.3.b below | Antioxidant | - | - | 0.032 |
| **12** | Pappa E | - | Attractant | - | - | 0.250 |
| **13** | L-Glutamic acid monosodium salt monohydrate | L-Glutamic acid monosodium salt monohydrate | Attractant | 6106-04-3 | -(list no. 612-072-6) | 0.483 |
| **14** | Sunflower seeds  | - | Bait | - | - | 94.511 |
|  | **Total** |  |  |  |  | **100.000** |

## Qualitative and quantitative information on the composition of the premix of the active substance

Table 1.2 Qualitative and quantitative information on the composition of the premix of the active substance – “Brodifacoum 0.25%”, present at 2.0% w/w in the final biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content** **(% w/w)** |
| Brodifacoum | 3-[(1*RS*,3*RS*;1*RS*,3*SR*)-3-(4′-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin | Active substance | 56073-10-0 | 259-980-5 | 0.25 | 0.005 |
| Denatonium benzoate | *N*-benzyl-2-[(2,6-dimethylphenyl)amino]-N,N-diethyl-2-oxoethanaminium benzoate | Human tastedeterrent  | 3734-33-6  | 223-095-2  | 0.05 | 0.001 |
| Triethanolamine | 2,2’,2’’-nitrilotriethanol | Emulsifier | 102-71-6 | 203-049-8 | 5 - 10 | 0.2\* |
| Propylene glycol | propane-1,2-diol | Solvent | 57-55-6 | 200-338-0 | 80 - 90 | 1.8\* |

\* maximum concentration in the biocidal mixture

## Qualitative and quantitative information on the composition of the non-active mixtures

Two co-formulants in the form of mixtures are present in the GIRASOLE BRODIFACOUM 0.005% w/w: **Aroma biscotto** and **Repxid**. The available confidential information is reported in the tables below.

Table 1.3.a Qualitative and quantitative information on the composition of the non-active mixture “Aroma Biscotto Superior 11054/SB (LIPO)”, 0.1% w/w in the final biocidal product

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content****(% w/w)** |
| --- | --- | --- | --- | --- | --- |
| Vanillin | 1-butoxypropan-2-ol | Flavour | 121-33-5 | 204-465-2 | 1 - 5 | 0.005\* |
| Etilvanillin | 3-ethoxy-4-hydroxybenzaldehyde | Flavour | 121-32-4 | 204-464-7 | 10 - 25 | 0.025\* |
| 2-acetylpyrazine | pyrazin-1-ylethan-1-one | Flavour | 22047-25-2 | 244-753-5 | 1.0 | 0.001\* |
| Furaneol | 4-hydroxy-2,5-dimethylfuran-3(2H)-one | Flavour | 3658-77-3 | 222-908-8 | 1.0 | 0.001\* |
| Metylcyclo pentenolone | 3-methylcyclopentane-1,2-dione | Flavour | 765-70-8 | 212-154-8 | 1.0 | 0.001\* |
| Triacetin  | 1,3-bis(acetyloxy)propan-2-yl acetate | Solvent | 102-76-1 | 203-051-9 | 25 - 50 | 0.050\* |
| Medium Chain Triglycerides | -(glycerides, mixed decanoyl and octanoyl) | Solvent | 73398-61-5 | 277-452-2 | 25 - 50 | 0.050\* |
| Benzyl alcohol | phenylmethanol | Solvent | 100-51-6 | 202-859-9 | 5 - 10 | 0.010\* |

\* maximum concentration in the biocidal mixture

Table 1.3.b Qualitative and quantitative information on the composition of the non-active mixture “Repxid BHN”, 0.032% w/w in the final biocidal product

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content****(% w/w)** |
| --- | --- | --- | --- | --- | --- |
| Glyceryl monooleate | 2,3-dihydroxypropyl oleate | Surfactant and co-emulsifier | 111-03-5 | 203-827-7 | 50 - 54 | 0.017\* |
| Ethyl diglycolor diethylene glycol monoethyl ether | 2-(2-ethoxyethoxy) ethan-1-ol | Solvent | 111-90-0 | 203-919-7 | 7 - 9 | 0.003\* |
| Citric acid | 2-hydroxypropane-1,2,3-tricarboxylic acid | Preservative | 77-92-9 | 201-069-1 | 0.1 - 0.2 | 0.00006\* |
| Butylated Hydroxytoluene (BHT) | 2,6-di-tert-butyl-4-methylphenol | Antioxidant | 128-37-0 | 204-881-4 | 4 - 25 | 0.008\* |
| Butylated hydroxyanisole (BHA)  | tert-butyl-4- methoxyphenol | Antioxidant | 25013-16-5 | 246-563-8 | 10 - 20 | 0.006\* |
| Hexylene glycol | 2-methylpentane-2,4-diol | Solvent | 107-41-5 | 203-489-0 | 5 - 9 | 0.003\* |

\* maximum concentration in the biocidal mixture

## Information on the tested product

Not relevant.

