OXTERIL®

Regulatory Dossier of Hydrogen Peroxide for the Aseptic Food Packaging

EVONIK
Leading Beyond Chemistry

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1. General Information

OXTERIL® 350 BATH, OXTERIL® 350 SPRAY, OXTERIL® 350 SPRAY S and OXTERIL® 350 COMBI are specialty hydrogen peroxide grades, which are designed for the use in the aseptic packaging industry as well as other sterilization applications in food processing. The products are based on the aqueous solutions of highly purified high quality hydrogen peroxide and recommended by leading packaging machine manufacturers

For more detailed information, please visit our home page in internet www.active-oxygens.com or contact us.

2. Detailed Product- and Production Information

2.1. Product Identifier

Trade Name:	OXTERIL® 350 BATH
CAS-No.:	7722-84-1
EINES No.	231-765-0
UFI No:	SXF0-70WN-Y000-X60M
Trade Name:	OXTERIL® 350 COMBI
CAS-No.:	7722-84-1
EINES No.	231-765-0
UFI No:	RJG0-S0RF-300F-JK32
Trade Name:	OXTERIL® 350 SPRAY
CAS-No.:	7722-84-1
EINES No.	231-765-0
UFI No:	U6G0-R0YU-V00G-W6RT
Trade Name:	OXTERIL® 350 SPRAY S
CAS-No.:	7722-84-1
EINES No.	231-765-0
UFI No:	8FG0-9021-S00Y-W7H0

2.2. Production sites

European production sites of the Evonik Operations GmbH for OXTERIL® grades.

Austria

Evonik Peroxid GmbH
Industriestrasse 1
9721 Weissenstein

Belgium

Evonik Antwerpen N.V.
Tijsmanstunnel West 4
2040 Antwerpen

Germany

Evonik Operations GmbH
Untere Kanalstraße 3
79618 Rheinfelden

2.3. Certification according ISO 9001 / 14001 /50001

The processes of the Evonik Industries AG with the locations and organizational units as listed in Production sites are managed by ISO 9001/ 14001 / 50001.

Please refer to the recent version of ISO certificate, which you can order by marketing or product management.

3. Legal Requirements

OXTERIL® grades comply with the Regulation (EC) 528/2012 concerning the making available on the market and use of biocidal products (BPR). OXTERIL® grades are aqueous solutions of hydrogen peroxide, biocidal active substance, approved for the use in food industry (PT4) under the EU legislation. National biocidal registrations are available in the countries where these products are commercialized while BPR dossiers are being evaluated.

Approved active substances listed under the BPR are considered to be already registered under REACH; however, other obligations included in Regulation (EC) 1907/2006 apply.

In Accordance to the different applicable regulations , we certify for all OXTERIL® grades that are mentioned in chapter 2.1 the following.

3.1. Regulatory Status

3.1.1. EU Biocide registrations

Evonik has submitted a Union Authorization dossier for these products.

Till approval, national biocide registrations for OXTERIL® grades are available for different countries. Contact us for specific country information.

3.1.2. REACh Status

REACh-No.: 01-2119485845-22-XXXX

3.1.3. Chemical inventories of other countries

Country		Listed
United States of America	TSCA	YES
Canada	DSL	YES
China	IECSC	YES
Japan	ENCS / ISHL	YES / YES
South Korea	KECI	YES
Philippines	PICCS	YES
Taiwan	TCSI	YES
Australia	AICS	YES
New Zealand	NZIoC	YES
Mexico	INSQ	YES

Russian Federation	Draft Russian Chemical Inventory	YES

3.1.7. UK REACh

We confirm that we take appropriate measures to ensure supply and compliance of our products after BREXIT according to the withdrawal act. This includes the pre-notification of all relevant substances contained in quantities above 1 t/y in our products which, according to our knowledge, are marketed in UK until October 27th 2021, as well as the intention to register these substances within the respective time frame in accordance with the business decision.

3.1.8. UK Biocides

We confirm that a biocide dossier has been submitted in UK for all OXTERIL® grades that are mentioned in chapter 2.1. All products can be legally commercialized in UK.

