1. Date

May 8th, 2026

2. Name of Applicant/Petitioner

DSM Nutritional Products, LLC

3. Address

45 Waterview Blvd
Parsippany, NJ 07054-1298

4. DESCRIPTION OF PROPOSED ACTION

4.1. Requested Approval

DSM is submitting a Tier 1 Over the Counter (OTC) Monograph Order Request (OMOR) for a Generally Recognized as Safe and Effective (GRASE) determination for Bemotrizinol (BEMT) 6% as a new sunscreen active ingredient under FDA's OTC Monograph M020: Sunscreen Drug Products for OTC Human Use (21 CFR Part 352).

4.2. Need for Action

BEMT offers effective protection against sunburn and is not yet covered by an existing final order under the OTC monograph system. BEMT, at a concentration of 6%, is indicated as a broad-spectrum UV filter for use in topical OTC sunscreen products to prevent sunburn. Its high photostability and broad-spectrum coverage across UVB (280-320 nm) and UVA (320-400 nm) ranges, along with its synergistic compatibility with other sunscreen actives, make BEMT a valuable component in modern formulations.
The inclusion of BEMT in the OTC sunscreen drug monograph aims to address the unmet need for a new photostable UVA and UVB filter in the U.S. market, thereby expanding consumer options and enhancing public health protection against harmful UV radiation.

4.3. Locations of Use

There is no specific location of use as BEMT, at a concentration of 6%, is indicated as a broad-spectrum UV filter for use in topical OTC sunscreen products to prevent sunburn in compliance with 21 CFR Part 352 and the FDA's Over-the-Counter Sunscreen Monograph M020.

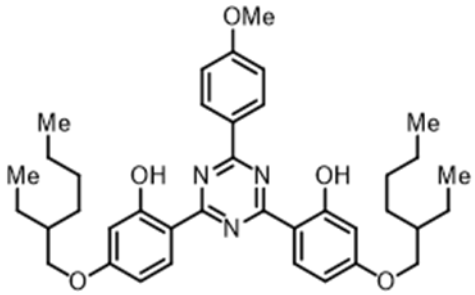
4.4. Disposal Sites

Empty or partially empty containers will typically be disposed of by a community's solid waste management system, which may include landfills, incineration, and recycling, although minimal quantities of the unused drug could be disposed of in the sewer system.

5. IDENTIFICATION OF SUBSTANCES THAT ARE THE SUBJECT OF THE PROPOSED ACTION

5.1. Nomenclature

Established Name (USAN):	Bemotrizinol (BEMT)
Brand/Proprietary Name/Tradename:	PARSOL® Shield
CAS Name:	Phenol,2,2'-[6-(4-methoxyphenyl)-1,3,5-triazine-2,4-diyl]bis(5-((2-ethylhexyl)oxy)
IUPAC Names:	6,6'-(6-(4-methoxyphenyl)-1,3,5-triazine-2,4-diyl) bis(3-((2-ethylhexyl)oxy)phenol) 2,2′-[6-(4-Methoxyphenyl)-1,3,5-triazine-2,4-diyl] bis{5-[(2-ethylhexyl)oxy]phenol} 2,4-bis{[4-(2-ethyl-hexyloxy-2-hydroxy]-phenyl}-6-(4-methoxyphenyl)-(1,3,5)-triazine 5-[(2-ethylhexloxy)]-2-[4-[4-(2-ethylhexoxy)-2-hydroxyphenyl]-6-(4-methoxyphenyl)-1,3,5-triazin-2-yl] phenol
CAS Registration Number:	187393-00-6
Molecular Formula:	$C_{38}H_{49}N_3O_5$
Molecular Weight:	627.81 g/mol
Structural (graphic) Formula	



6. ENVIRONMENTAL ISSUES

6.1. Environmental Fate of Released Substances

6.1.1. Identification of Substance of Interest

An Environmental Assessment (EA) has been conducted on BEMT, demonstrating its high stability, even under environmentally irrelevant harsh conditions. There are no structurally related substances (SRSs) that represent more than 10% of the dose, and the known impurities are present at very low levels (total impurities <2% w/w as per the USP monograph). BEMT remains stable across the environmentally relevant pH range of 5 to 8, and it is not biodegradable in water or soil (refer to sections 6.1.2. and 6.1.3. Below for more details). A forced degradation study further confirmed that the compound is highly stable under various stress factors, including heat, humidity, acidic and basic conditions, oxidation, and photostability. No degradation products were formed, even under extreme conditions. Additionally, BEMT has proven to be stable in various sunscreen formulations (refer to section 3.2.S.7.3.3 for further details).

6.1.2. Physical and Chemical Characterization

The physical and chemical properties of BEMT that are environmentally relevant are summarized as follows, and in Appendix 1: Bemotrizinol Data Summary Table.

Water solubility < 0.014 mg/L at 20 °C[1]

4.5 ng/L at 25 °C[2]

[1] Measured in a GLP test according to the OECD guideline No. 105 (Column Elution Method) (RCC Ltd, 1998a).

2 Measured in a non-GLP test according to the OECD guideline No. 105 (Column Elution Method) (Ciba, 2003).

Dissociation Constant -3 and 9.4 for the triazin (3x) and phenol (2x) sites.

Estimated according to the Hammett correlation method (ECHA, 2024). This indicates that BEMT is not dissociated or protonated in the environmentally relevant pH range of 5 to 8.

Octanol/Water Partition Coefficient (Log K_{ow}) > 5.7 at 20 °C

Measured in a GLP test according to the OECD guidelines No. 107 (Flask Shaking Method) and No. 117 (HPLC Method) (RCC Ltd, 1998b).

Vapor Pressure 5.9×10^{-20} Pa at 25 °C

Measured in a GLP test according to the OECD guideline No. 104 (RCC Ltd, 1997).

6.1.3. Environmental Depletion Mechanisms

Forced Degradation Study

This study was performed upon FDA request and according to the DSM internal SOP "SISMS-06-01-SQCM-SOP-100511 Forced Degradation Study", version 2.0. Within this study, the following stress factors were investigated: (1) Thermal (heat) at 80 °C, (2) Humidity at 80 °C and 75 % RH, (3) Acid at room temperature and at 60 °C with 0.1 M HCl, (4) Base at room temperature and at 60 °C with 0.1 M NaOH, (5) Oxidation at room temperature with 1 % H2O2, and (6) Photo stability at room temperature exposed to > 1.2 MLux*h / 200 W*h/m2.

The outcome of this study showed that both the mass balance loss and degradation of BEMT peak are not significant (< 5 % w/w), in any of the stress conditions, even when harsher hydrolytic conditions were applied (See section 3.2.S.7.3.3 for the detailed study reports).

Fate in water

Biodegradation

The ready biodegradation of BEMT in water was assessed in a GLP study following the OECD guideline No. 301F (RCC Ltd, 1998c). Biodegradation was monitored by exposing the test item to an activated sludge from the aeration tank of a domestic wastewater treatment plant for 28 days. During the test, O_2 consumption was measured as a proxy for biodegradation. The obtained result was ca. 3% of biodegradation, indicating that BEMT is not biodegradable under the test conditions. This may be due to its high hydrophobicity, which also makes it impossible to test the degradation in a water-sediment test as detailed below in section "Fate in sediment".

Fate in soil

Biodegradation

A GLP-compliant study conducted according to the procedures of the OECD guideline No. 307 investigated the biodegradation of BEMT in soil. The study was conducted without any radiolabeling and in aerobic conditions. Three soils were tested. The properties of the soils are reported in table 1 below.

