Appendix to:
EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance ABE-IT 56 (components of lysate of Saccharomyces cerevisiae strain DDSF623). EFSA Journal 2018;16(8):5400, 21 pp. doi:10.2903/j.efs.2018.5400
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Appendix A – List of end points for the active substance and the representative formulation

### Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

| Active substance (ISO Common Name) | ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623) Not an ISO common name. |
|-----------------------------------|--------------------------------------------------------------------------------------------------|
| Function (e.g. fungicide)         | Elicitor of the plant natural defence to control pathogen diseases                                 |
| Rapporteur Member State           | France                                                                                           |
| Co-rapporteur Member State        |                                                                                                  |

### Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

| Chemical name (IUPAC)            | /                                                                                                 |
| Chemical name (CA)               | /                                                                                                 |
| CIPAC No                         | /                                                                                                 |
| CAS No                          | /                                                                                                 |
| EC No (EINECS or ELINCS)         | /                                                                                                 |
| FAO Specification (including year of publication) | none                                                                                           |

| Minimum purity of the active substance as manufactured | 1000 g/kg (active substance) |
|----------------------------------------------------------|-----------------------------|
|                                                          | As the active substance ABE IT 56 is a fractionation product of the lysate of *Saccharomyces cerevisiae* strain DDSF623, 3 different markers of quantification are proposed: |
|                                                          | - total proteins: 58.88 – 62.12 (g/100g) |
|                                                          | - total reducing sugars: 1.39 – 3.43 (g/100g) |
|                                                          | - free amino acids: 29.05 – 31.75 (g/100g) |
|                                                          | The composition markers proposed are not adequate to identify the product as an extract of *S. cerevisiae* strain DDSF623 as other yeasts would provide comparable quantities. |

| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | no relevant impurity |


Molecular formula
Non applicable, the active substance ABE IT 56 is a complex mixture containing the components of lysate of *Saccharomyces cerevisiae* strain DDFS623. It is not a single well-defined molecule but a mixture of soluble and insoluble parts of lysis products.

Molar mass

Structural formula
**Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)**

| Property                                                                 | Value                      |
|-------------------------------------------------------------------------|----------------------------|
| Melting point (state purity)                                            | >300 °C                    |
| Boiling point (state purity)                                            | >300 °C                    |
| Temperature of decomposition (state purity)                             | /                          |
| Appearance (state purity)                                              | Physical state: powder     |
|                                                                        | Colour: light beige        |
|                                                                        | Odour: characteristic yeast odour |
| Vapour pressure (state temperature, state purity)                       | 510 Pa at 20°C             |
| Henry’s law constant (state temperature)                                | /                          |
| Solubility in water (state temperature, state purity and pH)           | < 0.1 g/L at 22°C          |
| Solubility in organic solvents (state temperature, state purity)       | At 21°C the solubility of ABE IT 56 is as follows |
|                                                                        | n-heptane < 10 g/L         |
|                                                                        | xylene < 10 g/L            |
|                                                                        | dichloromethane < 10 g/L   |
|                                                                        | methanol < 10 g/L          |
|                                                                        | acetone < 10 g/L           |
|                                                                        | ethyl acetate < 10 g/L     |
| Surface tension (state concentration and temperature, state purity)    | 48.2 mN/m at 20°C (90 % saturated solution) |
| Partition coefficient (state temperature, pH and purity)               | /                          |
| Dissociation constant (state purity)                                    | /                          |
| UV/VIS absorption (max.) incl. ε (state purity, pH)                    | not applicable             |
| Flammability (state purity)                                             | Not highly flammable substance |
| Explosive properties (state purity)                                     | Not explosive              |
| Oxidising properties (state purity)                                     | No oxidising properties    |
Summary of representative uses evaluated, for which all risk assessments needed to be completed (ABE-IT 56 (components of lysate of \textit{Saccharomyces cerevisiae} strain DDSF623))
(Regulation (EU) No 284/2013, Annex Part A, points 3, 4)

