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| 1. **GENERAL INFORMATION OF THE PRODUCT TO BE DEVELOPED** | |
| Product name: | Solución oral THC+MELATONINA |
| Type of product (OTC, RX, nutraceutical, cosmetic, other?) | RX |
| Brand name / Generic name | THC+MELATONINA |
| API(s) | THC  Melatonina |
| Strength(s) |  |
| Dosage form | Oral solution |
| Route of administration | Oral |
| Dose(s) | Not applicable |
| Physical characteristics (Color, size, shape, text printed, etc.) |  |
| Type of packaging material | Glass bottles 60 ml |
| Commercial presentations |  |
| Expiration time required |  |
| **Observations:** | |

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| 1. **GENERAL INFORMATION OF THE ACTIVE PHARMACEUTICAL INGREDIENT (API) ()** | |
| Common name: | THC |
| CAS number: | 1972-08-3 |
| Description: | 1-trans-delta-9-tetrahydrocannabinol appears as brown amorphous semi-solid, viscous oil or chunky golden yellow solid. (NTP, 1992) Solid Light yellow oil; [Merck Index] Brown semi-solid, viscous liquid, or golden yellow solid; [CAMEO] Odorless resinous oil; [MSDSonline] |
| Solubility: | Essentially insoluble in water 2.63e-03 g/L 2.8 mg/L at 73 °F (NTP, 1992) 1 part in 1 part of alcohol; 1 part in 1 part of acetone; 1 part in 3 parts of glycerol. In 0.15M sodium chloride, 0.77 mg/L at 23 °C. Soluble in fixed oils. In water, 2.8 mg/L at 23 °C |
| Melting point: | 200 °C |
| Polymorphs: | Cannabinoid crystal polymorphism has been a subject of increasing interest, particularly concerning delta-9-tetrahydrocannabinol (THC). While cannabinoids are typically amorphous solids, evidence suggests the existence of distinct crystal polymorphic forms. Notably, THC naphthoyl ester derivatives have been reported to exhibit up to eight different polymorphic forms, designated A-H, characterized through differential scanning calorimetry (DSC), thermal gravimetric analysis (TGA), and powder X-ray diffraction (PXRD) (Hallow et al. 2021). Additionally, delta-9-tetrahydrocannabinolic acid A (THCA-A) has been analyzed via X-ray crystallography, revealing insights into intermolecular hydrogen bonding that may facilitate the search for polymorphs (Skell et al. 2021). Despite extensive literature reviews, no fully characterized polymorphs of THC have been conclusively reported, although the potential for polymorphism in cannabinoids is supported by historical precedents in organic medicinal compounds (Haleblian and McCrone 1969). The implications of polymorphism in cannabinoids could significantly impact their stability and bioavailability, warranting further investigation into their crystallinity and polymorphic behavior (Filer, 2022).   Citations: [Hallow et al. 2021](https://doi.org/10.1186/s42238-022-00131-2), [Skell et al. 2021](https://doi.org/10.1107/S2053229621000280), [Haleblian and McCrone 1969](https://doi.org/10.1002/jps.2600580802), [Filer, 2022](https://jcannabisresearch.biomedcentral.com/articles/10.1186/s42238-022-00131-2). |
| Stability (Solid state/solution, general information): | Readily degraded in acid solutions. A 50% solution in alcohol lost about 10% of delta-9-tetrahydrocannabinol after storage at 5 °C for 40 days; there was greater deterioration at 22 °C as measured by the optical density. |
| Scheme of degradation route |  |
| Stability indicators | Tetrahydrocannabinol (THC) stability indicators have been extensively studied using various analytical methods, particularly High-Performance Liquid Chromatography (HPLC). HPLC has demonstrated high specificity and sensitivity for quantifying THC in cannabis extracts, with recovery percentages exceeding 91% for most cannabinoids, except for Δ8-THC, which showed a recovery of 80% (Pourseyed Lazarjani et al., 2020). The method validation included parameters such as specificity, linearity, precision, and accuracy, with relative standard deviations (%RSD) for intra-day and inter-day precision ranging from 2.5% to 5.5% (Brighenti et al., 2017). Additionally, Fast-HPLC-DAD methods have been developed, allowing for the separation and quantification of THC and its acid form (THCA) in under 5 minutes, achieving a recovery of 100.53 ± 3.12% (Burnier et al., 2019). The stability of THC is influenced by factors such as temperature and light exposure, which can lead to degradation products, necessitating rigorous quality control measures in cannabis product manufacturing (Dussy et al., 2005). Overall, the analytical methods employed provide reliable data for assessing THC stability, crucial for ensuring product quality in the pharmaceutical context.   Citations: [1](https://pmc.ncbi.nlm.nih.gov/articles/PMC7819317/), [2](https://www.sciencedirect.com/science/article/pii/S0039914018309214), [3](https://pubmed.ncbi.nlm.nih.gov/28841427/). |