Table 1

Soil	1	2	3
Soil characteristics			
Soil type	Loamy sand	Sandy loam	Clay
% Clay	8.2	8.7	40.7
% Silt	15.3	28.2	34.5
% Sand	76.5	63.1	24.8
% Org. C	1.74	1	1.66

pH	5.5	6.8	7.1
Applied experimental conditions			
Temperature	17.9 - 22.5 °C	17.9 - 22.5 °C	17.9 - 22.5 °C
Humidity	33.7%	31.7%	31.8%
Microbial biomass	212 µg C/g DW	85.1 µg C/g DW	321 µg C/g DW

Soil characteristics were determined by CEM Analytical Services (CEMAS), Berkshire, UK as a separate GLP study. Upon receipt at WIL Research Europe, the sieved soils were stored at 4°C. Prior to start of the equilibration period, the soil moisture content of a 50 g sample of each soil was determined by oven drying overnight at approximately 108°C. The soils were brought to 40% of their maximum water holding capacity by adding Milli-Q water. Portions of 50-g oven dry weight equivalent soil were weighed out in 1L cylindrical, brown metabolism flasks. Per soil 20 flasks were prepared. The soils were maintained at 40% of their maximum water holding capacity by adding Milli-Q water as necessary (checked at least once every two weeks). The equilibration period started on 24 January 2014 for all soils. The three soils were equilibrated in the dark at 20°C ± 2°C for a period of 3 days. At the end of the equilibration period, the soil of four flasks for each soil system were combined and shipped to Cranfield University, UK for the determination of the microbial biomass using the fumigation-extraction method (excluded from GLP).

The duration of the test was 120 days, and the initial test substance concentration was 2 mg/kg soil dry weight for all three soils. Single samples of each soil were taken after 0, 3, 7, 14, 28, 70, and 120 days of incubation. Soil samples were extracted with 50 mL acetonitrile at 300 rpm for 10 minutes. 50 mL of dichloromethane was added to these suspensions, and the samples were shaken again for 10 minutes at 300 rpm. The extracts were analyzed by UPLC-MS/MS.

The measured concentrations relative to nominal concentrations (%) over the duration of the test are available in the following table 2:

Table 2

Time [days]	Soil 1	Soil 2	Soil 3
0	118	99	122
3	99	109	105
7	107	109	107
14	77	92	94
28	79	94	99
70	91	102	115
120	103	102	112

At the end of the test (120 days), the concentration measured was 2.0- 2.2 mg/kg (102-112% of the nominal concentration). Based on the measured concentrations, the degradation rate was calculated according to the FOCUS Guidance Document. It was calculated to be 0% in all three soils after 120 days. Therefore, based on a (pseudo-)first order kinetics, the calculated half-life

(DT50) was > 1,000 days (default output of the software CAKE which is used for the assessment when no biodegradation is observed and hence the regression is flat) for all three soils.

No transformation products were observed, indicating that BEMT did not transform or breakdown during the test.

It is noteworthy that the high level of recovery and the lack of non-extractable residues in this study are unexpected based on the properties of the substance. The results of this study need to be considered with caution.

Adsorption

The adsorption of BEMT to soil was investigated in a GLP-compliant OECD guideline No. 106 study (batch equilibrium method) (ECHA, 2024).

The adsorption of Escalol S [BEMT] on the surface of the test vessel (glass and polypropylene containers) and the stability of the test substance in 0.01M CaCl2 solution were assessed by equilibrating the 100 µg/L solution in test vessels under identical experimental conditions (duplicate samples per vessel material per contact time). The experiment was performed at 20 ± 2°C in the dark on a roller mixer. After 0, 6 and 24 hours of contact time, 20 mL samples were taken and stored at ≤ -15°C until analysis. After sampling (t=24 hours) the containers were completely emptied and rinsed with 10 mL dichloromethane of which a 1.5 mL sample was taken and stored at ≤ -15°C until analysis.

Soil: solution ratios of approximately 1:10, 1:50 and 1:250 were investigated for Speyer 2.1, Speyer 2.2 and Speyer 6S. An appropriate volume of 0.01M CaCl2 solution was added to the soils in glass containers. The slurries were equilibrated overnight on a roller mixer at 20 ± 2°C in the dark prior to spiking. After equilibration, the samples were spiked with an appropriate amount of the 111 mg/L spike solution to obtain a final Escalol S [BEMT] concentration in the test solutions of approximately 100 µg/L. The experiment was performed at 20 ± 2°C in the dark. After 24 hours of contact time, the soil slurries were removed from the roller mixer and centrifuged for 5 minutes at 160 g and 20°C. Aliquots of 20 mL were taken and stored at ≤ -15°C until analysis. After sampling (t=24 hours) the glass containers were completely emptied (0.01M CaCl2 solution and soil) and rinsed with 10 mL dichloromethane, of which a 1.5 mL sample was taken and stored at ≤ -15°C until analysis. Since the results of a first experiment were not reliable, a second kinetics experiment was performed. A soil:solution ratio of 1:250 was selected for all soils.

The slurries (approximately 0.18 g soil and 45 mL 0.01 M CaCl2 solution) were equilibrated in glass vials on a roller mixer at 20 +/- 2°C for three days in the dark prior to spiking. One vial was prepared for t=3 and 6 hours and two vials were prepared for t=24 hour, of which one was used as a reserve sample. The adsorption kinetics experiment was initiated by adding a weighed volume of approximately 41 µL of spike solution to the pre-equilibrated soil slurries. Hence, the initial concentration of Escalol S [BEMT] in the solution was approximately 100 µg/L. A control without soil was included, as well as a blank sample of each soil (soil without test substance). The samples were placed on a roller mixer at 20 ± 2°C in the dark. After the various contact times (3, 6, and 24 hours), the slurries were removed from the roller mixer and centrifuged for 30 minutes at 160 g (the controls were not centrifuged). After centrifugation, a 20 mL aliquot of the supernatant was taken from each sample and stored at ≤ -15°C until analysis.

Blanks and controls were sampled only after 24 hours. After each sampling point, the CaCl2 solution was carefully removed from the soil until a small part of the CaCl2 solution was left on top of the soil, to avoid the transfer of soil particles into the CaCl2 solution. After removing the last part of the CaCl2 solution by evaporation, first 200 µL acetonitrile was added to the soil and then the soil was extracted with 10 mL dichloromethane, of which a 1.5 mL sample was taken and stored at ≤ -15°C until analysis.

Details on matrices
Speyer 2.1 soil: Sand
Speyer 2.2 soil: Loamy sand
Speyer 2.3 soil: Sandy loam
Speyer 2.4 soil: Loam
Speyer 6S soil: Clay

Results
Log Koc 5.7 - 6.8 L/kg
The logarithm of the adsorption coefficient Kd (Log Kd) in the various soils ranged from 3.9 - 5.0 and normalized for organic carbon (log Koc) it ranged from 5.7 - 6.8.

Mass balance
In a first experiment, the total test substance recovered at each sampling point was between 35% and 85%, indicating that not all test substance was recovered at each sampling point. In the second experiment, the total test substance recovered at each sampling point was between 18% and 66%. These rather low recoveries were expected to be caused by the low recovery of test substance from the soil extractions.

Mass balance after 3h: 18.1 - 47.1%
Mass balance after 6h: 36.1 - 66%
Mass balance after 24h: 24.3 - 58.7%

Details on results
The data show a rapid increase of the adsorption of Escalol S [BEMT] to all the soils in the first 3 hours of contact time. Adsorption equilibrium was reached after 3 hours for Speyer 2.3, Speyer 2.4 and Speyer 6S. For Speyer 2.1 equilibrium was reached after 6 hours and for Speyer 2.2 after 24 hours. Kd values ranged from 7820 mL/g for Speyer 2.2 to 105975 mL/g for Speyer 6S soil; Koc values ranged from 449439 mL/g (Speyer 2.2) to 6384059 mL/g (Speyer 6S).