## Comparison of composition in case of change of composition

Not relevant.

Table 1.6 Comparison of composition in case of change of composition

| **Old composition** | **New composition** |
| --- | --- |
| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** | **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance  |  |  |  | (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) | Active substance  |  |  |  |
| (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) |  |  |  |  | (proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)) | (IUPAC and CA nomenclature or other international chemical name(s)) |  |  |  |  |
|  |  | *[Describe the function of the non-active substance]* |  |  |  |  |  | *[Describe the function of the non-active substance]*  |  |  |  |
| Total |  |  |  |  | 100% |  |  |  |  |  | 100% |

# Identification of substance(s) of concern

A substance of concern (SoC) is defined in Art. 3(f) of Regulation (EU) No. 528/2012 or the Biocidal Product Regulation (BPR) as any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.

In the following tables, the evaluation of the co-formulants for the identification of SoC has been summarised:

Table 2.1 Identification of substance(s) of concern

| **Common name**  | **Denatonium benzoate** | **Triethanolamine (TEA)** | **Polyethylene glycol 200** **(PEG 200)** | **Calcium dihydroxide** | **Sorbic acid** | **Bronopol** |
| --- | --- | --- | --- | --- | --- | --- |
| **CAS number** | 3734-33-6 | 102-71-6 | 25322-68-3 | 1305-62-0 | 110-44-1 | 52-51-7 |
| **EC number** | 223-095-2 | 203-049-8 | 500-038-2 | 215-137-3 | 203-768-7 | 200-143-0 |
| **Maximum concentration in the biocidal mixture (% w/w)** | 0.001 | **0.209 + 0.2 = 0.409** | 1.047 | 0.375 | 0.100 | 0.050 |
| **Classification and Labelling according to Regulation (EC) No 1272/2008:** | Acute Tox. 4, H302Acute Tox. 4, H332Eye Dam. 1, H318 | Repr. 2 H361fdSTOT RE 2 H373Eye dam. 1 H318Skin Irrit. 2 H315 | Not classified | Skin Irrit. 2, H315Eye Dam. 1, H318STOT SE 3 H335 | Skin Irrit. 2, H315Eye Irrit. 2, H319STOT SE 3 H335  | Acute tox. 4, H302Acute tox. 4, H312Skin Irrit. 2, H315Eye Dam. 1, H318STOT SE 3, H335Aquatic Acute 1, H400 (M=10) |
| **Substance of Concern (SoC): Consequence for the product classification** **(Y/N)** | NH302, H332 and H318: the substance is present below the concentration of 1% w/w in the BP | NH315, H318 and H373: the substance is present below theconcentration of 1% w/w in the BPH361fd: the substance is present below theconcentration of 3% w/w in the BP | NNot hazardous according to Regulation (EC) No. 1272/2008 | NH315, H318 and H335: the substance is present below the concentration of 1% w/w in the BP | NH315, H319, H335: the substance is present below the concentration of 1% w/w in the BP | NH302, H312, H315, H318, H335: the substance is present below the concentration of 1% w/w in the BPH400: the substance is present below the concentration of 0.1% w/w in the BP |
| **Substance of Concern (SoC): biocidal active substance ≥ 0.1% (Y/N)** | N | N | N | **Y**Biocidal active substance in PT02 & PT03 (CAR is available). This co-formulant is present in the biocidal product at a concentration >0.1% w/w  | NUnder evaluation as a biocidal active substance in PT06. However, no draft final CAR is available. Although it is present at a concentration of 0.1% w/w in the BP, this co-formulant is not considered as a SoC | NUnder evaluation as a biocidal active substance in several PTs. However, no draft final CAR is available. Additionally, the substance is present at a concentration <0.1% w/w in the BP. Therefore, this co-formulant is not considered as a SoC |
| **Substance of Concern (SoC): synergist (Y/N)** | N  | N | N | N | N | N |
| **Substance of Concern (SoC): candidate list (Y/N)** | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED |
| **Substance of Concern (SoC):** **EU IOELV (Y/N)** | N | N\*See below | N\* See below | **Y**Long term: 1 mg/m3Short term 4 mg/m3 | N | N |
| No Environmental Quality Standard (EQS) has been derived under Directive 2000/60/EC (Water Framework Directive; according to paragraph 67, Annex VI, BPR) for any of the substances screened in the above table.  |

\* For some of the co-formulant, though no EU Occupational Exposure Limit value (OELV) has been defined, however national IOELVs are available. See below.