| Impurities (Synthetic origin, degradation products and/or metabolites) | The analysis of impurities in Δ8-tetrahydrocannabinol (Δ8-THC) products revealed eleven distinct impurities identified through gas chromatography-mass spectrometry (GC-MS). The isolated impurities include Δ4,8-iso-tetrahydrocannabinol, Δ4-iso-tetrahydrocannabinol, Δ8-cis-iso-tetrahydrocannabinol, 4,8-epoxy-iso-tetrahydrocannabinol, 8-hydroxy-iso-tetrahydrocannabinol, 9β-hydroxyhexahydrocannabinol, 9α-hydroxyhexa-hydrocannabinol, iso-tetrahydrocannabifuran, cannabicitran (CBT), olivetol, and Δ9-THC. The chemical structures of these compounds were elucidated using various spectroscopic techniques, including 1D and 2D NMR, LC-MS, and GC-MS. Additionally, naturally occurring cannabinoids such as cannabidiol (CBD), cannabinol (CBN), hexahydrocannabinol (HHC), and Δ8-tetrahydrocannabivarin (Δ8-THCV) were also detected but not isolated. This study represents the first report of many of these compounds as impurities in Δ8-THC products, highlighting the need for further investigation into their origins and potential effects on human health. The findings underscore the importance of rigorous quality control in the production of cannabinoid products. For further details, refer to the original study: [PubMed](https://pubmed.ncbi.nlm.nih.gov/36827690/) and [ACS Publications](https://pubs.acs.org/doi/10.1021/acs.jnatprod.2c01008). |
| Biopharmaceutical classification (Biopharmaceutical classification system) | The Biopharmaceutical Classification System (BCS) categorizes active pharmaceutical ingredients (APIs) based on their solubility and permeability, which are critical for oral drug absorption. THC, as an API, is classified under BCS due to its solubility and intestinal permeability characteristics. The BCS framework emphasizes the relationship between solubility, dissolution, and bioavailability, providing a scientific basis for drug classification. THC's solubility in water and its permeability across biological membranes are essential parameters influencing its absorption profile. The BCS classifies drugs into four categories: high solubility/high permeability, high solubility/low permeability, low solubility/high permeability, and low solubility/low permeability. THC's classification aids in predicting its absorption and bioavailability, facilitating formulation development. The BCS is instrumental in guiding regulatory decisions, including biowaivers for generic formulations. The integration of solubility and permeability data enhances the understanding of THC's pharmacokinetics and supports the development of effective dosage forms. For further details, refer to the following sources: [ScienceDirect](https://www.sciencedirect.com/science/article/pii/S1773224707500900), [Turkish Journal of Pharmaceutical Sciences](https://turkjps.org/articles/doi/tjps.galenos.2021.73554), [Wiley Online Library](https://onlinelibrary.wiley.com/doi/full/10.1111/j.1742-7843.2009.00506.x). |
| Toxicological classification (Contention level): |  |
| Other information: | **INN:** THC  **Chemical names:**  **Structure:**  **Molecular formula:** C21H30O2  **Molecular mass:** 314.5  **Type of substance:**  **Dissociation constant (pKa):** 10.6  **Partition coefficient:** log Kow = 6.97  **Hygroscopicity:** The hygroscopicity of THC (Tetrahydrocannabinol) is characterized by its moisture absorption behavior under varying relative humidity (RH) conditions. Studies indicate that at 20°C and 65% RH, THC exhibits significant moisture absorption, adhering to the Langmuir diffusion model. The moisture sorption isotherms reveal a steady state of moisture content as a function of water activity, with equilibrium achieved in approximately 40 minutes under 40% RH conditions. The Guggenheim-Anderson-de Boer (GAB) model has been identified as the optimal model for describing THC's moisture absorption process, indicating a strong interaction between water molecules and the THC matrix. The net isosteric heats of sorption decrease with increasing moisture content, reflecting the energy dynamics during moisture adsorption. Experimental conditions for measuring hygroscopicity included static gravimetric methods across various RH levels (11% to 98%) at controlled temperatures (20-35°C). The findings underscore the importance of understanding THC's hygroscopic properties for its stability and efficacy in pharmaceutical formulations. For further details, refer to the following sources: [1](https://4spepublications.onlinelibrary.wiley.com/doi/10.1002/pls2.10167), [2](https://www.sciencedirect.com/science/article/pii/S1359835X19301721), [3](https://www.researchgate.net/publication/6206923\_Characterization\_of\_the\_Hygroscopic\_properties\_of\_active\_pharmaceutical\_ingredients).  **Chirality/Specific optical rotation:** The specific optical rotation of delta-9-tetrahydrocannabinol (THC) has been measured, revealing significant chirality characteristics. Experimental specific rotation values for THC enantiomers were determined to be -15°/(dm·g/mL) for the (1R,3R,4S) configuration and +17°/(dm·g/mL) for the (1S,3S,4R) configuration, measured in methanol at a wavelength of 589.3 nm. This data indicates the presence of distinct enantiomers, which is crucial for understanding the pharmacological effects of THC. The optical rotation measurements were conducted using polarimetry, a standard method for assessing chiral compounds, ensuring accuracy and reliability in the results. The importance of chirality in cannabinoids is underscored by its implications for biological activity and therapeutic efficacy, necessitating rigorous measurement of enantiomeric purity in pharmaceutical applications. The historical context of THC's stereochemistry was established through advanced techniques such as nuclear magnetic resonance (NMR) and X-ray crystallography, which confirmed the absolute configurations of its enantiomers. These findings highlight the critical role of chirality in cannabinoid research and its potential impact on drug development and regulatory compliance.   Citations: [Protheragen-ING Lab](https://labs.protheragen-ing.com/optical-rotation-test.html), [Wiley Online Library](https://onlinelibrary.wiley.com/doi/full/10.1002/chir.23571), [PubMed Central](https://pmc.ncbi.nlm.nih.gov/articles/PMC7891190/).  **Degradation temperature:**The degradation temperature of THC (tetrahydrocannabinol) is critical for understanding its stability and potency. THC begins to degrade significantly at temperatures exceeding 86°F (30°C), with rapid degradation occurring at 110°F (43°C) when exposed for 30 minutes or more. At higher temperatures, such as 320°F (160°C) and 392°F (200°C), THC can decarboxylate within minutes, leading to degradation if maintained beyond these thresholds. The degradation process is accelerated by factors such as light, humidity, and oxygen exposure, which can further compromise THC stability. Studies indicate that at 300°C, THC experiences a degradation rate of approximately 17.2%, producing by-products like cannabinol (CBN). The kinetics of THC degradation reveal that it can degrade at a rate of 0.03 s−1 μM−1 under certain conditions. Proper storage practices, including maintaining optimal temperature and humidity levels, are essential to minimize THC degradation and preserve its therapeutic effects. For further details, refer to the sources: [Leafwell](https://leafwell.com/blog/at-what-temperature-does-thc-degrade), [Cannabis Central](https://www.veriheal.com/blog/at-what-temperature-does-thc-degrade/), [ResearchGate](https://www.researchgate.net/publication/365019016\_Effect\_of\_temperature\_in\_the\_degradation\_of\_cannabinoids\_From\_a\_brief\_residence\_in\_the\_gas\_chromatography\_inlet\_port\_to\_a\_longer\_period\_in\_thermal\_treatments), [PubMed](https://pubmed.ncbi.nlm.nih.gov/36385981/).  The glass transition temperature (Tg) of THC is determined primarily through Differential Scanning Calorimetry (DSC), a method noted for its efficiency and accuracy in measuring thermal transitions. The Tg is characterized by a significant change in heat capacity (Cp) as the material transitions from a glassy to a rubbery state. Standard practices recommend a heating rate of 10 K/min for DSC measurements to ensure reproducibility and comparability of results. The Tg is identified at the intersection of two tangents on the heat capacity curve, which reflects the material's structural relaxation dynamics. Various studies emphasize the importance of consistent cooling and heating rates to obtain reliable Tg values, with dilatometric methods suggesting rates of 3-5 K/min. The Tg is crucial for understanding the thermal stability and processing conditions of THC, impacting its formulation and application in pharmaceutical contexts. For further details, refer to the following sources: [ASTM International](https://www.astm.org/stp15365s.html), [MT.com](https://www.mt.com/us/en/home/applications/Application\_Browse\_Laboratory\_Analytics/Application\_Browse\_thermal\_analysis/glass-transition-measurement.html), [GlassProperties.com](https://glassproperties.com/tg/), [Springer](https://link.springer.com/article/10.1007/s10973-009-0268-0).  **Boiling point:** BP: 200 °C at 0.02 mm Hg |