Table 3

Soil	Texture	%oc	Kd(L/kg)	Koc(L/kg)
Speyer 2.1 soil	Sand	0.66	12707	1925274
Speyer 2.2 soil	Loamy sand	1.74	7820	449439
Speyer 2.3 soil	Sandy loam	1.0	54830	5482962

Speyer 2.4 soil	Loam	2.42	62315	2574996
Speyer 6S soil	Clay	1.66	105975	6384059

Based upon the results of the analysis of the aqueous samples of the 24 hours samples taken in the adsorption kinetics experiment, the logarithm of the adsorption coefficient Kd (LogKd) in the various soils ranged from 3.9 - 5.0 and normalized for organic carbon (log Koc) it ranged from 5.7 - 6.8. These values relate to a relatively high binding capacity of the test substance on organic matter of soil.

As six Koc values were derived from soil, the geometric mean of Kd (i.e. 32450) was calculated and used subsequently for risk assessment. Moreover, the Excel tool Input Decision available from Bund was used to assess whether the Kd was correlated with organic carbon as recommended in the EMA guidance (2024). This hypothesis was found to be false.

Fate in sediment

Dissipation mechanisms

To assess the distribution and dissipation of BEMT between the water phase and sediment under controlled aerobic conditions, a non-GLP test was performed according to a modified design of the OECD guideline No. 308. The detailed study report is provided in Appendix 2. A key objective of the study was to characterize the non-extractable residue (NER) fraction of BEMT in sediment. Two natural systems, a river sediment and a lake sediment, were selected and incubated under aerobic conditions at 20 ± 2 °C. Following a four-week acclimation period, the systems were treated once with BEMT at a nominal concentration of 20 µg/L, and duplicate samples were taken at time 0 and at 3, 7, and 14, 20 and 26 days after application.

During method development and preliminary testing, substantial analytical challenges were encountered that directly affected the ability to reliably distinguish between extractable residues, non-extractable residues, and potential losses. BEMT exhibits very low water solubility and strong adsorption behavior, leading to pronounced carry-over effects and adsorption to laboratory and LC-MS instrument surfaces. Extensive optimization was required to achieve acceptable chromatographic performance, and reliable quantification was only possible under narrowly defined conditions using freshly prepared calibration standards and same-day analysis. Even under these conditions, large variability in measured concentrations was observed. Increasing the proportion of organic solvents to improve solubility is not feasible, as it will result in unacceptable chromatographic performance.

In parallel, extraction experiments revealed unexpected contamination of untreated sediment samples, particularly in the river system, with BEMT or structurally related analogues. This contamination prevented a reliable assessment of extraction efficiency and background correction and therefore compromised the ability to quantify extractable residues with sufficient confidence. As a consequence, the calculation of NERs by difference, as foreseen in the study design, was rendered unachievable. Despite these limitations, the main study was initiated due to the advanced stage of test system acclimation and timeline constraints.

The results showed large variability in recoveries from both water and sediment, with values frequently exceeding 100% of the applied amount and poor repeatability between duplicate samples. Although the data qualitatively suggests as expected a rapid transfer of BEMT from the water phase into the sediment shortly after application, the inconsistent mass balances and incomplete sediment extraction precluded a reliable quantification of extractable residues. As a result, the magnitude of the NER fraction could not be determined with confidence, nor could it be distinguished from analytical artefacts, adsorption losses, or precipitation effects. Fortified blank samples showed highly variable recoveries, further demonstrating that the analytical and extraction procedures were not sufficiently robust to support a reliable NER assessment.

Additional investigations indicated that BEMT may precipitate from solution or adsorb to container surfaces during short-term storage, even under refrigerated or frozen conditions. These effects impacted both calibration standards and test samples, and further complicated mass balance closure. Under these circumstances, apparent increases or decreases in sediment-associated residues could not be unequivocally attributed to true NER formation. Consequently, the data generated does not allow a scientifically defensible assessment of NER formation, degradation kinetics, or dissipation rates.

Overall, while the study was initiated and conducted in line with the intent of OECD guideline No. 308, the intrinsic properties of BEMT, combined with unresolved analytical limitations and sediment contamination, prevent a reliable determination of NERs. As the quantification of the NER fraction was the main objective of the study as requested by the FDA, the study was deemed technically not feasible.

Considering the technical infeasibility of the standard OECD guideline No. 308 study, additional information on the fate of BEMT in the aquatic environment, and in particular on its partitioning to sediment was collected to assess its behavior.

Fagervold et al. (2019) investigated the occurrence, environmental distribution, and partitioning behavior of five organic UV filters, including BEMT, during the summer season in two highly frequented aquatic systems: a freshwater lake (Villeneuve-de-la-Raho) and a coastal marine bay (Banyuls-sur-Mer). Samples were collected repeatedly before, during, and after the bathing season from three compartments: surface water, the surface microlayer (SML), and sediments.

BEMT was detected in all environmental compartments investigated at both sites. In surface waters, BEMT occurred at low but measurable concentrations during peak summer months, with maximum values of approximately 14 ng/L in the lake and up to 18 ng/L in the coastal bay. Higher concentrations were measured in the SML, particularly in the lake during periods of intense recreational activity, where BEMT reached peak concentrations exceeding 4 µg/L. This confirms a strong enrichment of BEMT at the air–water interface relative to the underlying water column. The highest concentrations of BEMT were observed in sediments, demonstrating that sediment is the dominant environmental sink for this compound. In lake sediments, BEMT was already present at the start of the monitoring period (before the bathing season) and increased progressively over the summer, reaching mean concentrations of up to 87 ng/g dry weight by late September. In coastal sediments, BEMT was also detected throughout the season, with evidence of persistence and potential carry-over from previous years.

In parallel to the field monitoring, the authors conducted controlled batch experiments using natural sediments that were spiked with known amounts of BEMT (100 ng, 1 µg, or 10 µg). After equilibration, sediment and water phases were separated, extracted using solvent-based methods identical to those applied to environmental samples, and analyzed quantitatively. Sediment–water distribution coefficients (Kd = Cs/Cw) were calculated, and sorption data were fitted to the Freundlich model to assess sorption intensity and linearity.

BEMT showed the strongest affinity for sediments among all UV filters tested, with experimental Kd values on the order of 3,000–3,500 L/kg, indicating rapid and extensive partitioning into the solid phase within 24h. Freundlich fits showed good linearity, with evidence of slightly higher proportional sorption at lower concentrations, consistent with behavior of highly hydrophobic organic compounds. Importantly, these experimentally derived Kd values were in the same order of magnitude as sediment–water distribution coefficients calculated from field data, supporting the relevance of the laboratory findings for environmental conditions. The experiments quantified extractable parent BEMT only and were designed to assess distribution rather than degradation or formation of non-extractable residues, confirming sediments as the dominant sink for BEMT in aquatic systems.

Indeed, BEMT exhibits a high affinity for sediment and organic matter, with a partition coefficient (Log Koc > 6.8) that limits its mobility to groundwater and reduces its bioavailability in aquatic systems. Its low water solubility (< 0.014 mg/L) and extremely low vapor pressure indicate that BEMT is more likely to remain in sediment or soil rather than dissolve in water or evaporate into air. While data on BEMT's behavior in sediment are limited, the OECD 301F, forced degradation, and OECD 307 studies demonstrate that BEMT is highly resistant to degradation under a range of environmental conditions, even under extreme stress. This stability rules out significant (bio)degradation or photo-transformation in water, suggesting that BEMT, once settled in sediments, could persist for extended durations without substantial breakdown in typical environmental settings.

6.1.4. Environmental Concentrations

Down the Drain Scenario

Estimated yearly use of BEMT in the U.S: Global BEMT production was approximately (b) (4) metric tons in 2023 (Kline + Company, 2024). In the U.S., which held a 26% market share for sunscreens in 2023 (Euromonitor International, 2024), this would translate to about (b) (4) metric tons if BEMT were available domestically. With a projected 4% annual growth rate (Euromonitor International, 2024), U.S. BEMT production could reach approximately (b) (4) metric tons by 2037.