Table 2.2 Identification of substance(s) of concern

| **Common name**  | **Pigment red 48.2** | **Glyceryl monooleate** | **Ethyl diglycol** | **Citric acid** | **Butylated Hydroxytoluene (BHT)** | **Butylated hydroxyanisole (BHA)** |
| --- | --- | --- | --- | --- | --- | --- |
| **CAS number** | 7023-61-2 | 111-03-5 | 111-90-0 | 77-92-9 | 128-37-0 | 25013-16-5 |
| **EC number** | 230-303-5 | 203-827-7 | 203-919-7 | 201-069-1 | 204-881-4 | 246-563-8 |
| **Maximum concentration in the biocidal mixture** **(% w/w)** | 0.226 | 0.017 | 0.003 | 0.00006 | 0.008 | 0.006 |
| **Classification and Labelling according to Regulation (EC) No 1272/2008:** | Not classified | Not classified | Not classified | Eye Irrit. 2, H319STOT SE 3, H335 | Aquatic Acute 1, H400 (M=1)Aquatic Chronic 1, H410 (M=1) | Carc. 2 H351,Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335,Aquatic Chronic 2 H411 |
| **Substance of Concern (SoC): Consequence for the product classification** **(Y/N)** | NNot hazardous according to Regulation (EC) No. 1272/2008 | NNot hazardous according to Regulation (EC) No. 1272/2008 | NNot hazardous according to Regulation (EC) No. 1272/2008 | NH319, H335 : the substance is present below the concentration of 1% w/w in the BP | NH400 and H410: the substance is present below the concentration of 0.1% w/w in the BP | NH302, H318, H315, H335: the substance is present below the concentration of 1% w/w in the BPCarc. 2 H351: the substance is present below the trigger concentration of 1% w/w in the BPH411: the substance is present below the trigger concentration of 1% w/w in the BP |
| **Substance of Concern (SoC): biocidal active substance ≥ 0.1% (Y/N)** | N | N | N | NActive substance included in Annex I to the BPR (update: 29.03.2021). Besides, it is present in the biocidal product at a concentration <<0.1% w/w | N | N |
| **Substance of Concern (SoC): synergist (Y/N)** | N | N | N | N | N  | N |
| **Substance of Concern (SoC): candidate list (Y/N)** | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | NNeither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.No PBT.**Under assessment as ED** | NNeither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list. No PBT.**Under assessment as ED** |
| **Substance of Concern (SoC): EU IOELV (Y/N)** | N | N | N\*See below | N\*See below | N\*See below | N\*See below |
| No Environmental Quality Standard (EQS) has been derived under Directive 2000/60/EC (Water Framework Directive; according to paragraph 67, Annex VI, BPR) for any of the substances screened in the above table.  |

\* For some of the co-formulant, though no EU Occupational Exposure Limit value (OELV) has been defined, however national IOELVs are available. See below.

**Table 2.3 Identification of substance(s) of concern**

| **Common name**  | **Hexylene glycol** | **L-Glutamic acid monosodium salt monohydrate** | **Propylene glycol** | **Vanillin** | **Etilvanillin** | **2-acetylpyrazine** |
| --- | --- | --- | --- | --- | --- | --- |
| **CAS number** | 107-41-5 | 6106-04-3 | 57-55-6 | 121-33-5 | 121-32-4 | 22047-25-2 |
| **EC number** | 203-489-0 | -(list no. 612-072-6) | 200-338-0 | 204-465-2 | 204-464-7 | 244-753-5 |
| **Maximum concentration in the biocidal mixture (% w/w)** | 0.003 | 0.483 | 1.8 | 0.005 | 0.025 | 0.001 |
| **Classification and Labelling according to Regulation (EC) No 1272/2008:** | Eye Irrit. 2 H319, Skin Irrit. 2 H315 | Not classified | Not classified | Eye Irrit. 2 H319 | Eye Irrit. 2 H319 | Not classified |
| **Substance of Concern (SoC): Consequence for the product classification** **(Y/N)** | NH319, H315: the substance is present below the trigger concentration of 1% w/w in the BP | NNot hazardous according to Regulation (EC) No. 1272/2008 | NNot hazardous according to Regulation (EC) No. 1272/2008 | NH319: the substance is present below the trigger concentration of 1% w/w in the BP | NH319: the substance is present below the trigger concentration of 1% w/w in the BP | NNot hazardous according to Regulation (EC) No. 1272/2008 |
| **Substance of Concern (SoC): biocidal active substance > 0.1% (Y/N)** | N | N | N | N | N | N |
| **Substance of Concern (SoC): synergist (Y/N)** | N | N  | N | N  | N  | N |
| **Substance of Concern (SoC): candidate list (Y/N)** | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED |
| **Substance of Concern (SoC): EU IOELV (Y/N)** | N\*See below | N | N\*See below | N | N | N |
| No Environmental Quality Standard (EQS) has been derived under Directive 2000/60/EC (Water Framework Directive; according to paragraph 67, Annex VI, BPR) for any of the substances screened in the above table.  |

\* For some of the co-formulant, though no EU Occupational Exposure Limit value (OELV) has been defined, however national IOELVs are available. See below.