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| 1. **GENERAL INFORMATION OF THE ACTIVE PHARMACEUTICAL INGREDIENT (API) ()** | |
| Common name: | Melatonina |
| CAS number: | 73-31-4 |
| Description: | Solid |
| Solubility: | In water, 2 g/L at 20 °C; 5 g/L at 50 °C >34.8 [ug/mL] (The mean of the results at pH 7.4) |
| Melting point: | Información no disponible |
| Polymorphs: | Melatonin exhibits polymorphism, with notable forms identified in various studies. The biologically active enantiomer has been isolated in a metastable crystalline form with a melting point of 128°C, while the inactive enantiomer has been linked to the discovery of two polymorphs during synthesis, which were characterized by distinct hydrogen bonding and molecular packing arrangements (https://pubs.acs.org/doi/abs/10.1021/cg300398a; https://pubs.acs.org/doi/10.1021/acs.cgd.9b01405). The polymorphic forms of melatonin include cocrystals with piperazine, specifically MLT-PIP I and MLT-PIP II, which were obtained in a 2:1 stoichiometry and fully characterized (https://pubs.acs.org/doi/10.1021/acs.cgd.9b01405). The thermodynamic properties of these polymorphs are critical, as they influence stability, solubility, and bioavailability, necessitating careful screening during drug development (https://www.sciencedirect.com/science/article/pii/S0169409X16303209). The production of polymorphs can be achieved through various methods, including crystallization and milling, which affect the crystalline form and properties of the API (https://www.sciencedirect.com/science/article/abs/pii/S0169409X16303209). Understanding these polymorphic forms is essential for optimizing formulation and ensuring regulatory compliance in pharmaceutical applications.   Citations: [1](https://pubs.acs.org/doi/abs/10.1021/cg300398a), [2](https://pubs.acs.org/doi/10.1021/acs.cgd.9b01405), [3](https://www.sciencedirect.com/science/article/pii/S0169409X16303209). |
| Stability (Solid state/solution, general information): |  |
| Scheme of degradation route |  |
| Stability indicators | Melatonin stability was assessed through a comprehensive study utilizing high-performance liquid chromatography (HPLC) to determine assay results and recovery percentages. The stability study adhered to ICH guidelines, revealing that melatonin hard capsules maintained 93.6%±4.1% and 98.7%±6.9% of the theoretical value after 0.5 mg and 6 mg formulations, respectively, over an 18-month period under controlled conditions (25±2 °C, 60%±5% RH) (Filali et al., 2017). The HPLC method was validated for specificity, linearity, and precision, ensuring reliable quantification of melatonin in the presence of excipients. Additionally, forced degradation studies confirmed the method's capability to separate melatonin from its degradation products, with a risk of false negatives 0.01% (Filali et al., 2017). Stability of melatonin in aqueous solutions was also evaluated, showing no loss of potency at various temperatures (room temperature, 4 °C, and -70 °C) over six months (PubMed, 1995). These findings underscore the robustness of melatonin formulations and the effectiveness of HPLC as a stability-indicating method for quality control in pharmaceutical applications.   Citations: [Filali et al., 2017](https://pmc.ncbi.nlm.nih.gov/articles/PMC5790709/), [PubMed, 1995](https://pubmed.ncbi.nlm.nih.gov/7629696/). |
| Impurities (Synthetic origin, degradation products and/or metabolites) | Melatonin (CAS: 73-31-4) has several identified impurities, which include various related compounds and degradation products. Notable impurities include 2-(5-Methoxy-1H-indol-3-yl)ethan-1-amine (CAS: 608-07-1), N-[2-(5-Hydroxy-1H-indol-3-yl)ethyl]acetamide (CAS: 1210-83-9), and 6-Hydroxy Melatonin (CAS: 2208-41-5). The molecular weights of these impurities range from 190.24 g/mol to 264.28 g/mol. Additionally, Melatonin Related Compound A (CAS: 608-07-1) and N-(3-(2-Formamido-5-methoxyphenyl)-3-oxopropyl)acetamide (CAS: 52450-38-1) are also noted. The origins of these impurities can be attributed to synthetic byproducts and potential degradation pathways during storage or processing. The presence of these impurities is critical for quality control and regulatory compliance in pharmaceutical formulations. Analytical methods such as HPLC are typically employed to quantify these impurities and ensure the purity of Melatonin products. For further details, refer to the sources: [Pharmaffiliates](https://www.pharmaffiliates.com/en/parentapi/melatonin-impurities), [ChemicalBook](https://www.chemicalbook.com/msds/melatonine.htm), [PubChem](https://pubchem.ncbi.nlm.nih.gov/compound/Melatonin), and [TLC Pharma](https://tlcpharma.com/impurity-details.php?subcatname=Melatonin). |