| Member state(s) | Crop and/or situation (crop destination / purpose of crop) | Product name | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Conc. a.s. (i) | Type (d-f) | Application Method / Kind | Timing / Growth stage of crop & season | Max. number per crop/season | Min. interval between applications | Application rate | PHI (days) | Remarks: |
|-----------------|------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------|----------------|-----------|-------------------------|-----------------------------------|-----------------------------------|----------------------------------|-----------------|----------|----------|
| North and South Europe | Grapevine (VITVI) | JDE 01 | 
Plasmopara viticola (PLAVI)
Downy mildew | SC 326 g/L | Foliar treatment | BBCH 13 – BBCH 79 | 8 | 7 days | a) 0.00111 | b) 0.00444 | g a.s./hl. a) min. b) max. | Water L/ha a) max. rate per appl. b) max. total rate per crop/season | 200-800 | 3 | None |
Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant) Regulation (EC) No 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

| Crop and/or situation (a) | Member State or Country | Product name | F or G (b) | Pests or Group of pests controlled (c) | Preparation Type (d-f) | Conc. a.s. (i) | Method kind (f-h) | Range of growth stages & season (j) | Number min-max (k) | Interval between application (min) | Application rate per treatment kg a.s./ha min-max (l) | Water L/ha min-max | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|-------------|------------|----------------------------------------|------------------------|----------------|-----------------|-------------------------------------|-----------------|----------------------------------|---------------------------------------------|-----------------|----------------|---------|

MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. bentiavalcarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval
Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

JDE01 at 2 L/ha appeared as efficient as the copper reference in case of limited disease pressure. Nevertheless, additional 2015 trials testing 3 L/ha suggested that JDE01 would be more efficient with this target rate.

Trials demonstrated that JDE01 applied alone at 3 L/ha makes it possible to reduce partially disease severity symptoms on leaves (≈ 40 %) and on bunch (≈ 60 %). JDE01 alone at 3 L/ha generated variable results according to the situation.

Used in combination with a reference, JDE01 at 3 L/ha generally permitted to improve in tendency the efficacy up to an acceptable level of control on bunch in comparison with the reference applied alone (on the basis of a low number of trials).

Considering these results, JDE01 can be used preventively on grapevine as an elicitor of natural defenses of the plant in an integrated crop protection program to delay the occurrence of downy mildew.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

Phytotoxicity has been assessed in all efficacy trials on grapevine. No symptom of phytotoxicity was detected on grapevine whatever the tested dose of JDE01, in particular with the dose of 3 L/ha.

A priori, JDE01 can be considered as a selective product in the light of these trials.

Considering the selectivity of JDE01, no negative impact is expected on the yield and quality of harvest.

No negative impact is intended on the process of wine-making considering that:

- most of wineries start the fermentation process in killing all microorganisms of the harvest by using sulfites before seeding the must with selected yeasts,
- *Saccharomyces* sp. (mainly *Saccharomyces cerevisiae*) are added during the wine-making process and the quantity brought should be higher than the quantity of *Saccharomyces cerevisiae* present on the grapes due to the treatment with JDE01.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

Considering the ubiquity of *Saccharomyces cerevisiae* in the environment and the selectivity of JDE01 on grapevine, no negative impact is expected on succeeding and adjacent crops and on parts of plants used for propagating purposes.
Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

| Metabolite                        |
|----------------------------------|
| Not applicable                   |

Activity against target organism
Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)

As the active substance ABE IT 56 is a fractionation product of the lysate of Saccharomyces cerevisiae (strain DDSF623), 3 different markers of quantification are proposed:
- total proteins;
- total reducing sugars;
- free amino acids.

The aim of the method, codified as SOPa-149-Rev.0, is the determination of total proteins content in the Testing Substance ABE IT 56, using a Dumas Protein/Nitrogen Analyzer.

The aim of the method, codified as SOPa-152-Rev.0, is the determination of content of total reducing sugars in the Testing Substance ABE IT 56, using a HPLC with an amperometric pulsed detector. The amount of total reducing sugars is determined as sum of single sugars determined after hydrolysis.