As sunscreen usage may differ among U.S. regions, we also estimated the yearly use for each region. To the best of our knowledge, there is currently no available data on sunscreen usage categorized by U.S. state or region. However, we have collected market data on sunscreen sales per U.S. region over the past three years (Nielsen IQ, 2024). The results indicate that the South Region accounts for approximately 41% of sunscreen sales in the U.S., followed by the West Region with 23%, and both the Northeast and Midwest Regions with 18% each. We therefore calculated the Expected Introduction Concentrations (EIC) and the Expected Environmental

concentrations (EEC) for the U.S at the national level as well as for the South Region and the West Region.

EIC and EEC calculations

Given its high Log K_{oc} (5.7 to 6.8) and low water solubility (< 0.014 mg/L), BEMT is expected to bind on organic matter of soil and sludge. Using the USEPA STP Fugacity Model v4.11 for fate prediction in wastewater treatment facilities, 89.58 % of BEMT in the wastewater influent will be retained by the Primary and Waste sludges while only 9.66 % are estimated to be in the final water effluent (Predictions generated in August 2024; Detailed Report in Appendix 3). EIC and EEC were calculated for the soil, aquatic, and sediment compartments as recommended by the FDA. The calculations were made on the basis of the estimated use of (b) (4) metric tons of BEMT per year as well as a conservative scenario of (b) (4) metric tons of BEMT per year (i.e., approximately seven folds higher than the realistic estimations).

The **EICs and EECs soil** were calculated as requested by the FDA according to section 4.2.6.1. of the EMA guidance (EMA, 2024) for the soil exposure assessment. Since there is no method specifically mentioning the EIC in the guideline, we used Equation 21 of the EMA guideline along with the Wet Weight-to-Dry Weight conversion factor of 1.13. Equation 21 allows estimating the initial predicted environmental concentration (PEC, equivalent to EEC) in wet soil after the first biosolid application.

To ensure a worst-case assessment, we considered the biosolid application rate of 22.4 kg DW/m² (for forest land and reclamation sites), even though a more representative rate would be the 5 kg DW/m² for agricultural land. Indeed, based on the National Biosolids Data Project, 40% of the generated biosolids are applied to agricultural land in both South and West regions, while only 3% are used for forest land and reclamation sites.

The detailed calculations and results of the EICs and EECs are provided in Appendix 4.

Table 4 below summarizes the calculated soil EICs and EECs (mg/kg DW). The South and West regions show comparable values, with slightly lower concentrations in the West; both regional estimates exceed the U.S. national level.

	1. U.S. National Level	2. South Region	3. West Region
Realistic scenario of (b) (4) tons BEMT per year			
EIC $_{soil}$	4.88E+00	6.89E+00	6.71E+00
EEC $_{soil}$	2.18E+01	3.08E+01	3.00E+01
Conservative scenario of (b) (4) tons BEMT per year			
EIC $_{soil}$	3.38E+01	4.77E+01	4.65E+01
EEC $_{soil}$	1.51E+02	2.14E+02	2.08E+02

The **aquatic EICs and EECs** were calculated using the equation provided in the FDA Guidance Document (1998). The detailed calculations and results of the EICs are provided in Appendix 5. Dilution factors of 10 and 100 were subsequently applied to the EICs to derive the aquatic EECs for freshwater and marine systems, respectively (FDA guidance document, 1998 and EPA, 2023, respectively).

Table 5 below summarizes the calculated aquatic EICs and EECs (µg/L). Values for the South and West regions are comparable, with slightly lower levels in the West; both regional estimates exceed the U.S. national level.

	1. U.S. National Level	2. South Region	3. West Region
Realistic scenario of (b) (4) *tons BEMT per year*			
$EIC_{aquatic}$	1.10E+00	1.41E+00	1.31E+00
$EEC_{freshwater}$	1.10E-01	1.41E-01	1.31E-01
EEC_{marine}	1.10E-02	1.41E-02	1.31E-02
Conservative scenario of (b) (4) *tons BEMT per year*			
$EIC_{aquatic}$	7.63E+00	9.77E+00	9.07E+00
$EEC_{freshwater}$	7.63E-01	9.77E-01	9.07E-01
EEC_{marine}	7.63E-02	9.77E-02	9.07E-02

Given the analytical and methodological challenges encountered in the OECD 308 study, as described above in Section 6.1.3., and in line with the FDA request, **sediment EECs** were calculated in accordance with Section 4.2.4.1 of the EMA guideline for sediment exposure assessment, using the calculated aquatic EECs as input. These calculations were performed using the Equilibrium Partitioning Method (EPM), which estimates sediment concentrations of BEMT based on measured or predicted surface-water concentrations and its adsorption coefficient (Koc).

The EPM has been successfully applied in environmental risk assessments under multiple regulatory frameworks, including assessments conducted by the U.S. Environmental Protection Agency (e.g., Redman et al., 2014; EPA, 2012; Nowell et al., 2016; Burgess et al., 2013). This method is widely recognized as inherently conservative and protective, as it intentionally represents a worst-case exposure scenario for benthic organisms.

Prior to the EEC calculation, and because the OECD 106 study yielded a range of Koc values rather than a single value (see Section 6.1.3,), the relationship between the sediment–water partition coefficient (K_D) and organic-carbon (OC) content was evaluated[1]. The analysis demonstrated a statistically non-significant correlation between K_D and OC (Kendall's tau 0.2, p-

[1] Correlation was assessed with the Excel-tool Input_Decision freely available: https://www.bvl.bund.de/EN/Tasks/04_Plant_protection_products/03_Applicants/04_AuthorisationProcedure/08_Environment/01_Tool_input_decision/ppp_Tool_Input_Decision_node.html.

value> 0.05). We therefore, and as requested by the FDA, used the geometric mean K_D value of 32450 L/Kg as Kp_{SUSP} for the calculation of sediment EECs.

The detailed calculations and results are provided in Appendix 6.

Table 6 below summarizes the calculated sediment EECs (mg/kg DW). Values for the South and West regions are comparable, with slightly lower levels in the West; both regional estimates exceed the U.S. national level.

	Realistic scenario ((b) (4) tons per year)		**Conservative scenario (b) (4) tons per year)**	
	Fresh water	*Marine Water*	*Fresh water*	*Marine Water*
U.S. National Level	3.57	0.36	24.76	2.47
South Region	4.57	0.46	31.71	3.17
West Region	4.25	0.42	29.43	2.94

Direct Release Scenario

A second emission pathway by which UV filters in sunscreen products may enter the aquatic environment is their direct release during consumer recreational activities such as swimming or snorkeling. Therefore, we assessed direct wash-off scenarios into surface and coastal waters using a conservative exposure modelling tool, supplemented by existing monitoring data.

To estimate the environmental concentrations of UV filters in aquatic systems related to recreational use and direct release scenarios, we utilized the environmental exposure scenario on biocidal active substances (PT 19: Repellents and attractants; application to human skin & garments - release to surface water bodies through swimming (ESD § 3.1.4.2, p.28; Table 3-7, p.30 & Table 3-8, p.32), with modifications according to the SCCS notes of Guidance for the testing of cosmetic ingredients and their safety evaluation (12th Revision, 16 May 2023) as described by Gouin et al. (2026). The model enables the estimation of environmental concentrations in water and sediments of lakes and marine coastal environments, as well as the calculation of related Risk Characterization Ratios (RCRs; synonym to Risk Quotients) for these compartments. The RCRs represent the ratio between the EEC - or, when available, the MEC (Measured Environmental Concentrations) - and the PNEC (Predicted No-Effect Concentration) derived from ecotoxicity studies. An RCR below one indicates no environmental risk for the assessed compartment.

Appendix 7 provides all parameters defined in PT19, including the adjustments from the SCCS guidance, along with detailed calculations and results for the EICs and EECs as well as the maximum Measured Environmental Concentrations (MEC) across all compartments.