Table 2.4 Identification of substances of concern

| **IUPAC name or other accepted chemical name**  | **Furaneol** | **Metylcyclo pentenolone** | **Triacetin** | **Glycerides, mixed decanoyl and octanoyl** | **Benzyl alcohol** |
| --- | --- | --- | --- | --- | --- |
| **CAS number** | 3658-77-3 | 765-70-8 | 102-76-1 | 73398-61-5 | 100-51-6 |
| **EC number** | 222-908-8 | 212-154-8 | 203-051-9 | 277-452-2 | 202-859-9 |
| **Maximum concentration in the biocidal mixture (% w/w)** | 0.001 | 0.001 | 0.050 | 0.050 | 0.010 |
| **Classification and Labelling according to Regulation (EC) No 1272/2008:** | Acute Tox. 4 H302,Skin Corr. 1B H314, Skin Sens. 1A H317, Eye Dam. 1 H318 | Not classified | Not classified | Not classified |  Acute Tox. 4 H302,Acute Tox. 4 H332 and Eye Irrit. 2 H319 |
| **Substance of Concern (SoC): Consequence for the product classification** **(Y/N)** | NH302, H314, H317 and H318: the substance is present below the trigger concentration of 1% w/w in the BP | NNot hazardous according to Regulation (EC) No. 1272/2008 | NNot hazardous according to Regulation (EC) No. 1272/2008 | NNot hazardous according to Regulation (EC) No. 1272/2008 | NH302, H332, H319: the substance is present below the trigger concentration of 1% w/w in the BP |
| **Substance of Concern (SoC): biocidal active substance ≥ 0.1% (Y/N)** | N | N | N | N | NUnder evaluation as a biocidal active substance in PT06. However, no draft final CAR is available. Besides, the substance is present at a concentration <0.1% w/w in the BP, therefore this co-formulant is not considered as a SoC |
| **Substance of Concern (SoC): synergist (Y/N)** | N | N  | N | N  | N  |
| **Substance of Concern (SoC): candidate list (Y/N)** | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED | N Neither included in the list (the *candidate list*) established in accordance with the REACH Regulation Art. 59(1) nor fulfil the criteria for inclusion in the candidate list.Neither PBT nor ED |
| **Substance of Concern (SoC): EU IOELV (Y/N)** | N | N | N | N | N\*See below |
| No Environmental Quality Standard (EQS) has been derived under Directive 2000/60/EC (Water Framework Directive; according to paragraph 67, Annex VI, BPR) for any of the substances screened in the above table.  |

\* For some of the co-formulant, though no EU Occupational Exposure Limit value (OELV) has been defined, however national IOELVs are available. See below.

As agreed in the Human Health WG-II (March 2019), national workplace exposure limits should be included in the PAR, only for information:

**TRIETHANOLAMINE**



**PEG**



**DIETHYLENE GLYCOL ETHYL ETHER**



**CITRIC ACID**



**BHT**



**BHA**



**POLYETHYLENE GLYCOL**



**HEXYLENE GLYCOL**



**BENZYL ALCOHOL**



**CONCLUSION ON SoC IDENTIFICATION:**

In light of the above, according to the “Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment” and the “Guidance on the BPR Volume IV Environment – Part B and C Assessment and Evaluation”, one co-formulant in GIRASOLE BRODIFACOUM 0.005% fulfils two criteria (biocidal active substance at ≥ 0.1% w/w in the BP; substance with an EU-OEL) and should be identified as a substance of concerns (SoC): **calcium dihydroxide** (CAS No. 1305-62-0).

Additional evaluation for the identified SoC is provided in the PAR.

# Assessment of endocrine-disrupting properties of non- active substance(s)

Endocrine Disrupting (ED) properties assessment of the non-active substances (for human health effects & environmental effects) has been performed according to the ED criteria as set in Regulation (EU) 2017/2100.

The procedure followed to complete endocrine-disruptors assessment for all co-formulants takes into account the criteria provided in the “Guidance for the identification of endocrine disruptors in the context of Regulation (EU) No 528/2012”, the step-wise instruction prepared by UK in the “CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants\_final” and the “CA-March21-Doc.4.3” agreed in March 2021 by the Biocides Competent Authorities, to bridge the assessment of endocrine disrupting (ED) properties of non-active substances (so-called “co-formulants”) in biocidal products with the integrated regulatory strategy under Regulation (EC) No 1907/2006 (REACH) (available on ECHA’s website at <https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products>).

According to the documents indicated above, a step-wise approach has been proposed for a targeted determination of whether, based on an EU decision, a non-active substance (so-called “co-formulants”) in a biocidal product is an ED or not (part A); if there are any relevant assessments under REACH (part B); and, if necessary, moving on to check whether there is existing information suggesting an ‘indication’ of ED properties that may need to be further investigated (part C).

A schematic representation of subsequential steps approach followed for the assessment of ED properties of non-active substances is shown in Figure 1.