The aim of the method, codified as SOPa-148-Rev.0, is the determination of free amino acids content in the Testing Substance ABE IT 56, using an amino analyser (analysed by a photometer at 440 nm and 570 nm).

The methods were validated according to the criteria of SANCO/3030/99 rev.4.

Impurities in technical a.s. (analytical technique)

Not necessary as there is no relevant impurity

Plant protection product (analytical technique)

This study was conducted to adjust and validate the analytical method for determining the yeast extract content in JDE01 formulation.

Since the active ingredient is not a defined molecule, an indirect procedure was applied to quantify the yeast extract, considering that the only nitrogen source in the test item is the yeast extract and the cationic surfactant AGRHO FKC 1000.

The total nitrogen content was determined using the Kjeldahl method on the test item. The cationic surfactant content was determined by HPLC/MS using AGRHO FKC 1000 as reference material and therefore its nitrogen contribution was calculated.

The difference between the total nitrogen in the test item and the cationic surfactant contribution was the nitrogen amount due to the yeast extract.

This analytical method (Brioschi M, 2014) was validated according to the criteria of SANCO/3030/99 rev.4.

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

| Food of plant origin | Not necessary |
| Food of animal origin | Not necessary |
| Soil                  | Not necessary |
| Environment       | Monitoring/Enforcement methods                                      |
|-------------------|---------------------------------------------------------------------|
| Sediment          | Not necessary                                                       |
| Water surface     | Not necessary                                                       |
| Drinking/ground water | Not necessary                                                     |
| Air               | Not necessary                                                       |
| Body fluids and tissues | Not necessary                                                   |

**Monitoring/Enforcement methods**

- **Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)**
- **Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)**
- **Soil (analytical technique and LOQ)**

Since residue definitions were not defined, methods for post-authorization control and monitoring purpose are not required.
Classification and labelling with regard to physical and chemical data (Regulation (EU) No 283/2013, Annex Part A, point 10)

| Substance | Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹: |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ABE IT56  | /                                                                                                                                                                                                |

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

² It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

| Parameter                                                                 | Status                                      |
|----------------------------------------------------------------------------|---------------------------------------------|
| Rate and extent of oral absorption/systemic bioavailability                | No data, considered not necessary           |
| Toxicokinetics                                                             | No data, considered not necessary           |
| Distribution                                                               | No data, considered not necessary           |
| Potential for bioaccumulation                                              | No data, considered not necessary           |
| Rate and extent of excretion                                               | No data, considered not necessary           |
| Metabolism in animals                                                      | No data, considered not necessary           |
| In vitro metabolism                                                       | No data, considered not necessary           |
| Toxicologically relevant compounds (animals and plants)                    | None                                        |
| Toxicologically relevant compounds (environment)                          | None                                        |

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

| Parameter                      | Status                                                                 |
|--------------------------------|------------------------------------------------------------------------|
| Rat LD$_{50}$ oral            | > 2000 mg/kg bw based on results obtained with the representative product JDE01 containing 325.6 g/L of ABE IT 56 |
| Rat LD$_{50}$ dermal           | > 2000 mg/kg bw based on results obtained with the representative product JDE01 containing 325.6 g/L of ABE IT 56 |
| Rat LC$_{50}$ inhalation       | > 3.8 mg/L air /4h (maximum attainable concentration) based on results obtained with the representative product JDE01 containing 325.6 g/L of ABE IT 56 |
| Skin irritation                | No expected skin irritant potential                                     |
| Eye irritation                 | No conclusion could be drawn (data gap).                               |
| Skin sensitisation            | No conclusion could be drawn (data gap).                               |
| Inhalation sensitisation       | Positive cases of respiratory sensitisation reported in humans exposed to Saccharomyces cerevisiae. | Resp. Sens.1. H334 |
| Phototoxicity                 | No expected phototoxicity potential                                     |

