



BASF SE, 67114 Ludwigshafen, Germany To whom it may concern

24 Feb 2017 E-EMC/QR - J 550 Ellen Pfrommer

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### Dear Valued Customer:

Due to increasing regulatory requirements, BASF SE receives a significant amount of questionnaires and surveys from our customers regarding our products that essentially address the same issues. Unfortunately we are unable to individually complete each customer's specific form.

In order to respond to these requests in a timely and efficient manner, we have established a standardized Quality & Regulatory Product Information package (Q&R PI) to facilitate the exchange of standard regulatory, quality and safety information with our customers.

By responding to surveys, questionnaires and other requests for information in this manner, we can respond more quickly and efficiently to all requests as well as ensure that consistent information is provided in all cases.

We are convinced that this is an improvement in information management for both sides and we will do our best to provide our customers also in future with excellent service. Thank you for your continued interest in our products.

Sincerely,

BASF SE Quality & Regulatory Personal Care

i. V. Pfrommer

# **Quality & Regulatory Product Information Oxygen Complex LS 9641**



| 1. | Identity and Source Information [x] see attached composition sheet and Source  |   |  |  |
|----|--|---|--|--|
| 2. | Current Technical Information including specification with comprehensive physical and chemical data on the substance   |   |  |  |
|    | [x] Specification end<br>[ ] Specification will  |   |  |  |
| 3. | Manufacturing of the   | ne product  |  |  |
|    | Manufacturer:  | <ul><li>[X] BASF Beauty Care Solutions</li><li>[ ] BASF Corporation</li><li>[ ] The product is manufactured by a contract manufacturer according to the BASF specification.</li></ul>         |  |  |
|    | Country of Origin:   | France  |  |  |
|    | Manufacturing:   | <ul><li>[X] Following the ISO 9001/2008</li><li>[X] Following GMP compliance</li><li>[ ] Other:</li></ul>   |  |  |
|    | Manufacturing pro  | [ ] Synthetic [ ] Fermentation [ ] Purification of natural product [ ] Extraction [ ] Wet blend [X] Other: see attached composition sheet [ ] Brief description of the manufacturing process: |  |  |
| 4. | Storage recommen   | dations for protecting product  |  |  |
|    | <ul> <li>[X] No particular recommendations required</li> <li>[X] Storage temperature: 10 - 30° C</li> <li>[ ] The product must be stored in a refrigerated warehouse</li> <li>[ ] Store protected from light</li> <li>[ ] Store protected from moisture</li> <li>[ ] Other:</li> <li>[ ] Low storage temperatures (&lt;°C) lead to the following phenomena:</li> </ul> |   |  |  |
|    | [ ] which is reversib<br>[ ] which is irreversi  |   |  |  |
|    | Special storage or handling conditions   |   |  |  |
|    | [ ] Store the substa   | the container after opening<br>nce under N <sub>2</sub><br>bove storage temperature is maintained: 720 days   |  |  |

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| 5. | The following substances are added to the product (during or after manufacture) for purposes of stabilization: |  |  |  |
|----|--|--|--|--|
|    | []   | Preservatives:   |  |  |
|    | [ ]  | Antioxidants: Sequestering/Complexing agents: Other substances:  |  |  |
|    | [X]  | There are no additives in this product.  |  |  |
| 6. | So   | ource information  |  |  |
|    | a.   | Origin of the compounds: see also Composition Sheet and Source cited under item 1.   |  |  |
|    |  | <ul> <li>[x] BSE free</li> <li>[x] GMO-free (produced without genetic engineering)</li> <li>[x] Derived from non-genetically modified plant</li> <li>[x] GMO-DNA free (not containing GMO-DNA)</li> </ul>  |  |  |
|    | b.   | Residual solvents:   |  |  |
|    |  | <ul> <li>[ ] Based on our actual knowledge of our production process, raw materials and equipment used, we do not expect solvents to be present.</li> <li>[X] Complies with the recommendation in the "ICH Note for Guidance on Impurities: Residual solvents (CPMP/ICH/283/95)":         Ethanol (Class 3): max 1 ppm [CALCULATED] - Acetone (Class 3): max 1 ppm [CALCULATED] - Methanol (Class 2): max 20 ppm.     </li> </ul>  |  |  |
|    | c.   | Heavy metals   |  |  |
|    |  | <ul> <li>[ ] Based on our actual knowledge of our production process, raw materials and equipment used, we do not expect heavy metals to be present.</li> <li>[ ] Not tested.</li> <li>[X] Based on results of random testing on the raw materials or the products itself or representative material, we do not expect sum of heavy metals to be superior to: 10 ppm according to the Ph. Eur.2.4.8 (antimony, arsenic, lead, bismuth, cadmium, copper, mercury and tin).</li> </ul> |  |  |
|    | d.   | Pesticides (organochlorine and organophosphorous)  |  |  |
|    |  | [X] Based on results of random testing on the raw materials or the products itself or<br>representative material, pesticides are expected to conform with concentration limits of<br>the: table 2.8.131. of the European Pharmacopoeia Version 4, 2002 : section 2.8.13.<br>Pesticides residues.   |  |  |
|    |  | <ul> <li>Based on our actual knowledge of our production process, raw materials and equipment used, we do not expect pesticides to be present</li> <li>Not tested.</li> </ul>  |  |  |