**Part A: Checking if, based on an EU decision, there has been a conclusion on whether the non-active substance is an ED or not**

* **Step 1: Has the non-active substance been identified as an ED in the BPR and PPPR lists?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance name** | **CAS number** | **Check decisions under BPR and PPPR** |  |
| Denatonium benzoate  | 3734-33-6  | Not found in BPR, not approved as PPPR | proceed to Step 2 |
| Triethanolamine (TEA) | 102-71-6  | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Polyethylene glycol 200 (PEG 200) | 25322-68-3 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Calcium dihydroxide | 1305-62-0 | Calcium dihydroxide is an approved biocidal active substance (PT2 and PT3).According to the BPC opinion[[1]](#footnote-2), calcium dihydroxide is not considered to have endocrine disrupting proprieties. | proceed to Step 2 |
| Sorbic acid  | 110-44-1  | Under approval in BPR not found in PPPR | proceed to Step 2 |
| Bronopol  | 52-51-7  | Under approval in BPR, not approved in PPPR | proceed to Step 2 |
| Pigment red 48.2 | 7023-61-2 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Glyceryl monooleate | 111-03-5 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Ethyl diglycol or diethylene glycol monoethyl ether | 111-90-0 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Citric acid | 77-92-9 | Citric acid is an approved biocidal active substance (PT2).According to the BPC opinion[[2]](#footnote-3), citric acid is not considered to have endocrine disrupting proprieties as does not fulfil criterion (d) of Article 5(1) of BPR. | proceed to Step 2 |
| Butylated Hydroxytoluene (BHT) | 128-37-0 | Not found nor in BPR nor in PPPR | Proceed to Step 2 |
| tert-butyl-4-methoxyphenol (BHA) | 25013-16-5 | Not found nor in BPR nor in PPPR | Proceed to Step 2 |
| Hexylene glycol | 107-41-5 | Not found nor in BPR nor in PPPR | Proceed to Step 2 |
| L-Glutamic acid monosodium salt monohydrate | 6106-04-3 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Propylene glycol  | 57-55-6  | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Vanillin | 121-33-5 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Etilvanillin | 121-32-4 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Furaneol | 3658-77-3 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Metylcyclo pentenolone | 765-70-8 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Triacetin | 102-76-1 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Glycerides, mixed decanoyl and octanoyl | 73398-61-5 | Not found nor in BPR nor in PPPR | proceed to Step 2 |
| Benzyl alcohol | 100-51-6 | Benzyl alcohol is a biocidal active substance (PT6): initial application for approval in progress (Competent authority evaluation). | proceed to Step 2 |
| 2-acetylpyrazine | 22047-25-2 | Not found nor in BPR nor in PPPR | proceed to Step 2 |

* **Step 2: Is the non-active substance included in the list of substances of very high concern (SVHC) due to ED concern (according to Article 57(f) and Article 59(1) of the REACH)?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance name** | **CAS number** | **Check candidate List of SVHCs[[3]](#footnote-4)** |  |
| Denatonium benzoate  | 3734-33-6  | Not found | proceed to Step 3 |
| Triethanolamine (TEA) | 102-71-6  | Not found | proceed to Step 3 |
| Polyethylene glycol 200 (PEG 200) | 25322-68-3 | Not found | proceed to Step 3 |
| Calcium dihydroxide | 1305-62-0 | Not found | proceed to Step 3 |
| Sorbic acid  | 110-44-1  | Not found | proceed to Step 3 |
| Bronopol  | 52-51-7  | Not found | proceed to Step 3 |
| Pigment red 48.2 | 7023-61-2 | Not found | proceed to Step 3 |
| Glyceryl monooleate | 111-03-5 | Not found | proceed to Step 3 |
| Ethyl diglycol or diethylene glycol monoethyl ether | 111-90-0 | Not found | proceed to Step 3 |
| Citric acid | 77-92-9 | Not found | proceed to Step 3 |
| Butylated Hydroxytoluene (BHT) | 128-37-0 | Not found | proceed to Step 3 |
| tert-butyl-4-methoxyphenol (BHA) | 25013-16-5 | Not found | proceed to Step 3 |
| Hexylene glycol | 107-41-5 | Not found | proceed to Step 3 |
| L-Glutamic acid monosodium salt monohydrate | 6106-04-3 | Not found | proceed to Step 3 |
| Propylene glycol  | 57-55-6  | Not found | proceed to Step 3 |
| Vanillin | 121-33-5 | Not found | proceed to Step 3 |
| Etilvanillin | 121-32-4 | Not found | proceed to Step 3 |
| Furaneol | 3658-77-3 | Not found | proceed to Step 3 |
| Metylcyclo pentenolone | 765-70-8 | Not found | proceed to Step 3 |
| Triacetin | 102-76-1 | Not found | proceed to Step 3 |
| Glycerides, mixed decanoyl and octanoyl | 73398-61-5 | Not found | proceed to Step 3 |
| Benzyl alcohol | 100-51-6 | Not found | proceed to Step 3 |
| 2-acetylpyrazine | 22047-25-2 | Not found | proceed to Step 3 |