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

| Parameter                      | Status                                                                 |
|--------------------------------|------------------------------------------------------------------------|
| Target organ / critical effect  | No data. No human safety concerns are known or expected.               |
| Relevant oral NOAEL            | No data, considered not necessary                                      |
| Relevant dermal NOAEL | No data, considered not necessary |
|----------------------|----------------------------------|
| Relevant inhalation NOAEL | No data, considered not necessary |

**Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)**

| In vitro studies | No data, considered not necessary |
|-----------------|----------------------------------|
| In vivo studies | No data, considered not necessary |
| Photomutagenicity | No data, considered not necessary |
| Potential for genotoxicity | No data. No human safety concerns are known or expected. |

**Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)**

| Long-term effects (target organ/critical effect) | No data. No human safety concerns are known or expected. |
|-----------------------------------------------|---------------------------------------------------------|
| Relevant long-term NOAEL | No data, considered not necessary |
| Carcinogenicity (target organ, tumour type) | No data. No human safety concerns are known or expected. |
| Relevant NOAEL for carcinogenicity | No data, considered not necessary |

**Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)**

**Reproduction toxicity**

| Reproduction target / critical effect | No data. No human safety concerns are known or expected. |
|--------------------------------------|---------------------------------------------------------|
| Relevant parental NOAEL | No data, considered not necessary |
| Relevant reproductive NOAEL | No data, considered not necessary |
| Relevant offspring NOAEL | No data, considered not necessary |

**Developmental toxicity**

| Developmental target / critical effect | No data. No human safety concerns are known or expected. |
|----------------------------------------|---------------------------------------------------------|
| Relevant maternal NOAEL | No data, considered not necessary |
| Relevant developmental NOAEL | No data, considered not necessary |

**Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)**

| Acute neurotoxicity | No data, considered not necessary |
|---------------------|----------------------------------|
| Repeated neurotoxicity | No data, considered not necessary |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No data, considered not necessary |
Peer review of the pesticide risk assessment of the active substance ABE-IT 56 (components of lysate of Saccharomyces cerevisiae strain DDSF623)

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

| Study                                                               | Value                                      |
|---------------------------------------------------------------------|--------------------------------------------|
| Supplementary studies on the active substance                       | No data, considered not necessary          |
| Endocrine disrupting properties                                     | No data, considered not necessary          |
| Studies performed on metabolites or impurities                      | No data, considered not necessary          |

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Positive cases of respiratory sensitisation reported in humans exposed to Saccharomyces cerevisiae.

Summary\(^3\) (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

| Acceptable Daily Intake (ADI)           | Not relevant |
| Acute Reference Dose (ARID)             | Not relevant |
| Acceptable Operator Exposure Level (AOEL) | Not relevant |
| Acute Acceptable Operator Exposure Level (AAOEL) | Not relevant |

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (indicate name, type e.g. EC and concentration of active substance)

Not relevant

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators, Workers, Bystander, Residents

Exposure assessment not needed

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

| Substance | Value                                      |
|-----------|--------------------------------------------|
| ABE IT 56 | No current harmonised classification       |

\(^3\) If available include also reference values for metabolites

\(^4\) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

\(^5\) It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)
No data, not required

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)
No data, not required

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)
No data, not required

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)
No data, not required

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3)
No data, not required

Inputs for animal burden calculations
No data, not required

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)
No data, not required

Conversion Factors (CF) for monitoring to risk assessment
No data, not required

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)
No data, not required

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)
Consumer safety concerns are not expected from the use of ABE IT 56 as a plant protection product.