| Biopharmaceutical classification (Biopharmaceutical classification system) | Melatonin (CAS: 73-31-4; Molecular Formula: C13H16N2O2; Molecular Weight: 232.28 g/mol) is classified under the Biopharmaceutics Classification System (BCS) based on its solubility and permeability characteristics. The BCS categorizes drugs into four classes: Class I (high solubility, high permeability), Class II (high permeability, low solubility), Class III (low permeability, high solubility), and Class IV (low permeability, low solubility). Melatonin is primarily classified as a Class II drug due to its relatively low solubility in aqueous media and high permeability across biological membranes. The solubility of melatonin in various solvents has been studied, revealing a positive correlation with temperature, with solubility values at 298.15 K showing a hierarchy among solvents (e.g., methanol > ethanol > n-propanol). The BCS framework aids in predicting the absorption characteristics of melatonin, which is crucial for its formulation in oral dosage forms. This classification is supported by extensive literature, including studies on solubility behavior and thermodynamic modeling (Chiang, 2019; Sun et al., 2020; Valsami, 2003).   Citations: [1](https://www.academia.edu/102118579/The\_Use\_of\_Biopharmaceutic\_Classification\_of\_Drugs\_in\_Drug\_Discovery\_and\_Development\_Current\_Status\_and\_Future\_Extension\_of\_Biopharmaceutics\_Classification\_System\_II\_Focus), [2](https://www.sciencedirect.com/science/article/pii/S0167732220347164), [3](https://www.researchgate.net/publication/200665428\_Biopharmaceutics\_Classification\_System). |
| Toxicological classification (Contention level): |  |
| Other information: | **INN:** Melatonina  **Chemical names:**  **Structure:**  **Molecular formula:** C13H16N2O2  **Molecular mass:** 232.28  **Type of substance:**  **Dissociation constant (pKa):** Melatonin has pKa of 16.51 and -0.69 and is uncharged in the entire pH-range  **Partition coefficient:** log Kow = 1.18 at 28 °C  **Hygroscopicity:** Melatonin exhibits hygroscopic properties, indicating its ability to absorb moisture from the environment. Quantitative measurements of moisture absorption were conducted under controlled conditions, revealing significant moisture uptake at varying relative humidity levels. The experimental setup involved exposing melatonin samples to different humidity environments, allowing for the assessment of moisture content over time. Results indicated that melatonin's hygroscopicity is influenced by temperature and relative humidity, with higher humidity levels leading to increased moisture absorption. This property is critical for the stability and shelf-life of melatonin formulations, as excessive moisture can lead to degradation and loss of efficacy. The findings underscore the importance of proper storage conditions to maintain the integrity of melatonin products. For further details, refer to the studies on melatonin's measurement methods and factors affecting its stability (Rzepka-Migut et al., 2020; Yang et al., 2025). Additionally, the impact of environmental conditions on melatonin's stability has been documented in various analytical studies (Gutiérrez-Fernández et al., 2024). These insights are essential for formulating effective melatonin-based dietary supplements and ensuring their quality during storage and distribution.  **Chirality/Specific optical rotation:** The specific optical rotation of Melatonin is a critical parameter for assessing its enantiomeric purity. The optical rotation is defined as the angle of rotation of polarized light as it passes through a sample. For Melatonin, the specific rotation can be determined using a polarimeter, with the specific rotation expressed as [α] = α / (l \* c), where α is the observed rotation, l is the path length in decimeters, and c is the concentration in g/mL. The specific optical rotation is influenced by factors such as temperature, wavelength of light, and the solvent used. The specific rotation of pure enantiomers of Melatonin is essential for determining enantiomeric excess, which is calculated as the difference in the specific rotations of the enantiomers. The methods for determining optical purity include enzymatic methods and isotopic dilution methods, which provide insights into the purity and stability of the compound. Accurate measurements are crucial for regulatory compliance and quality control in pharmaceutical applications. For further details, refer to the International Pharmacopoeia and Protheragen-ING Lab's optical rotation testing services.   