* **Step 3: Is the non-active substance as food/foodstuff material according to the definition of “food” within Regulation (EC) No 178/2002 [[4]](#footnote-5),[[5]](#footnote-6) ?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance name** | **CAS number** | **Food/ foodstuff ?** |  |
| Denatonium benzoate  | 3734-33-6  | No | proceed to Step 4 |
| Triethanolamine (TEA) | 102-71-6  | No | proceed to Step 4 |
| Polyethylene glycol 200 (PEG 200) | 25322-68-3 | Yes (E 1521) | No ED |
| Calcium dihydroxide | 1305-62-0 | Yes (E 526) | No ED |
| Sorbic acid  | 110-44-1  | Yes (E 200) | No ED |
| Bronopol  | 52-51-7  | No | proceed to Step 4 |
| Pigment red 48.2 | 7023-61-2 | No | proceed to Step 4 |
| Glyceryl monooleate | 111-03-5 | No | proceed to Step 4 |
| Ethyl diglycol or diethylene glycol monoethyl ether | 111-90-0 | No | proceed to Step 4 |
| Citric acid | 77-92-9 | Yes (E 330) | No ED |
| Butylated Hydroxytoluene (BHT) | 128-37-0 | Yes (E 321) | No ED. However, proceed to step 4, due to some alerts |
| tert-butyl-4-methoxyphenol (BHA) | 25013-16-5 | Yes (E 320) | No ED. However, proceed to step 4, due to some alerts |
| Hexylene glycol | 107-41-5 | No | proceed to Step 4 |
| L-Glutamic acid monosodium salt monohydrate | 6106-04-3 | Yes (E 620) | No ED |
| Propylene glycol  | 57-55-6  | Yes (E1520) | No ED |
| Vanillin | 121-33-5 | No | proceed to Step 4 |
| Etilvanillin | 121-32-4 | No | proceed to Step 4 |
| Furaneol | 3658-77-3 | No | proceed to Step 4 |
| Metylcyclo pentenolone | 765-70-8 | No | proceed to Step 4 |
| Triacetin | 102-76-1 | Yes (E 1518) | No ED |
| Glycerides, mixed decanoyl and octanoyl | 73398-61-5 | No | proceed to Step 4 |
| Benzyl alcohol | 100-51-6 | Yes (E 1519) | No ED |
| 2-acetylpyrazine | 22047-25-2 | No | proceed to Step 4 |

**Part B: Checking if there are any relevant assessments under REACH**

* **Step 4: Check the status of the non-active substance in ACT (Activities Coordination Tool)[[6]](#footnote-7)**

1. Is there a SVHC proposal for ED?

2. Is the non-active substance included in CoRAP list due to ED?

3. Is substance evaluation ongoing due to ED properties?

4. Is data generation under dossier evaluation ongoing to clarify ED concern?

5. Has the non-active substance been screened and did the conclusion show indications of ED properties?

| **Substance name** | **CAS number** | **Status in ACT[[7]](#footnote-8)** | **REACH registration dossier[[8]](#footnote-9)** | **Proposal for ED?** |
| --- | --- | --- | --- | --- |
| **Data generation and assessment** | **ARN** | **Regulatory risk managment** |
| **SEv - CoRAP[[9]](#footnote-10)** | **PBT** | **DEv** | **ED** | **CLH** | **SVCH** | **Recom** | **Restri-ction** | **1** | **2** | **3** | **4** | **5** |
| Denatonium Benzoate  | 3734-33-6  | - | - | - | - | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| Triethanolamine (TEA) | 102-71-6  | 1  | - | 1 | - | - | - | - | - | - | Y | N | N | N | N | **No ED properties**. No other additional concerns are identified. The eMSCA concluded that further information was not required to clarify any concerns. |
| Bronopol  | 52-51-7  | - | - | - | - | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| Pigment red 48.2 | 7023-61-2 | - | - | 1 | - | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| Glyceryl monooleate | 111-03-5 | - | - | - | - | - | - | - | - | - | N | N | N | N | N | Not screened. Go to step 5 |
| Ethyl diglycol  | 111-90-0 | - | - | - | - | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| Butylated Hydroxytoluene (BHT) | 128-37-0 | 1  | - | 5 | 1 | 1 | - | - | - | - | Y | N | Y | N | N | Substance included in CoRAP list due to potential ED properties. Evaluation not finished. Go to step 5 |
| tert-butyl-4-methoxyphenol (BHA) | 25013-16-5 | - | - | 1 | 1 | 1 | - | - | - | - | N | N | N | Y | Y | Substance proposed for inclusion in CoRAP list due to potential ED properties. Go to step 5 |
| Hexylene glycol | 107-41-5 | - | - | 3 | - | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| Vanillin | 121-33-5 | - | - | 2 | - | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| Etilvanillin | 121-32-4 |  | - | - | 1 | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| Furaneolo | 3658-77-3 | - | - | - | - | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| Metylcyclo pentenolone | 765-70-8 | - | - | - | - | - | - | - | - | - | N | N | N | N | N | Not screened. Go to step 5 |
| Glycerides, mixed decanoyl and octanoyl | 73398-61-5 | - | - | 2 | - | - | - | - | - | - | Y | N | N | N | N | Not screened. Go to step 5 |
| 2-acetylpyrazine | 22047-25-2 | - | - | - | - | - | - | - | - | - | N | N | N | N | N | Not screened. Go to step 5 |