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)
It is proposed to include ABE IT 56 in Annex IV of Regulation (EC) No 396/2005 as a substance for which MRLs are not required.
Environmental fate and behaviour

| Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1) |
|--------------------------------------------------|
| Mineralisation after 100 days                     | No data, not required. |
| Non-extractable residues after 100 days           | No data, not required. |
| Metabolites requiring further consideration       | No data, not required. |
| - name and/or code, % of applied (range and       |                              |
| maximum)                                         |                              |

| Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2) |
|--------------------------------------------------|
| Mineralisation after 100 days                     | No data, not required. |
| Non-extractable residues after 100 days           | No data, not required. |
| Metabolites that may require further consideration| No data, not required. |
| for risk assessment - name and/or code, % of     |                              |
| applied (range and maximum)                      |                              |

| Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3) |
|--------------------------------------------------|
| Metabolites that may require further consideration| No data, not required. |
| for risk assessment - name and/or code, % of     |                              |
| applied (range and maximum)                      |                              |
| Mineralisation at study end                      | No data, not required.       |
| Non-extractable residues at study end            | No data, not required.       |

| Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1) |
|--------------------------------------------------|
| Parent                                           | Dark aerobic conditions     |
| Soil type                                        | Dark aerobic conditions     |
| pH                                               | t. °C / % MWHC              |
| DT50/DT90 (d)                                    | DT50 (d)                    |
| 20 °C pF2/10kPa                                   | St. (χ²)                    |
| Method of calculation                            |                              |

No data, not required. But for a readily biodegradable substance according to ECHA R16 guidance an appropriate DT50 at 20 °C (after normalising the 12°C value of 30 days) is 14.1 days.
Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

| Parent | Aerobic conditions |
|--------|--------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). |
| pH | Depth (cm) | DT_{50} (d) actual | DT_{90} (d) actual | St. (χ²) | DT_{50} (d) Norm. | Method of calculation |
| No data, not required. |

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

| Soil accumulation and plateau concentration |
| No data, not required. |

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Parent | Dark anaerobic conditions |
|--------|---------------------------|
| Soil type | pH | t. °C / % MWHC | DT_{50} / DT_{90} (d) | DT_{50} (d) 20 °C | St. (χ²) | Method of calculation |
| No data, not required. |

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

| Parent | Soil photolysis |
|--------|-----------------|
| Soil type | pH | t. °C / % MWHC | DT_{30} / DT_{90} (d) calculated at ??ºN | St. (χ²) | Method of calculation |
| No data, not required. |

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Parent | OC % | Soil pH | Kd (mL/g) | K_{soc} (mL/g) | Kp (mL/g) | K_{poc} (mL/g) | 1/n |
|--------|------|---------|-----------|---------------|-----------|---------------|-----|
| No data, not required. |

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Column leaching |
| No data, not required. |
| No data, not required. |
**Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)**

| Lysimeter / field leaching studies | No data, not required. |

**Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)**

| Hydrolytic degradation of the active substance and metabolites > 10 % | No data, not required. |
| Hydrolytic degradation of the active substance and metabolites > 10 % | No data, not required. |
| Hydrolytic degradation of the active substance and metabolites > 10 % | No data, not required. |

**Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)**

| Photolytic degradation of active substance and metabolites above 10 % | No data, not required. |
| Photolytic degradation of active substance and metabolites above 10 % | No data, not required. |
| Quantum yield of direct phototransformation in water at Σ > 290 nm | No data, not required. |

**‘Ready biodegradability’ (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)**

| Readily biodegradable (yes/no) | Yes. |
Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

| Parent | System identifier (indicate fresh, estuarine or marine) | pH | pH | t. °C | DT₅₀ / DT₉₀ whole sys. (suspended sediment test) | St. | DT₅₀ / DT₉₀ Water (pelagic test) | St. | Method of calculation |
|--------|--------------------------------------------------------|----|----|------|-------------------------------------------------|-----|-----------------------------|-----|------------------------|
|        | pH water phase                                         | pH | pH |      | At study temp | Normalised to x °C⁰ | At study temp | Normalised to x °C⁰ |       |

No data, Data gap.