3.1.9. Regulation KKDIK - Turkey

According to the Turkish KKDIK regulation, all existing chemical substances manufactured or imported into Turkey equal or above 1 ton/a need to be pre-registered until December 31, 2020 and registered until December 31, 2023 – Published By-Law on Registration, Evaluation, Authorization and Restriction of Chemicals (KKDIK) published on the Official Gazette on 23 June 2017 (numbered 30105).

For the below mentioned products of Evonik Operations GmbH, we confirm that we have appointed REACH Global Services (RGS; contact person: Ms. Tuğçe Gizem Gürleroğlu; email address; evonik-cr@reach-gs.eu) as Only Representative (OR) in Turkey in order to ensure supply and compliance of our products manufactured outside Turkey under KKDIK. Our commissioned OR in Turkey is still pre-registering all relevant substances contained in related product(s) that are marketed in Turkey in quantities of at least 1 ton/a according to our present knowledge until December 31, 2020. In addition, it is intended to register these substances within the respective time frame in accordance with the business decision.

3.2. REACH Related Confirmations

3.2.1. Annex VI of Regulation (EC) 1272/2008 – CMR Substances

The Annex VI of the Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP-Regulation) define certain chemical substances as carcinogenic, mutagenic and reprotoxic (CMR-Substances).

OXTERIL® grades are aqueous solutions of hydrogen peroxide, which are of purely synthetic origin. Based on our best knowledge of the manufacturing process, raw materials and additives involved, analytical measurements on OXTERIL® grades as well as characterisation of its precursor - high purity hydrogen peroxide, we can state with reasonable certainty that OXTERIL® grades are not contaminated with CMR substances in the concentrations over 0,01% (w/w). The analysis of the above mentioned substances is not part of our quality and production analysis.

3.2.2. Annex XIV of Regulation (EC) 1907/2006 – SVHC

The Annex XIV of the Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as well its amendments (Regulations No 143/2011/EC; 125/2012/EC; 348/2013/EC) define the list of substances subjected to authorization.

We herewith confirm, that OXTERIL® grades are aqueous solutions of hydrogen peroxide, which are of purely synthetic origin. No SVHC-Substances, as defined by the above Regulation, are used during the manufacturing, handling and storage of the product.Based on our best knowledge of the manufacturing process as well as raw materials and additives involved, we can state with reasonable certainty that OXTERIL® grades are not contaminated by any substances, subject to authorization, in the concentrations over 0,01% (w/w). Therefore the analysis of the above mentioned substances is not part of our quality and production analysis.

3.2.3. Article 59 of Regulation (EC) 1907/2006 - Echa`s candidate List

Article 59 of the Regulation (EC) No. 1907/2006 requires that European Chemicals Agency (ECHA) recommends the addition of substances for the inclusion in the "Candidate List". In a further step the EU-Commission, ECHA and Member states decide, after a public consultation, the addition of new substances to Annex XIV.

We herewith confirm that OXTERIL® grades are aqueous solutions of hydrogen peroxide, which are of purely synthetic origin. No substances from the candidate list are used during the manufacturing, handling and storage of OXTERIL® grades. Based on our best knowledge of the manufacturing process, raw materials and additives involved, analytical measurements on OXTERIL® grades as well as characterisation of its precursor - high purity hydrogen peroxide, we can state with reasonable certainty that OXTERIL® grades are not contaminated by any substances, defined in the ECHA's candidate list in the concentrations over 0,01% (w/w). The analysis of the above mentioned substances is not part of our quality and production analysis.

3.2.4. Annex XIII of Regulation (EC) 1907/2006 - PBT or vPvB-Substances

Annex XIII of Regulation (EC) No. 1907/2006 of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACh) defines criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances (PBT or vPvB-Substances).

OXTERIL® grades are aqueous solutions of hydrogen peroxide, which are of purely synthetic origin. Based on our best knowledge of the manufacturing process, raw materials and additives involved, analytical measurements on OXTERIL® grades as well as characterisation of its precursor - high purity hydrogen peroxide, we can state with reasonable certainty that OXTERIL® grades are not contaminated with PBT or vPvB-substances in concentration more than 0,01% (w/w). The analysis of the above mentioned substances is not part of our quality and production analysis.

3.2.5. Annex XVII of Regulation (EC) 1907/2006 – not listing of Hydrogen Peroxide

Annex XVII of Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACh) restricts the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

OXTERIL® grades are aqueous solutions of hydrogen peroxide. Hydrogen peroxide and all components of OXTERIL® grades are not mentioned on the Annex XVII.