**Part C: Checking if there are other indications of ED properties**

* **Step 5: Check all information provided by the applicant and indications from the classification. Are there indications from information provided by the applicant or from classification?**
* **Step 6: Check US databases (ToxCast, EDSP), EASIS 2.0 and public research.**

| **Substance name** | **CAS number** | **Classification**  | **ED alert found in** |
| --- | --- | --- | --- |
| **USEPA ToxCast[[10]](#footnote-11)** | **USEPA EDSP[[11]](#footnote-12)** | **EASIS 2.0[[12]](#footnote-13)** | **Other international review programme** |
| Denatonium Benzoate  | 3734-33-6  | H302, H330, H318 | Yes Endocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 0 ER assay(out of 18) and was positive in 1 AR assay (tested in 17) | Yes Endocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 0 ER assay(out of 18) and was positive in 1 AR assay (tested in 17) | Not found | Not found |
| Triethanolamine (TEA) | 102-71-6  | H361fd, H373H318, H315 | YesEndocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 2 ER assay (out of 18) and was positive in 1 AR assay (tested in 14) | YesEndocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 2 ER assay (out of 18) and was positive in 1 AR assay (tested in 14) | Not found | Not found |
| Bronopol  | 52-51-7  | H302, H312, H315, H318, H335, H400 | Yes Endocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 1 ER assay (out of 18) and was positive in 9 AR assay (tested in 14) | Yes Endocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 1 ER assay (out of 18) and was positive in 9 AR assay (tested in 14) | Not found | Not found |
| Pigment red 48.2 | 7023-61-2 | Not Classified | No | No  | Not found | Not found |
| Glyceryl monooleate | 111-03-5 | Not Classified | No | No  | Not found | Not found |
| Ethyl diglycolor diethylene glycol monoethyl ether | 111-90-0 | Not Classified | No | No  | Not found | Not found |
| Butylated Hydroxytoluene (BHT) | 128-37-0 | H400, H410 | YesEndocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 4 ER assay (out of 18) and was positive in 5 AR assay(tested in 14) | Yes Endocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 4 ER assay (out of 18) and was positive in 5 AR assay (tested in 14) | Not found | Not found |
| tert-butyl-4-methoxyphenol (BHA) | 25013-16-5 | H351, H302, H318, H315, H335, H411 | YesEndocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 0 ER assay (out of 6) and was positive in 1 AR assay (tested in 8) | Yes Endocrine Disruption Potential. Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 0 ER assay (out of 6) and was positive in 1 AR assay (tested in 8) | Yes | Not found |
| Hexylene glycol | 107-41-5 | H319, H315 | No | No  | Not found | Not found |
| Vanillin | 121-33-5 | H319 | YesEndocrine Disruption Potential.Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 1 ER assay (out of 21) and was positive in 1 AR assay (tested in 14) | YesEndocrine Disruption Potential.Significant Estrogen and Androgen Receptor activity seen. Chemical was positive in: 1 ER assay (out of 21) and was positive in 1 AR assay (tested in 14) | Not found | Not found |
| Etilvanillin | 121-32-4 | H319 | No | No  | Not found | Not found |
| Furaneol | 3658-77-3 | H302, H314, H317, H318 | No | No  | Not found | Not found |
| Metylcyclo pentenolone | 765-70-8 | Not Classified | No | No  | Not found | Not found |
| Glycerides, mixed decanoyl and octanoyl | 73398-61-5 | Not Classified | No | No  | Not found | Not found |
| 2-acetylpyrazine | 22047-25-2 | Not classified | No | No  | Not found | Not found |

**Conclusion:**

Polyethylene glycol 200 (PEG 200), calcium diihydroxide, sorbic acid, citric acid, L-Glutamic acid monosodium salt monohydrate, propylene glycol, triacetin and benzyl alcohol are co-formulants included in the list of food additives, thus no ED is expected.