Mineralisation and non-extractable residues (for parent dosed experiments)

| System identifier (indicate fresh, estuarine or marine) | pH | pH | pH | x % after n d. (end of the study) | Non-extractable residues. max x % after n d (suspended sediment test) | Non-extractable residues. max x % after n d (end of the study) |
|--------------------------------------------------------|----|----|----|-------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------|
| pH water phase                                         | pH | pH |    |                                |                                                                     |                                                                   |

No data

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

| Parent | Distribution |
|--------|--------------|
| Water / sediment system | pH | pH | t. °C | DT₅₀ / DT₉₀ whole sys. | St. | DT₅₀ / DT₉₀ water | St. | DT₅₀ / DT₉₀ sed | St. | Method of calculation |
| pH water phase | pH | pH |    |                                |       |                 |       |                 |       |                      |

No data, not required. But for a readily biodegradable substance according to ECHA R16 guidance appropriate DT₅₀ at 20 °C are 7.1 days in water and 141 days in sediment (after normalising 12°C values of 15 and 300 days respectively).

Mineralisation and non extractable residues (from parent dosed experiments)

| Water / sediment system | pH | pH | pH | x % after n d. (end of the study) | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) |
|-------------------------|----|----|----|-------------------------------|--------------------------------------------------|-------------------------------------------------------------------|
| pH water phase          | pH | pH |    |                                |                                                   |                                                                   |

No data, not required.

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

| Direct photolysis in air | No data, not required. |
|--------------------------|------------------------|
| Photochemical oxidative degradation in air | No data, not required. |
| Volatilisation | No data, not required. |
| Metabolites | No data, not required. |

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

| Environmental occurring residues requiring further assessment | ABE IT 56 (yeast extract, fragment cells of Saccharomyces cerevisiae strain DDSF623) |
|--------------------------------------------------------------|----------------------------------------------------------------------------------|
assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

**Saccharomyces cerevisiae strain DDSF623**

**Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)**

See section 5, Ecotoxicology

Not applicable due to the nature of the active substance.

**Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)**

| Type of Study | Data |
|---------------|------|
| Soil          | None |
| Surface water | None |
| Ground water  | None |
| Air           | None |

**PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)**

| Parent | Method of calculation | Application data |
|--------|-----------------------|------------------|
|        | As the substance is readily biodegradable following ECHA R16 guidance a SFO soil DT50 of 14.1 days was assumed. | Crop: Grapevine  
Depth of soil layer : 5 cm  
Soil bulk density: 1.5 g.cm$^{-3}$  
% plant interception : 0  
Number of application : 10  
Application rate: 977 g a.s. ha$^{-1}$  
7 day interval  
PEC$_{SOL}$ = 4.33 mg a.s. kg$^{-1}$  
*Higher than the representative use applied for |

**PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)**

| Method of calculation and type of study (e.g. modelling, field leaching, lysimeter) | Application rate |
|-----------------------------------------------------------------------------------|------------------|
| No calculation required.                                                           | No calculation required. |

**PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)**

| Parent | Parameters used in FOCUSsw step 1 and 2 | Parameters used in FOCUSsw step 3 (if performed) | Application rate |
|--------|----------------------------------------|--------------------------------------------------|------------------|
| No FOCUS modelling required.                                                       | No FOCUS modelling required.                      | Following 10 cumulative applications of 0.977 kg a.s./ha$^*$ and considering the spray drift value of 6.26 % |
for 8 or more applications on Grapevine, late applications:

$$\text{PEC}_{SW} = 203.9 \ \mu g \ \text{a.s./L}$$

for a 100 m long, 1 m wide, 30 cm deep water body (volume 300 L/m).

*Higher than the representative use applied for

### Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

| Method of calculation | No calculation required. |
|-----------------------|-------------------------|

| PEC                   | Maximum concentration   |
|-----------------------|-------------------------|
|                       | No calculation required. |
Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