3.2.6. Annex XVII of Regulation (EC) 1907/2006 – Presence of Phthalates

Annex XVII of the Regulation (EC) No. 1907/ 2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACh) restricts the use of bis (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP) to 0,1 % by weight in the plasticised material in toys and childcare articles.

We herewith confirm that OXTERIL® grades are aqueous solutions of hydrogen peroxide, which are of purely synthetic origin. None of the substances described above are used during the manufacturing, handling and storage of OXTERIL® grades. Based on our best knowledge of the manufacturing process as well as raw materials and additives involved, we can state with reasonable certainty that OXTERIL® grades are not contaminated with the substances mentioned above in the concentration more than 0,01% (w/w). The analysis of the above mentioned substances is not part of our quality and production analysis.

3.2.7. Annex XVII of Regulation (EC) 1907/2006 – Restrictions on dangerous substances, mixtures and articles

Annex XVII of Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACh) restricts the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

OXTERIL® grades are aqueous solutions of hydrogen peroxide. Hydrogen peroxide or any of the components of OXTERIL® grades are not mentioned on the Annex XVII.

3.2.8. Nanomaterials

Regulation (EU) 2018/1881amends Reach Regulation to address nanoforms of substances. Commission Recommendation of 18 October 2011 includes the definition of nanomaterial.

We herewith confirm that all OXTERIL® grades are aqueous solution of hydrogen peroxide, which are of purely synthetic origin. Based on our best knowledge of the manufacturing process as well as raw materials and additives involved, we can state with reasonable certainty that OXTERIL® grades are not contaminated with nanomaterials in the concentration more than 0,01% (w/w). The analysis of the above mentioned substances is not part of our quality and production analysis.

3.2.9. Microplastics

In June 2020 RAC has adopted its opinion on ECHA's proposal to restrict the use of microplastics that are intentionally added to products on the EU/EEA market, in concentrations of more than 0.01 % weight by weight. The proposal was considered appropriate for reducing releases to the environment.

The Commission's proposal to amend the list of substances restricted under Annex XVII of REACH to include microplastics is expected to be submitted in 2021 and enter into force in 2022.

Hereby we certify that the OXTERIL® Grades are completely of synthetic origin. Synthetic microplastic particles are not used in the production process, neither as raw materials nor process chemicals. Based on our best knowledge of the manufacturing process as well as raw materials and additives involved, we can state with reasonable certainty that OXTERIL® Grades are not contaminated with microplastic particles in concentrations more than 0.01% (w/w). The analysis of the above-mentioned substances is not part of our quality and production analysis.

3.3. Obligations as active substance supplier for Hydrogen Peroxide under the European Biocidal Products Regulation (BPR) (EU) No 528/2012 (Article 95)

Evonik fulfils the obligations as active substance supplier for Hydrogen Peroxide under the European Biocidal Products Regulation (Article 95)

The Biocidal Products Regulation (BPR) (EU) No 528/2012, replacing the Biocidal Products Directive (BPD) 98/8/EC, regulates the use and making available on the market of biocidal products in the European Union.

The aim of the BPR is to harmonize the European rules for biocidal products and their active substances. Through risk assessment, it intends to provide a high level of protection for people, animals and the environment and to ensure that products are sufficiently effective against the target species. The BPR stipulates a two-step process, in which the active substance evaluation is followed by a product authorization of individual biocidal products.

Article 95 of the BPR regulates the transitional measures for placing active substances on the market on its own or biocidal products containing active substances. For that purpose, the European Chemicals Agency (ECHA) has published a list of companies that have submitted a dossier in support of an active substance under the review program for existing substances.

As of September 1st, 2015 active substances included in all biocidal products placed on the market in the European Union must come from companies included in article 95 list.

Evonik as member of the Hydrogen Peroxide BPR Task Force has supported hydrogen peroxide (CAS No 7722-84-1; EC No 231-765-0) as active substance in the framework of the BPD/BPR.

Thus, Evonik fulfils the obligations according to article 95 and is listed on the above-mentioned list of active substance suppliers. Therefore, biocidal products from Evonik containing hydrogen peroxide are allowed to be made available in the European Union after September 1st, 2015 providing an authorization for the biocidal product is in place.