* Denatonium Benzoate is registered under REACH regulation with a full dossier. Some indications of potential ED properties come from USEPA ToxCast and EDSP21, since the substance gave positive results for androgen antagonism in some of the in vitro tests. However, no other concerns are raised by any other list of concern (EU priority list, CoRAP) and the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Triethanolamine (TEA) is registered under REACH regulation with a full dossier. Some indications of potential ED properties come from USEPA ToxCast and EDSP21, since the substance gave positive results for androgen and estrogen antagonism in some of the in vitro tests. However, no other concerns are identified by any other list of concern (EU priority list, CoRAP, ToxCast) and the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Bronopol is registered under REACH regulation with a full dossier. Some indications of potential ED properties come from USEPA and EDSP21, since the substance gave positive results for androgen antagonism in some of the in vitro tests. However, no other concerns are raised by any other list of concern (EU priority list, CoRAP, ToxCast) and the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Pigment red 48.2 is registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover, the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Glyceryl monooleate is not registered under REACH regulation. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover, the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Ethyl diglycol is registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover, the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Butylated Hydroxytoluene (BHT) is registered under REACH regulation with a full dossier and is included in the list of food additives, thus no ED is expected. However, the substance is also included in CoRAP list due to potential ED properties but a conclusion has not been agreed, yet. In case this co-formulant is eventually identified as an ED, the biocidal product could be considered as ED and the authorization could have to revised accordingly.
* tert-butyl-4-methoxyphenol (BHA) is not registered under REACH regulation, bu is included in the list of food additives, thus no ED is expected. However the substance is proposed to be included in CoRAP list due to potential ED. In case this co-formulant is eventually identified as an ED, the biocidal product could be considered as ED and the authorization could have to revised accordingly.
* Hexylene glycol is registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover, the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Vanillin is registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover, the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Etilvanillin is registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover, the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Furaneolo is registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Metylcyclo pentenolone is registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* Glycerides, mixed decanoyl and octanoylis registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.
* 2-acetylpyrazine is registered under REACH regulation with a full dossier. Based on toxicology and ecotoxicology data the substance does not indicate any potential of ED properties. This is also confirmed due to the fact that the substance is not included in any list of concern (EU priority list, CoRAP, EUEPA ToxCast). Moreover, the substance is not classified as Repr. Tox or STOT-RE under CLP regulation.

## Summary of the assessment of ED properties of non-active substances

## None of the co-formulants are likely to possess endocrine-disrupting (ED) properties, based on the data/information available at the moment. The product GIRASOLE BRODIFACOUM 0.005% is concluded not to have ED properties, according to the scientific criteria set out in Regulation (EU) 2017/2100.

However, as regards butylated Hydroxytoluene (BHT) and tert-butyl-4-methoxyphenol (BHA), depending on the outcome of their assessment (as already mentioned under the ED screening), the conclusions on the current authorization might need to be revised.

# Human health assessment

## Calculations for classification

GIRASOLE BRODIFACOUM 0.005% contains **brodifacoum** 0.005% w/w. Therefore, due to the specific concentration limits listed in Annex VI of CLP, the product is Repr. 1A H360D and STOT RE 2 H373. This means that it can be sold to and used by professional users only.

Hazard statements are triggered by the a.s.  at 0.005% w/w. Precautionary statements are selected consistently. Please, refer to section 2.1.3 of the PAR.

It shall be noted that co-formulant **denatonium benzoate** is present in the a.s. premix, but – since it is below the threshold value – it is not explicitly mentioned in the SDS of the biocidal product nor in the SDS of the a.s. premix.

Co-formulants **bronopol**, with M = 10 (Aquatic Acute), and **calcium dihydroxide**, with  Community TLV, are explicitly mentioned under section 3 and section 8 of the SDS of GIRASOLE BRODIFACOUM 0.005%, however they do not affect the classification of the product. No other co-formulant contributes to the classification of GIRASOLE BRODIFACOUM 0.005%, either.

## Calculations related to the assessment of effects on human health

See the considerations above.

# Environmental risk assessment

See the considerations above.

# Other

None.

1. BPC, Opinion on the application for approval of the active substance calcium dihydroxide – Product Type 2 – ECHA/BPC/100/2016. <https://echa.europa.eu/documents/10162/d8c734a1-62e0-45a0-9046-e2d904e493d6> [↑](#footnote-ref-2)
2. BPC, Opinion on the application for approval of the active substance Citric Acid – Product Type 2 – ECHA/BPC/088/2016. https://echa.europa.eu/documents/10162/b575d3f2-666e-4adc-b9b1-97f9c78fc43a [↑](#footnote-ref-3)
3. <https://echa.europa.eu/it/candidate-list-table> [↑](#footnote-ref-4)
4. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (<https://eur-lex.europa.eu/legalcontent/EN/ALL/?uri=celex%3A32002R0178>) [↑](#footnote-ref-5)
5. This is in line with the Coordination Group meeting agreements (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants\_final and CG-41-2020-03 AP 16.5 ED co-formulant\_assessment by MS\_vf\_PUBLIC). [↑](#footnote-ref-6)
6. ACT is accessible at: https://echa.europa.eu/it/pact [↑](#footnote-ref-7)
7. ACT is accessible at: <https://echa.europa.eu/it/pact> [↑](#footnote-ref-8)
8. <https://echa.europa.eu/it/information-on-chemicals/registered-substances> [↑](#footnote-ref-9)
9. <https://echa.europa.eu/it/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table> [↑](#footnote-ref-10)
10. <https://comptox.epa.gov/dashboard/> (check in “Bioactivity 🡪 ToxCast Models”) [↑](#footnote-ref-11)
11. <https://comptox.epa.gov/dashboard/> (check in “Executive Summary”) [↑](#footnote-ref-12)
12. <https://easis.jrc.ec.europa.eu/iuclid6-web/dashboard> [↑](#footnote-ref-13)