Table 7 below presents the EICs and EECs (mg/L or mg/kg DW) derived using the PT19 scenario, alongside the maximum MECs (mg/L or mg/kg DW) reported in the literature. The EECs for freshwater and marine sediment are derived based on emissions occurring over a 91-day period to reflect continuous high-end sunscreen use during the swimming season (i.e., cumulated $EEC_{sed\ /\ day}$). The 91-day period used in PT19 EEC calculations represents a highly conservative seasonal use scenario, corresponding to one quarter of a year, as recommended in ECHA BPR environmental guidance.

The results indicate that, in both freshwater and marine systems, BEMT concentrations are higher in the sediment compartment than in the corresponding water phase, regardless of whether assessed using predicted or measured values.

	Freshwater		**Marine**	
	Water	*Sediment*[*]	*Water*	*Sediment*[*]
EIC	4.7E-05	-	1.03E-04	-
EEC	4.15E-03	138.92	3.65E-05	30.33
MEC	4.28E-03	0.12	1.00E-05	8.5E-02

[*]EIC sediment is not calculated in the PT19 scenario.

6.1.5. Summary of the Environmental Fate

BEMT's environmental fate is characterized by high stability and strong adsorption properties, resulting in low mobility and bioavailability in both soil and aquatic environments. It is persistent in these environments, as no significant biodegradation was observed in a biodegradation test using activated sewage sludge or in a 120-day biodegradation simulation test with three different soil types. This high stability was further confirmed by a forced degradation study, in which BEMT remained intact under all tested stress conditions, even under harsher hydrolytic conditions. Additional testing to determine Log K_{ow} and Log K_{oc} values indicated that the substance strongly adsorbs to particulate matter. Consequently, approximately 89% of BEMT entering wastewater treatment plants will be retained by sludge, with less than 10% expected to be present in the final water effluent. When released into the terrestrial environment, such as through the application of biosolids to land, nearly 100% will remain in soil, while environmental concentrations in air or water are expected to be negligible.

6.2. Environmental Effects of Released Substances

Due to BEMT's limited bioavailability, all reliable acute and chronic ecotoxicity tests listed below indicate no hazard to aquatic, sediment and terrestrial environments at the tested concentrations even when solvents were used to achieve dissolved concentrations (e.g., 2 mg/L) far exceeding its solubility limit. Therefore, BEMT poses no environmental hazard, leading to negligible environmental effects and risk.

As no toxic effects were observed in all the valid and reliable acute and chronic environmental tests conducted, it was not possible to derive reliable toxicity values such as NOECs, LC_{50}s, or EC_{50}s for a quantitative risk assessment that can be compared to the Assessment Factors as per the FDA Guidance Document. Nevertheless, a qualitative risk assessment was performed for completeness, confirming the absence of risk to aquatic, sediment and terrestrial environments at the Maximum Expected Environmental Concentrations (MEECs), which were based on both realistic and conservative estimated use of (b) (4) and (b) (4) metric tons per year, respectively. We also considered a worst-case scenario risk assessment performed with the NOECs derived from the ostracod study notwithstanding the uncertainty surrounding the validity and reliability of this study (see below for more details).

Below, we provide detailed information on the ecotoxicity tests conducted with BEMT, covering all environmental compartments:

Sewage Microorganisms

A GLP-compliant Activated Sludge Respiration Inhibition Test was performed according to the OECD guideline No. 209 (RCC Ltd, 1998d). No significant inhibition of the activated sludge respiration was observed at all test concentrations, including the highest concentration of 1000 mg/L (nominal). Due to the absence of toxic effects, it is not possible to derive LOEC or EC_{50} values (≥ 1000 mg/L).

Terrestrial Ecotoxicity:

Chronic Toxicity to Soil Macroorganisms

A GLP-compliant 28-day Earthworm Reproduction Test was performed according to the OECD guideline No. 222 (BASF SE, 2017a). The test organism was *Eisenia fetida* as recommended by the test guideline, and nominal exposure concentrations ranged from 0 to 1000 mg/kg DW soil. As the substance is not soluble, it was mixed following adsorption to quartz sand and subsequent addition to the test substrate. No effects on reproduction, growth and survival were observed up to the highest tested concentration. Due to the absence of toxic effects, it is not possible to derive LOEC, EC_{10} or EC_{50} values for all measured endpoints (≥ 1000 mg/kg DW soil).

Chronic Toxicity to Soil Microorganisms

A GLP-compliant 28-day Soil Microorganisms: Nitrogen Transformation Test was performed according to the OECD guideline No. 216 (BASF SE, 2017b). Nominal exposure concentrations ranged from 0 to 1000 mg/kg DW soil, and nitrate formation rate was measured as an endpoint for this test. No inhibitory effects on the nitrogen formation were observed up to the highest test

concentration. Due to the absence of toxic effects, it is not possible to derive LOEC, EC_{10} or EC_{50} values for the measured endpoint (≥ 1000 mg/kg DW soil).

Freshwater Aquatic Ecotoxicity

Acute Toxicity to Fish

A 96-hour GLP-compliant Fish, Acute Toxicity Test was performed with *Danio rerio* (common name: zebrafish) according to the OECD guideline No 203 (RCC Ltd, 1998e). Due to its very low water solubility, a supersaturated suspension of the test item, with a nominal concentration of 100 mg/L was prepared (ultrasonic treatment, 72-hour stirring period) before being filtered (first 200 ml were discarded to avoid loss due to adsorption to the filter). In addition to a control (no test item added), only the undiluted filtrate with the maximum concentration of dissolved BEMT was used in the toxicity test. The mean measured concentration was 0.81 µg/L and was calculated as time-weighed average since the concentration decreased over the study period in particular in the last 48h. The test item had clearly no toxic effect on zebrafish during the 96-hour exposure period at a concentration at the water solubility limit of BEMT.

In addition, acute toxicity of BEMT to the fish species *Oryzias latipes* (common name: Japanese medaka) was assessed in a pre-test of a GLP study on the bioaccumulative potential in fish (Institute of Ecotoxicology, 1999). Fish were exposed for a duration of 48 hours to a range of concentrations from 61 to 205 mg test item/L in addition to a solvent control (Polyoxyethylene hardened castor oil). Here again, BEMT proved to be non-toxic to Japanese medaka at dispersions exceeding 200 mg/L, which is far above the water solubility limit for BEMT.

Due to the absence of toxic effects on both zebrafish and Japanese medaka up to the tested concentrations, the LOEC and LC_{50} could not be quantified.

Acute Toxicity to Aquatic Invertebrates

In a 48-hour GLP-compliant study, the acute toxicity of BEMT to *Daphnia magna* was assessed according to the OECD guideline No. 202 (RCC Ltd, 1998f). Due to its very low water solubility, a supersaturated suspension of the test item, with a nominal concentration of 100 mg/L was prepared (ultrasonic treatment, 72-hour stirring period) before being filtered (first 100 ml were discarded to avoid loss due to adsorption to the filter). In addition to a control (no test item added), only the undiluted filtrate with the maximum concentration of dissolved BEMT was used in the toxicity test. The mean measured concentration was 0.114 mg/L and remained stable over the 48-hour exposure period. No toxic effects on the mobility of *Daphnia magna* were observed up to the tested concentration at the water solubility limit of the test item. Due to the absence of toxicity, the 48-hour LOEC and 48-hour EC_{50} could not be quantified.