3.4. Confirmations related to the Food Industry

Under the EU legislation biocidal products are not allowed to be in direct contact with food with the exception of disinfection of drinking water. In case of doubt if your application falls under the BPR, please contact us.

3.4.1. Regulation (EC) No 396/2005 Article 12 - Anthraquinone

Reference: Statement on compliance with the ESFA opinion on the review of the existing maximum residue levels for anthraquinone according to Article 12 of Regulation (EC) No 396/2005[1]

On 29 March 2012 EFSA issued a reasoned opinion on maximum residue level of anthraquinone in food stuffs. Since no MRLs are currently set for anthraquinone, the default MRL of 0,01 mg/kg applies, according to article 18.1(b) of Regulation (EC) No 396/2005.

On November 2017, EFSA published the scientific opinion "Safety of hydroxyanthracene derivatives for use in food"[2]. The Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the safety of hydroxyanthracene derivatives and to provide advice on a daily intake that does not give rise to concerns about harmful effects to health. The Panel was unable to provide advice on a daily intake of hydroxyanthracene derivatives that does not give rise to concerns about harmful effects to health.

OXTERIL® grades are speciality hydrogen peroxide grades in our product portfolio. The current product specification includes determination of hydrogen peroxide content, decomposition rate and pH-value only. Anthraquinone is not used during the manufacturing, handling and storage of OXTERIL® grades. Based on our best knowledge of the manufacturing process as well as raw materials and additives involved, we can state with reasonable certainty that OXTERIL® grades are not contaminated with anthraquinone in the concentration more than 0,01% (w/w). The analysis of anthraquinone is not part of our quality and production analysis.

3.4.2. Regulation (EC) No 1169/2011 - Allergens

Reference: Statement on allergens according to the Regulation (EC) No 1169/2011

The Annex II of the Regulation (EC) No 1169/2011 on the provision of food information to consumers defines the substances or products causing allergies or intolerances. According to the Regulation any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II must be indicated on the food labelling.

We herewith confirm that OXTERIL® grades are completely of synthetic origin. Based on our best knowledge of the manufacturing process, raw materials and additives involved, analytical measurements on OXTERIL® grades as well as characterisation of their precursor - high purity hydrogen peroxide, we can state with reasonable certainty that OXTERIL® grades are not contaminated with allergens in the concentrations over 0,01% (w/w). The analysis of the above mentioned substances is not part of our quality and production analysis.

[1] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2761
[2] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5090

3.4.3. Directive 18/2001/EC, Regulations (EC) No 1829/2003, (EC) No 1830/2003 - GMO

Reference: Statement on GMO substances according to Directive 18/2001/EC and the Regulations (EC) No 1829/2003and (EC) No 1830/2003

The definition of genetic modified organisms (GMOs) is provided in the Directive 18/2001/EC on the deliberate release into the environment of genetically modified organisms. The Regulations (EC) No 1829/2003 and 1830/2003 define the rules for the pre-marketing authorization as well as for the traceability, labeling of GMOs and the traceability of food and feed produced from GMOs.

Hereby we certify that OXTERIL® grades are of completely synthetic origin. Materials from GMO origin are not used in the production process, neither as raw materials nor as solvents or process chemicals. Based on our best knowledge of the manufacturing process, raw materials and additives involved, analytical measurements on OXTERIL® grades as well as characterisation of its precursor - high purity hydrogen peroxide, we can state with reasonable certainty that OXTERIL® grades are not contaminated with any GMO related substances in concentration more than 0,01% (w/w). The analysis of the above mentioned substances is not part of our quality and production analysis.

3.4.4. Regulation (EC) No 1881/2006, Regulation (EC) No 1259/2011 – PCB

Reference: Statement on the presence of certain contaminants according to the Regulation (EC) No 1881/2006 and amending Regulation (EC) No 1259/2011

The Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs and amending Regulation (EC) No 1259/2011 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs define the upper limits of such contaminants as nitrate, mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, T-2 and HT-2 toxin), metals (lead, cadmium, mercury, tin), 3-monochloropropane-1,2-diol (MCPD), Dioxins, polychlorinated biphenyls (PCB) and polycyclic aromatic hydrocarbons (PAH) in foodstuffs.