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| e. | Polycyclic | aromatic | hydrocarbons |
|----|------------|----------|--------------|
|----|------------|----------|--------------|

| Are        | e the following requirements met?:  Benzo-(a)-pyrene: <1 ppb Fluoranthene: <10 ppb Benzo-(b)-fluoranthene: <10 ppb Benzo-(K)-fluoranthene: <10 ppb Benzo-(ghi)-perylene: <10 ppb Indeno-(1,2,3,cd)-pyrene: <10 ppb |
|------------|--|
| [x]<br>[ ] | Not tested as not to be expected from the production process<br>Yes<br>Not yet tested, will be tested by   |

### f. Other impurities and by products

| 1,4-dioxane           | max n.n |
|-----------------------|---------|
| Free ethylene oxide   | max n.n |
| Monochloroacetic acid | max n.n |
| Dichloroacetic acid   | max n.n |
| Sulfite               | max n.n |
| Monomer content       | max n.n |
| Nitrosamines          | max n.n |
| Residual reactant     | max n.n |
| Aromatic amines       | max n.n |
| Acrylamide            | max n.n |
| Diethylene Glycol     | max n.n |
| Formaldehyde          | max n.n |
| Other substances      | max     |
|                       |         |

n.n. = Not test as not expected from the process or the ingredients.

### g. Allergens listed in Annex III of Cosmetics Regulation (EC) 1223/2009

| Riergens listed in Affrex in of Cosmetics Regulation (EC) 1223/2009   |
|---|
| <ul> <li>Highly unlikely to be present</li> <li>May contain:</li> <li>Not tested</li> <li>Based on results of random testing on the raw materials or the products itself or representative material, allergens listed in Annex III of Cosmetics Regulation (EC) 1223/2009 are not expected to be present</li> </ul> |
|   |

#### h. Phthalates

- [X] Based on our current knowledge of our production process, raw materials and equipment used, we do not expect listed Phtalates\* to be present.
- [ ] Contains:
- [X] Not tested

<sup>\*</sup>According to Annex II of Cosmetics Regulation (EC) 1223/2009

7.

8.



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| i.    | CMR substances   |
|-------|--|
|       | <ul> <li>[X] Based on our current knowledge of our production process, raw materials and equipment used, we do not expect listed CMR substances to be present. (Bibliographic data)</li> <li>[ ] May contain the following CMR-material:</li> </ul>  |
|       | [X] Not tested   |
| j.    | Glycol ether   |
|       | <ul> <li>[X] based on our actual knowledge of our production process, raw materials and equipment used we do not expect any of the following glycol ethers to be present:</li> <li>Butyldiglycol (CAS #112-34-5)</li> <li>Ethyldiglycol (CAS #111-90-0)</li> <li>2-Butoxyethanol (CAS #111-76-2)</li> <li>[] May contain the following Glycol ether material:</li> <li>[] Not tested</li> </ul>  |
| k.    | Conformity Compliance with European Union cosmetics legislation [X] Based on our recommended dose of use in a final cosmetic product, we hereby confirm that the cosmetic raw material marketed by the BASF Care Chemicals division conforms with the requirements relevant to cosmetic ingredients of the Cosmetics Regulation (EC) 1223/2009 and its amendments as currently in force.   |
| М     | icrobiological Status  |
| [ ]   | No microbes detectable No microbes to be expected: Sensitive towards the following microbe(s): Part of the specification   |
| Sa    | afety and Environment  |
| [X]   | Material Safety Data Sheet available on request Environmental and Responsible Care policies: see <a href="http://www.basf.com/group/sustainability_en/index">http://www.basf.com/group/sustainability_en/index</a> <a href="http://www.basf.com/group/corporate/en/sustainability/our%2Dvalues/index">http://www.basf.com/group/corporate/en/sustainability/our%2Dvalues/index</a> Toxicological information available upon request Ecotoxicological information: see Safety Data Sheet Product has been animal tested. Date of last test sponsored by BASF: |
|       | Product has never been tested on animals by BASF <sup>(1)</sup> Safety summary documentation available on request  |
| (1    | ) "can contain ingredient from other BASF BCS products, which may have been subject to animal testing".  |
| If an | imal test performed later than 11th March 2009:  Type of test:   |
|       | ntry in which the test was performed:  Purpose of the study:  [ ] EU-chemical law (1907/2006/EC, REACH)  [ ] Non-EU chemical law:  [ ] EU-cosmetic legislation (76/768/EEC)  [ ] Non-EU cosmetic legislation:  |

Other purpose (e.g. pharma, OTC, biocide, medical device, feed or food, occupational safety etc):

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Issued by:
BASF Beauty Care Solutions
Care Chemicals
Strategic Marketing & Special Businesses/Regulatory Affairs

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