Toxicity to aquatic algae and cyanobacteria

The effect of BEMT on the growth of the green algal species *Desmodesmus subspicatus* (previous name: *Scenedesmus subspicatus*) was investigated in a 72-hour GLP-compliant test according to the OECD guideline No. 201 (RCC Ltd, 1998g). Due to its very low water solubility, a supersaturated suspension of the test item, with a nominal concentration of 100 mg/L was prepared (ultrasonic treatment, 72-hour stirring period) before being filtered (first 50 ml were discarded to avoid loss due to adsorption to the filter). In addition to a control (no test item added), only the undiluted filtrate with the maximum concentration of dissolved BEMT was used in the toxicity

test. The mean measured concentration was 17 µg/L and remained stable over the 72-hour exposure period. BEMT had clearly no inhibitory effect on the growth of *Desmodesmus subspicatus* during the exposure period of 72 hours at a concentration far above the water solubility limit of the test item. Due to the absence of toxic effects, the 72-hour LOEC and 72-hour EC_{50} could not be quantified.

Chronic Toxicity to Aquatic Invertebrates

The effect of BEMT on the reproduction, growth, and mortality of *Daphnia magna* was examined in a GLP-compliant test according to the OECD guideline No. 211. In addition, the procedures were designed to meet the test methods and validity criteria of the ISO International Standard 10706, 2000, the Commission Regulation (EC) No 440/2008 Part C.20, 2008 and the OECD guidance document number 23, 2000 (ECHA, 2024). The reproduction test was performed in a semi-static system for 21 days. Due to the low solubility of BEMT, stock solutions were prepared using acetone as a solvent. The daphnids were exposed to the nominal concentrations of 0.1 and 1.0 mg test item/L (corresponding to mean measured concentrations of 0.06 and 0.70 mg/L, respectively) in addition to a solvent control. No treatment-related mortality, as well as no reduction or delay in reproduction, of parental daphnids were observed during the test at any of the concentrations tested. The growth of daphnids was also not affected by the test substance. Overall, BEMT had no chronic effects on Daphnia magna at an average concentration of 0.7 mg/L, which is far above its solubility in the test medium. Due to the absence of toxic effects, the 21-day LOECs and 21-day EC_{50}s for all the measured endpoints could not be quantified.

Chronic Toxicity to Fish

No experimental data is available for this endpoint. Therefore, we have estimated the chronic toxicity to fish using several Quantitative Structure-Activity Relationship (QSAR) models.

The first model used was the USEPA ECOSAR v2.2 (predictions generated in August 2024). Overall, regardless of the chemical class considered by the software (Neutral Organics, Triazines, Aromatic, and Phenols, Poly), all results indicate that no effects at saturation levels are expected. This is because the estimated concentrations (ChV) are above the water solubility (generally ≥ 10 times) and/or that the Log K_{ow} threshold of the model is exceeded (Detailed Report in Appendix 8). To assess the accuracy and reliability of this prediction, we also used ECOSAR to estimate the acute toxicity to fish, daphnids and green algae and the chronic toxicity to the two latter. In those cases, also the results indicate no effects at saturation level, which corresponds to the results of experimental studies conducted for those endpoints.

The second model used was iSafeRat® fishEC10 v2.0 (predictions generated in November 2024). In a first step, the prediction was done using the water solubility of BEMT in the OECD guideline No. 105 study, namely 4.5 ng/L. In a second step, a prediction was also done taking into consideration the measured concentration of BEMT in the acute toxicity to fish study referenced above as the medium in the study would be the same as that in a chronic fish study, i.e. 0.81 µg/L. In both cases, the model predicted a 32-day EC10 value for BEMT surpassing its water solubility, confirming that BEMT's low solubility precludes sufficient exposure levels to cause 10% inhibition in fish growth or weight (Detailed QPRF and QMRF documentation for both predictions are provided in Appendix 9a., 9b. and 9c.).

Consequently, it can be confidently concluded that BEMT would show no toxic effects in case of chronic exposure to fish.

Bioaccumulation in Aquatic Species

To assess the potential bioaccumulation of BEMT in aquatic species, a GLP-compliant study was performed with the fish species *Cyprinus carpio* (common name: Carp) according to the MITI Guideline (Method for Testing the Degree of Accumulation of Chemical Substance in Fish Body) (Institute of Ecotoxicology, 1999). Based on an acute toxicity pre-test of 48-hour, which showed no effects up to the highest tested concentration of 205 mg/L, the concentrations for the bioaccumulation test were selected to 1.0 mg/L (Level 1) and 0.1 mg/L (Level 2) using Polyoxyethylene hardened castor oil as a dispersing agent. The exposure duration was 56 days in a flow-through system and the test concentrations were maintained throughout the test. The resulting Bioconcentration Factors of the test substance in Level 1 and Level 2 were calculated to be below 3 and 19, respectively. Accordingly, significant bioaccumulation of BEMT in aquatic organisms is not expected.

Marine water Ecotoxicity

No standard regulatory study investigating the effect of BEMT on marine organisms is available. However, supporting information can be found in the literature. Varella et al. (2022) examined sunscreen formulations containing BEMT in combination with other UV filters and their effects on the sea urchin *Paracentrotus lividus*. Assessing both gene expression responses and embryonic development anomalies, the authors found no significant impact on the sea urchins for all formulations that included BEMT alongside MBBT, DHHB, and EHT. Similarly, Stien et al. (2020) investigated the effect of BEMT on the coral *Pocillopora damicornis* over seven days and reported no adverse effects at concentrations up to 1000 µg/L (achieved using a solvent) - levels several times higher than those detected in marine and freshwater environments. Thorel et al. (2020) evaluated BEMT's toxicity in two marine species from different trophic levels: the microalga *Tetraselmis sp*. (autotrophs) and the brine shrimp *Artemia salina* (heterotrophs). Even at high concentrations (2000 µg/L, solvent added), no adverse effects on mortality or growth were observed.

Based on the available information, it appears that BEMT does not show toxic effects to marine organisms.

Sediment Ecotoxicity

Acute Toxicity to Sediment-dwelling organisms

Lucas et al. (2021) studied the ecotoxicity of BEMT on the embryo-larval stages of zebrafish (*Danio rerio*) using sediment contact assays, exposing fish eggs to sediment spiked with 10 mg/kg of BEMT for 96 hours. Because BEMT predominantly partitions into sediments, this method simulated multiple exposure pathways for benthic organisms. This method is particularly relevant for BEMT, which primarily partitions into sediments, simulating multiple exposure routes for benthic organisms. Although a slight increase in cardiac frequency was observed, the authors

showed that it was a transient response with no consequences on key endpoints, such as hatching success, survival, or the metabolism of the embryos. The main conclusion of the authors was "BEMT [...] had no effect on the different parameters tested. In our conditions, these compounds were not toxic for zebrafish embryo larvae".

Chronic Toxicity to Marine Amphipods

The chronic effects of BEMT on marine amphipods were investigated with *Leptocheirus plumulosus* according to procedures in the U.S. Environmental Protection Agency Series 600 – EPA 600/R-01/020 (Eurofins EAG Agroscience LLC, 2026). The test was conducted under flow-through conditions for a duration of 28 days. Due to the low solubility of BEMT, stock solutions were prepared using acetone as a solvent. The amphipods were exposed to spiked sediment using nominal concentrations of 12, 37, 111, 333 and 1000 mg/kg, in addition to a solvent control and a negative control. Overall, BEMT had no chronic effects on the survival, growth or reproduction of *Leptocheirus plumulosus* up to and including the highest tested concentration, 1000 mg/kg. Due to the absence of toxic effects, the 28-day LOECs and 28-day EC50s for all the measured endpoints could not be quantified. The detailed non-GLP report is provided as Appendix 10.

Chronic Toxicity to Freshwater Ostracods

The chronic effects of BEMT on freshwater ostracods were investigated with *Heterocypris incongruens* according to procedures in the ISO 14371 method as modified by Niyommaneerat et al. (2017) (SGS, 2026). The test was conducted under semi-static conditions for a duration of 31 days. Due to the low solubility of BEMT, stock solutions were prepared using acetone as a solvent. The ostracods were exposed to spiked sediment using nominal concentrations of 126, 505 and 1010 mg/kg, in addition to a solvent control and a negative control. Survival and growth were assessed after 14 days of exposure, whereas effects on reproduction were assessed over the second phase extending from day 14 to the death of the ostracod (without being exposed to spiked sediment). The detailed report is provided as Appendix 11.