Based on our best knowledge of the manufacturing process, raw materials and additives involved, analytical measurements on OXTERIL® grades as well as characterisation of their precursor - high purity hydrogen peroxide, we can state with reasonable certainty that OXTERIL® grades are not contaminated with the substances mentioned above in concentrations more than 0,01% (w/w). The analysis of the above mentioned impurities is not part of our quality and production analysis.

3.4.5. Directive 1999/2/EC and Directive 1999/3/EC - Ionisation

Reference: Statement on the treatment with ionizing radiation according to Directive 1999/2/EC and Directive 1999/3/EC

Directive 1999/2/EC on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation and Directive 1999/3/EC on the establishment of a Community list of foods and food ingredients treated with ionising radiation define the conditions for irradiated food authorisation as well as sources of ionising radiation and requires the labelling of foodstuffs, if they or their ingredient were treated with ionising radiation, as 'treated with ionizing radiation'.

We herewith confirm that OXTERIL® grades are not treated by any ionizing radiation.

3.4.6. Regulation (EC) 396/2005 - Pesticides

Reference: Statement on the presence pesticides according to the Regulation (EC) 396/2005

The Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin prohibits the placing on the market of those products, which are covered by the Annex I of the Regulation and used as food or feed, if any pesticide residue in the food or feed product exceeds the corresponding Maximum Residue Level (MRL) or 0,01ppm if no MRL has been yet defined.

OXTERIL® grades contain as an active substance hydrogen peroxide

Based on our best knowledge of the manufacturing process, raw materials and additives involved, analytical measurements on OXTERIL® grades as well as the characterisation of their precursor - high purity hydrogen peroxide, we can state with reasonable certainty that OXTERIL® grades are not contaminated with pesticides other than hydrogen peroxide in concentrations over 0,01% (w/w). The analysis of the above mentioned impurities is not part of our quality and production analysis.

3.4.7. ESFA expert opinion - Mineral oil saturated

Reference: Statement on compliance with the ESFA expert opinion on the review of mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH)

On 28th of August 2013 European Food Safety Authority (EFSA) published a reasoned expert opinion with reference to mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) of recycled food packaging [3].

Furthermore, on 15th of November 2019 EFSA issued a rapid risk assessment on the possible risk for public health due to the contamination of infant formula and follow-on formula by mineral oil aromatic hydrocarbons (MOAH)[4].

[3] https://www.efsa.europa.eu/en/efsajournal/pub/2704
[4] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2019.EN-1741

Based on our best knowledge of the manufacturing process as well as raw materials and additives involved, we can state with reasonable certainty that OXTERIL® grades are not contaminated with mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH), in the concentration more than 0,1% (w/w). The analysis of MOSH and MOAH residues is not part of our quality and production analysis.

3.4.8. Regulation (EU) No 1169/2011; Regulations (EC) No 1924/2006 and (EC) No 1925/2006 – Nanomaterials

Reference: Statement on nanomaterials according to Regulation (EU) No 1169/2011 of the European Parliament and the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council.

The Regulation (EU) No 1169/2011 provides the basis for the assurance of a high level of consumer protection in relation to food information, taking into account the differences in the perception of consumers and their information needs whilst ensuring the smooth functioning of the internal market.

Recommendation on the definition of a nanomaterial (2011/696/EU) provides the definition of nanomaterials. Article 18 of Regulation (EC) No 1169/2011 on the provision of food information to consumers defines that all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

Hereby we certify that the OXTERIL® grades are completely synthetic origin. Nanomaterials, as defined by Recommendation 2001/696/EU, are not used in the production process, neither as raw materials nor as solvents or process chemicals. Based on our best knowledge of the manufacturing process as well as raw materials and additives involved, we can state with reasonable certainty that OXTERIL® grades are not contaminated with nanomaterials. The analysis of the above mentioned substances is not part of our quality and production analysis.

3.4.9. Regulation (EC) No 999/2001 - BSE/TSE

Reference: Regulation (EC) No 999/2001 of the European Parliament and the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs).

The Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) and Bovine spongiform encephalopathy (BSE) in animals. It shall apply to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

We herewith confirm that OXTERIL® grades are completely synthetic origin. Products from animal origin, defined in Article 3 of Regulation (EC) No 999/2001 are not used in the production process, neither as raw materials nor as solvents or process chemicals. Based on our best knowledge of the manufacturing process, raw materials and additives involved, analytical measurements as well as characterization of its precursor - high purity hydrogen peroxide, we can state with reasonable certainty that OXTERIL® grades are not contaminated with any product of

animal origin in concentration more than 0,01% (w/w). The analysis of the before mentioned substances is not part of our quality and production analysis.

3.4.10. Statement on the product used in food processing industry

We herewith confirm, that OXTERIL® grades are an aqueous solution of high purity hydrogen peroxide, which is of purely synthetic origin. OXTERIL® grades compliy with the purity requirements of the European Pharmacopoeia, the German Pharmacopoeia and therefore may be used in the food processing industry.

OXTERIL® grades contain hydrogen peroxide as the active ingredient (s. SDS). According to provisions of Regulation (EC) No 1333/ 2008 on food additives, hydrogen peroxide is not listed as a "food additive", therefore it must not be detectable in the final food products.

The food producer has to ensure, that by using of OXTERIL® grades the final food products comply with the provisions of corresponding European and National food safety regulations (e.g. Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch, Regulation (EC) No 178/2002 on the general principles and requirements of food law, etc.).

3.5. General Confirmations

3.5.1. Kosher / Halal / Vegan Statement

We hereby certify that the OXTERIL® grades conforms to the following conditions:

- The products do not contain any ingredients of animal origin.
- The products do not contain alcohol and alcohol has not been used in the manufacturing process.
- The equipment used for the manufacturing, filling and packing of this product are not used for the manufacture, filling and packing of products of animal origin or products containing ingredients of animal origin (except seafood, dairy and egg origin).

During manufacture, filling, packing, transportation and storage, the products are fully separated from other foods containing ingredients of animal origin/ or alcohol.

3.5.2. Conflict Minerals Regulation

On 1 January 2021 the Regulation (EU) 2017/821 of the European Parliament and of the Council of 17 May 2017 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas (so called Conflict Minerals Regulation) entered into force. It aims to ensure that the trade in four minerals (tin, tantalum, tungsten and gold), which sometimes finance armed conflict or are mined using forced labour, meet international responsible sourcing standards.

We herewith confirm, that all OXTERIL® grades are an aqueous solution of hydrogen peroxide, which is of purely synthetic origin. Based on our best knowledge of the manufacturing process as well as raw materials and additives involved, we can state with reasonable certainty that OXTERIL® grades are not contaminated with "the conflict minerals" mentioned above in the

concentration more than 0,1% (w/w). The analysis of the above-mentioned substances is not part of our quality and production analysis.

3.5.3. Health Certificate according to DIN EN 902:2009

Reference: DIN EN 902 Drinking Water Directive

The DIN EN 902:2009 defines the requirements for the use of hydrogen peroxide for the treatment of water intended for human consumption.

OXTERIL® grades are aqueous solutions, which are of purely synthetic origin. Herewith we certify that OXTERIL® grades are compliant with the EN 902:2009.

3.5.4. VOC – Volatile Organic Compounds

Reference: Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC)

The Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) of Swiss Federal Council, based on Articles 35a and 35c of the Environmental Protection Act of 7 October 1983 (EPA) regulate the following substances for tax:

a) VOCs on the positive list of substances (Annex 1);
b) VOCs according to letter a) that are contained in products mentioned in the positive list of products (Annex 2).

We confirm herewith that the content of volatile organic compounds in OXTERIL® Grades are below 0,01% (w/w).

4. Responsible for Documentation

Name: María José Rodríguez
Function: Application Law & Marketing Manager

This document has been created electronically and is valid without signature.

Volume	Remarks	Date of Revision
2022/07	Revision 5	2022/07/07

Disclaimer

Some applications, in which hydrogen peroxide is used, are subject to an extensive regulation. The user of hydrogen peroxide is in his sole and entire liability in respect to fulfilment of those regulatory frameworks or prescriptions of any relevant authority. The user of hydrogen peroxide products must ensure the provisions of the applicable law, due to use of a hydrogen peroxide product, are fulfilled.

This information and all further technical advice is based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer.

Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

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