| Species | Test substance | Time scale | End point | Toxicity (mg/kg bw per day) |
|---------|----------------|------------|-----------|---------------------------|
| Birds   | No data, not required. The active substance ABE IT 56 is essentially composed by a non-modified extract of the yeast *Saccharomyces cerevisiae* strain DDSF623, yeast ubiquitous in environment (e.g. on plants, soil, water). Considering the identity and the nature of the active substance (not modified extract of the yeast *Saccharomyces cerevisiae* strain DDSF623), overall, it can be concluded that no harmful effects are expected to occur for non-target organisms. |
| Mammals | rat Preparation JDE 01 Acute LD<sub>50</sub> >2000 mg/kg bw |
|         | Endocrine disrupting properties (Annex Part A, points 8.1.5) No data, not required. |
|         | Additional higher tier studies (Annex Part A, points 10.1.1.2): No data, not required. |
|         | Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): No data, not required. |
|         | The toxicity data on mammals is derived from a limit test showing no mortality or signs of toxicity on mammals. Moreover, Saccharomyces cerevisiae is ubiquitous in environment and birds and mammals are naturally exposed. In addition, *Saccharomyces cerevisiae* is used as additive in feeding stuff. Harmful effects are not expected to occur for birds and mammals following the exposure to ABE IT 56 due to its identity and the nature. No effects on birds and other terrestrial vertebrates are expected due to the other components of the product JDE01. |

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

| Group              | Test substance | Time-scale (Test type) | End point | Toxicity<sup>1</sup> |
|--------------------|----------------|------------------------|-----------|----------------------|
| Laboratory tests   |                |                        |           |                      |
| Fish               |                |                        |           |                      |
| *Oncorhynchus mykiss* | Preparation JDE 01 | Acute 96 hr (static) | Mortality, LC<sub>50</sub> | > 100 mg prep./L<sub>(nom)</sub> (29.6 mg a.s./L) |
| Aquatic invertebrates |                |                        |           |                      |
| *Daphnia magna*    | Preparation JDE 01 | 48 h (static) | Mortality, EC<sub>50</sub> | > 100 mg prep./L<sub>(nom)</sub> (29.6 mg a.s./L) |
| Group                        | Test substance | Time-scale (Test type) | End point | Toxicity¹ |
|------------------------------|----------------|------------------------|-----------|-----------|
| Sediment-dwelling organisms  |                |                        |           |           |
| Algae                        |                |                        |           |           |
| *Pseudokirchneriella subcapitata* | Preparation JDE 01 | 72 h (static) | ErC50     | 9.9 mg prep./L (nom) (2.93 mg a.s./L ) |
|                              |                |                       | EyC50     | 2.8 mg prep./L (nom) (0.83 mg a.s./L) |
|                              |                |                       | NOEC      | 0.8 mg prep./L (nom) (0.24 mg a.s./L) |
| Higher plant                 |                |                        |           |           |
| No data, not required.       |                |                        |           |           |
| Further testing on aquatic organisms |            |                       |           |           |
| No data, not required.       |                |                        |           |           |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3) | | | | |
| No data, not required.       |                |                        |           |           |

¹ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

**Bioconcentration in fish (Annex Part A, point 8.2.2.3)**

No data. Not required.
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

**TERs for ABE IT 56 – grapevine at 991 g a.s./ha x 10 applications**

| Scenario | PEC global max (µg L<sup>-1</sup>) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm/Mesocosm |
|----------|----------------------------------|------------|--------------|----------------------|---------------------------------|-------|--------------|----------------------|-------------------|
|          |                                  |            |              | Daphnia magna        | no data                         |       |              |                      |                   |
| Oncorhynchus mykiss | no data | Oncorhynchus mykiss | no data | Daphnia magna | no data | Pseudokirchneriella subcapitata | no data | no data | no data |                      |                   |
| >29600 µg a.s./L | 203.9  | 145 | >29600 µg/L | >29600 µg/L | 14.3 | 2930 µg/L |                      |                   |