The study presents critical methodological flaws and the results for the negative control are unexpected compared to the data provided in Niyommaneerat et al. (2017).

First, while performing the test, the lab committed some errors:

- While the standard procedure provided with the kit for the assay specifically highlighted that the reference sediment should first be saturated with water, the lab did not perform this step resulting in questionable concentrations being tested. This is also a requirement of the ISO 14731 protocol.
- The sediment for the controls and treatments was not treated equally. The highest concentration was left to evaporate the solvent much longer than other treatments, and the controls (1 minute for the control conditions vs at least 30min for the highest concentration). The impact of this differential treatment is unknown.
- During preparation of the sediment, a thin, sticky film was observed on the surface of the grains, resulting in a wet-like appearance. This was observed at 505 and 1010 mg/kg. This phenomenon was observed in no other study, including the amphipod study referenced above. This further questions the concentrations and/or the method of preparation of the

sediment applied by the lab for this test. This unprecedent appearance could have impacted the results of the study due to e.g. inaccessibility to calcite (important for growth; Gu et al. (2020)), or food (important for all endpoints). Actually, the calcite access is considered so important that Gu et al. (2020) proposed to define a reference sediment for testing *Heterocypris incongruens* in laboratory experiments, and in particular using the method ISO 14371 which is the basis of this test.

Secondly, the performance of the negative control is unexpected compared to the "historical control" data provided in the study by Niyommaneerat et al. (2017). Indeed, the following results highlight the discrepancies:

Endpoint	Niyommaneerat et al. (2017)	Negative controls from the SGS study with BEMT
Egg-laying ratio (%)	66.8 ± 5.0 (CV 7.5%) Proposed test acceptability criteria: 56.8-76.8	47.50%
Mean day of egg production	23.3 ± 2.4 Range: 20.4-27.8	19.9
Lifetime egg production	All individuals 17.6 ± 6.9 Range: 10.8-29.9 Egg-laying individuals 25.1 ± 7.4 Range: 16.3-32.5	3.02

It is clear that a significant impact of the way the study was conducted was already seen in negative controls. Additionally, the solvent control had also a significant difference from the negative control for the number of egg-laying individuals and the egg-laying ratio (32.08) yet further reducing that ratio. Moreover, although the difference was also not statistically significant, for the lifetime egg production, the solvent control was also reduced compared to the control (2.40). The combined effect of handling and of the solvent have contributed significantly to a decreased performance of the ostracods even in control conditions, thereby casting doubt on the reliability and usefulness of the information obtained for the test material. And this doubt is further increased by the preparation of the sediment at the two highest concentrations for which it is unclear what the impact of the film formed had. Actually, Niyommaneerat et al. (2017) themselves acknowledge that the reproductive endpoints show high variability and that these "variations are dependent on either environmental factors in the test conditions such as overlying water quality or incubation temperature or biological factors such as the age of the test organisms, food quality and quantity, and the experience of those conducting the tests". On the latter, it is noteworthy that this was the first time SGS performed this study. As the ostracods are handled every other day during the reproduction phase, it is not implausible that being handled by an inexperienced technician could cause stress to the ostracods resulting in a high variability and a reduced reproductive output.

Given the number of uncertainties surrounding the relevance and reliability of the study, the results should not be used for further assessment. It is also noteworthy that this is the only study showing

effects on BEMT, although every other study, including sediment-dwellers, has shown no effects at all concentrations, including up to 1000 mg/kg.

Tentative results are provided below for all endpoints. However, they should be considered with extreme caution and are not reliable for further use in the risk assessment.

Mortality: While survival was affected at the highest concentration tested, the effect level of 50% was not reached. Therefore the 14-day LC50 was determined to be > 1010 mg/kg.

Length: Based on a Williams test, the length of the ostracods was significantly reduced at 1010 mg/kg. The NOEC is therefore 505 mg/kg. However, this result may have been significantly impacted by the presence of the film on the grains of the sediment limiting the calcification process and hence limiting the growth.

Life span: Williams test showed significant decreases at 505 mg/kg and 1010 mg/kg. However, further analysis of the data indicates only a minimal, not biologically-relevant decrease at 505 mg/kg (-6%). Therefore, the NOEC is set at 505 mg/kg and the LOEC is 1010 mg/kg for this endpoint.

Egg-laying ratio: Based on Shirley-Williams test, the egg-laying ratio was only significantly reduced at 1010 mg/kg. However, the negative and solvent controls for this endpoint demonstrated an egg-laying ratio significantly below the mean, the range and the proposed validity criteria in Niyommaneerat et al. (2017). This raises concerns about the validity of the test conducted on BEMT, and the interpretation that can be made for this endpoint. Given the uncertainty, all reproductive endpoints should be considered not usable as the effect seen here could also have indirectly impacted all other endpoints investigated.

Total number of eggs produced: Based on Shirley-Williams test, the decrease is significant at 1010 mg/kg. This outcome is supported by an additional Games-Howell comparison test which also concludes that the effect is significant at 1010 mg/kg only. Therefore, the NOEC is 505 mg/kg and the LOEC is 1010 mg/kg for this endpoint.

First day of brooding: Based on Williams test, the change in first day of brooding is significant only at 505 mg/kg. However, while statistically significant, the difference is not biologically relevant as the difference is minimal (< 10%) and not treatment-related as there is no dose-response observed across treatments. It is noteworthy that although the 18.5 days observed at 505 mg/kg is out of the range reported in Niyommaneerat et al. (2017) for this parameter, it is within the natural range of *Heterocypris incongruens* (average day 19, range 13-25; Havel and Talbott (1995)). Consequently, for this endpoint also, the NOEC was considered to be 1010 mg/kg. This conclusion is supported by an additional Games-Howell comparison test which concludes that there is no significant difference for all treatment groups.

Mean day of egg production: Based on Williams test, a significant decrease was observed at 505 mg/kg, while 126 mg/kg was not significant and this is confirmed by an additional Games-Howell comparison. Moreover, the change is not dose-dependent as the decrease is more pronounced at 505 mg/kg (-11.9%) compared to 1010 mg/kg (-9.3%). As all changes are not biologically relevant for 126 and 1010 (< 10%) and since there is no dose-dependence of the effect, these changes were considered as not treatment-related and the NOEC identified as 1010 mg/kg.

Mean lifetime egg production: Based on the Shirley-Williams test, the decrease in mean lifetime egg production was only significant at 1010 mg/kg. This was further supported by a Games-Howell comparison test which also concluded that only the 1010 mg/kg treatment was significantly different from the solvent control. Therefore, for this endpoint the NOEC is 505 mg/kg and the LOEC is 1010 mg/kg. This result should however be considered with caution as the mean lifetime egg production for the negative and solvent control are largely below the values reported for the mean and range in Niyommaneerat et al. (2017) for this endpoint.

Hatching ratio: Based on a Shirley-Williams test, the hatching ratio was significantly reduced at 126 mg/kg but not at 505 mg/kg. This implies that the response is not a monotone response across the 126-505 range in the fully replicated design, which is consistent with high variability and the medians being similar. Because the primary decision set (Solvent control/126/505 mg/kg) does not show a significant effect at 505 mg/kg (and the global Kruskal-Wallis is not significant), the NOEC is set at 505 mg/kg (highest fully replicated dose without significant adverse effect), while no LOEC can be determined. Nevertheless, it should be noted that in Niyommaneerat et al. (2017) it is explicitly mentioned that due to high coefficient of variation (CV) that are higher than 20 % (in our study: 56, 133 and 126 % in the solvent control, 126 and 505 mg/kg, respectively) the hatching ratio should not be used in the assessment.