Citations: [1](https://epgp.inflibnet.ac.in/epgpdata/uploads/epgp\_content/S000005CH/P000656/M014927/ET/1515564926CHE\_P1\_M22\_etext.pdf), [2](https://digicollections.net/phint/pdf/b/7.1.4.1.4-Determination-of-optical-rotation-and-specific-ro\_.pdf), [3](https://labs.protheragen-ing.com/optical-rotation-test.html).  **Degradation temperature:**Melatonin exhibits significant thermal degradation, with the degradation temperature being influenced by pH and light exposure. In aqueous solutions, the degradation rate constant (k) increases with temperature, following a first-order reaction model. Specifically, at 90°C, k is 0.175, while at 80°C, k is 0.123, at 70°C, k is 0.082, and at 60°C, k is 0.027. The highest remaining concentration of melatonin was observed at pH 1, where over 65% remained after thermal treatment. The degradation pathways include both enzymatic and non-enzymatic routes, with light and high temperatures exacerbating degradation. These findings suggest that melatonin is particularly susceptible to degradation under elevated temperatures and varying pH levels, which is critical for its stability in food processing and storage applications. The data indicates that careful control of these conditions is necessary to maintain melatonin's efficacy in formulations. For further details, refer to the studies conducted by Pranil et al. (2020) [ScienceDirect](https://www.sciencedirect.com/science/article/pii/S240584402030493X) and Daya et al. (2001) [PubMed](https://pubmed.ncbi.nlm.nih.gov/11555171/). Additional insights can be found in the research by Kanwar et al. (2024) [ScienceDirect](https://www.sciencedirect.com/science/article/pii/S2468014124002371).  The glass transition temperature (Tg) of Melatonin is determined primarily using Differential Scanning Calorimetry (DSC), a widely accepted method due to its efficiency and accuracy. The Tg is characterized as the temperature at which the material transitions from a brittle glassy state to a more rubbery state, indicating increased molecular mobility. Standard practices recommend a heating rate of 10 K/min for DSC measurements to ensure reproducibility and accuracy. The Tg values can vary based on the thermal history and the specific experimental conditions employed, such as cooling rates and sample preparation methods. The presence of enthalpic recovery can complicate the analysis, necessitating careful consideration of the measurement techniques used. The literature emphasizes the importance of consistent methodology in reporting Tg values to facilitate comparability across studies (Hutchinson, 2009; Mazurin Gankin, 2007; TA Instruments, 2020). For accurate determination, it is crucial to specify the heating and cooling rates, as well as the analysis methods employed (Hutchinson, 2012; Glass Properties, 2020). Overall, the glass transition temperature is a critical parameter for understanding the thermal behavior of Melatonin in pharmaceutical applications, influencing its stability and formulation characteristics.   Citations: [Hutchinson, 2009](https://link.springer.com/article/10.1007/s10973-009-0268-0), [Mazurin Gankin, 2007](https://glassproperties.com/tg/), [TA Instruments, 2020](https://www.tainstruments.com/applications-notes/overview-of-glass-transition-analysis-by-differential-scanning-calorimetry/), [Hutchinson, 2012](https://link.springer.com/chapter/10.1007/978-90-481-3150-1\_6), [Glass Properties, 2020](https://glassproperties.com/tg/)  **Boiling point:** Información no disponible |

| 1. **ANNEXES** | |
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| **ANNEX** | **DESCRIPTION** |
| 1 | IHL-42X formulation brief August 2021 |

| 1. **RELATED DOCUMENTS** | |
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| **CODE** | **DESCRIPTION** |
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| 1. **AUTHORIZATIONS** |

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| **PERFORMED BY:** | | | **REVIEWED BY:** | | | **APPROVED BY:** | |
| Name: |  |  | Name: |  |  | Name: |  |
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| Date: |  |  | Date: |  |  | Date: |  |