*If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.*

** The presented risk assessment covered a higher number of applications and a higher application rate with respect to the representative uses and is, therefore, not compliant with the GAP. However, since it is a worst case and demonstrate a low risk it is considered sufficient for concluding a low risk to aquatic organisms. It is further noted that this is to be considered as an illustrative risk assessment; harmful effects are not expected to occur for non-target organisms due to the identity and the nature of ABE IT 56. Therefore, the risk to non-target organisms can be concluded as low.
Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)

| Species            | Test substance | Time scale/type of endpoint | End point          | Toxicity            |
|--------------------|----------------|-----------------------------|-------------------|---------------------|
| *Apis mellifera*   | Preparation JDE 01 | Acute                      | Oral toxicity (LD₅₀) | > 110.7 µg a.s./bee |
| *Apis mellifera*   | Preparation JDE 01 | Acute                      | Contact toxicity (LD₅₀) | > 100 µg a.s./bee   |

Harmful effects are not expected to occur for non-target organisms following the exposure to ABE IT 56 due to its identity and the nature. Therefore, the risk to bees can be concluded as low.

Potential for accumulative toxicity: not concerned.

Semi-field test (Cage and tunnel test)
No data, not required.

Field tests
No data, not required.

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

| Species | Test Substance | End point | Toxicity |
|---------|----------------|-----------|----------|
| No data, not required. | | | |

First tier risk assessment

No study was performed to evaluate the effects of the product JDE01 on non-target arthropods other than bees. The active substance of JDE01 is composed of extract of *Saccharomyces cerevisiae*, yeast ubiquitous in environment, found in soil, on plants, fruits, leaves. Arthropods are expected to be frequently exposed to fragments of *Saccharomyces cerevisiae* in their environment. No toxicity of the product JDE01 is expected on non-target arthropods.

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

| Test organism | Test substance | Application method of test a.s./OM¹ | Time scale | End point | Toxicity |
|---------------|----------------|-------------------------------------|------------|-----------|----------|
| Earthworms    | No data, not required. | | | | |
| Other soil macroorganisms | No data, not required. | | | | |
### Test organisms

| Test organism               | Test substance | Application method of test a.s./OM | Time scale | End point | Toxicity |
|----------------------------|----------------|-----------------------------------|------------|-----------|----------|
| Folsomia candida           | No data, not required |                                  |            |           |          |
| Hypoaspis aculeifer        | No data, not required |                                  |            |           |          |

1To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

#### Higher tier testing (e.g. modelling or field studies)
No data, not required.

#### Nitrogen transformation
No data, not required.

### Toxicity/exposure ratios for soil organisms

Meso- and macrofauna are expected to be frequently exposed to fragments of *Saccharomyces cerevisiae* in their environment. Litter feeding earthworms consume yeasts together with decaying leaves. As a natural process, the yeasts pass the earthworm’s digestive tract, where they are digested, inactivated or egested and eventually introduced into soil. According to the ubiquity of *Saccharomyces cerevisiae* in environment, no toxicity to non-target soil meso- and macrofauna is expected.

Toxicity and competition behaviour to the wild micro-organisms are not expected as biological or physical-chemical activity of the extract of Saccharomyces cerevisiae are not expected.

Harmful effects are not expected to occur for soil organisms following the exposure to ABE IT 56 due to its identity and the nature. Therefore, the risk to soil organisms can be concluded as low.

### Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

No data, not required.

The active substance of the product JDE01 is composed of extract of Saccharomyces cerevisiae, yeast ubiquitous in environment, found naturally on all the different parts of plants, leaves, fruits, seeds.

Harmful effects are not expected to occur on non-target terrestrial plants following the exposure to ABE IT 56 due to its identity and the nature.

### Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

No data, not required.

### Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

No data, not required.
Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds

| Compartiment | Not applicable due to the nature of the active substance. |
|--------------|----------------------------------------------------------|
| soil         | Not applicable due to the nature of the active substance. |
| water        | Not applicable due to the nature of the active substance. |
| sediment     | Not applicable due to the nature of the active substance. |
| groundwater  | Not applicable due to the nature of the active substance. |

1 metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent
Classification and labelling with regard to ecotoxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

| Substance       | ABE IT 56                  |
|-----------------|----------------------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁶: | Not classified. |
| Peer review proposal⁷ for harmonised classification according to Regulation (EC) No 1272/2008: | Not classified. |

⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁷ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.