Reproductive rate: The Shirley-Williams test indicates a significant negative effect on the reproductive rate at 505 mg/kg but no difference in the 126 mg/kg treatment when compared to the solvent control. However, and similarly to the hatching ratio endpoint, the reproductive rate showed an extremely high variability, with CVs, ranging from 87 to 139% (see Table 14). Consequently, and as recommended by Niyommaneerat et al. (2017), this endpoint should not be considered for the assessment.

Overall, the lowest NOEC observed in this study was 505 mg/kg for multiple endpoints.

Since it was determined that the adsorption to soil correlates with the organic carbon content (from the data obtained in the OECD guideline No. 106 study), the toxicity results were normalized to a standard 10% organic carbon content using Equation 18 of the EMA Guidance (2024). The measured organic carbon of the sediment used in this study was 0.4%. Therefore, the standardized NOEC of this study was 12625 mg/kg.

Bioaccumulation in Sediment-dwelling Species

Clergeaud et al. (2022) assessed the potential transfer of BEMT after 28 days from artificial spiked sediments (10 mg/kg dry weight) to the sediment-dwelling worm *Hediste diversicolor*. Their experimental design was inspired by the OECD Test Guidelines No. 225 (Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment) and No. 315 (Bioaccumulation in Sediment-Dwelling Benthic Oligochaetes). The results show that BEMT did not bioaccumulate in the worms, with a Biota-Sediment Accumulation Factor (BSAF) of 0.2 (a BSAF < 1 indicates no bioaccumulation). The authors used homogenates of whole worms to assess the concentration "in" *Hediste diversicolor.* However, their method does not allow to differentiate between BEMT being potentially absorbed to the surface of the worm, or present on the sediment inside the gut of the worm, and/or actual adsorption by the worm. Therefore, the results of this study do present some limitations in how far they can be interpreted. The first two hypotheses are the most likely based on the information available. Besides the lack of bioaccumulation of BEMT, the worms did not

show any avoidance behavior toward the spiked sediment. Indeed, all the worms had burrowed after 24 hours of contact with the sediments, Moreover, no effects on survival were observed, which excludes potential physical effects of BEMT.

Bioavailability

Bio-accessibility and bioavailability are essential in assessing the environmental fate of BEMT and the associated risks to organisms.

Bioavailability is defined as the fraction of a chemical present in the environment that is or may become available for biological uptake by passage across cell membranes. Thus, a chemical being bio-accessible does not imply that it is bioavailable. This also applies to the evaluation of non-extractable residues and subsequent releases from soil or sediment particles (ECETOC, 2013).

According to Lipinski's rule of five and the molecular properties of BEMT (e.g., molecular mass = 627.8 daltons, Log Kow > 5.7), it is unlikely that BEMT can pass through cell membranes (Lipinski et al. 1997, Lipinski 2004). This is also supported by the average maximum diameter (Dmaxaver) of BEMT. Using Catalogic v5.17.1., the Dmaxaver of BEMT was calculated to be 2.37 nm. According to ECHA's guidance on the evaluation of bioaccumulation (ECHA, 2023), a substance with a Dmaxaver higher than 1.7 nm cannot easily cross cell membranes and is therefore considered as not bioavailable.

Moreover, experimental data obtained with a toxicokinetic study in rats following oral administration (CTL, 2002; (See section 2.6.4.3.4.2 in our OMOR submission for the detailed study reports) resulted in no measurable level of BEMT in organs or tissues while a rapid excretion via feces and urine was observed, further indicating the lack of cellular uptake. Additionally, the bioaccumulation study in fish demonstrates no bioavailability for aquatic organisms. The Bioconcentration Factors are reported as less than 3 and less than 19 for concentration levels of 1.0 mg/L and 0.1 mg/L respectively. They are reported as "less than" because the concentrations in fish were so low that they were below the limit of quantification in most instances. Therefore, it can be concluded that there was no uptake of the substance by the fish. Finally, studies with soil-dwelling organisms, which ingest particles with absorbed BEMT, showed no effects even at very high-test concentrations (1000 mg/kg), This indicates that BEMT is either not extracted from these particles and/or is not readily bioavailable even if released. This mechanism is similar to what would occur in sediment-dwelling organisms following the ingestion of contaminated particles (Sijm et al. 2000).

Finally, for the sediment compartment, Clergeaud et al. (2022) assessed the potential transfer of BEMT after 28 days from artificial spiked sediments (10 mg kg-1 dry weight) to the sediment-dwelling worm *Hediste diversicolor*. Their experimental design was inspired by the OECD Test Guidelines No. 225 (Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment) and No. 315 (Bioaccumulation in Sediment-Dwelling Benthic Oligochaetes). The results show that BEMT did not bioaccumulate in the worms, with a Biota-Sediment Accumulation Factor (BSAF) of 0.2 (a BSAF < 1 indicates No Bioaccumulation).

Consequently, BEMT was demonstrated to not be bioavailable for multiple compartments, vertebrates and non-vertebrates, and multiple trophic levels.

Risk Evaluation

Down the drain scenario

As no toxicity was observed in any of the reliable acute or chronic environmental studies conducted, it was not possible to derive quantitative toxicity endpoints (e.g., NOECs, LC_{50}s, or EC_{50}s) suitable for a quantitative risk assessment and comparison with the Assessment Factors defined in the FDA Guidance Document. Nevertheless, for completeness, a qualitative risk assessment was performed by comparing the Maximum Expected Environmental Concentrations (MEECs) to the highest tested concentration in the toxicity assays for each environmental compartment. These MEECs were derived using highly conservative exposure assumptions, based on both realistic and worst-case conservative annual use levels of (b) (4) and (b) (4) metric tons, respectively.

Soil compartment: for the soil compartment, and as suggested by the FDA, the EICs are considered as a worst-case assumption (Table 4). Under the annual use scenarios of (b) (4) and (b) (4) metric tons, the highest EICs were predicted for the South Region, with values of 47.7 and 6.9 mg/kg dry weight (DW), respectively.

When compared to the highest concentration tested in the soil toxicity studies at which no adverse effects were observed (1,000 mg/kg DW), these EECs represent margins of safety of approximately 21-fold and 145-fold, respectively. On this basis, and considering the conservative nature of the exposure assumptions applied, the results indicate no unreasonable risk to the soil compartment, including under the highly conservative (b) (4) metric tons per year scenario.

Aquatic compartment: the MEECs for the aquatic compartment correspond to the EICs (Table 5). For the annual use scenarios of (b) (4) and (b) (4) metric tons, the highest EICs were predicted for the South Region and were estimated at 9.77 and 1.41 mg/L, respectively.

When compared to the highest concentration tested in the aquatic toxicity studies (100 mg/L), at which no adverse effects were observed, these EICs correspond to margins of safety of approximately 10-fold and 71-fold, respectively. When EECs for freshwater and marine environments are considered, the resulting margins of safety increase further, by approximately one and two orders of magnitude, respectively. These conservative margins of safety indicate that BEMT does not pose an unreasonable risk to the aquatic compartment under the evaluated conditions.

Sediment compartment: for sediment, the calculated freshwater sediment EECs in the South Region (Table 6) result in margins of safety of approximately 31-fold and 218-fold for the annual use scenarios of (b) (4) and (b) (4) metric tons, respectively, when compared with the highest tested concentration of 1,000 mg/kg DW in a reliable chronic sediment toxicity study with amphipods.

In addition, a conservative, worst-case risk characterization was performed using the NOEC value derived from the ostracod study, despite the substantial uncertainty associated with the validity and reliability of this study.

In accordance with the EMA guidance, and based on the availability of two chronic studies with sediment dwelling organisms representing different ecological niches and exposure pathways, an

assessment factor (AF) of 50 was applied to derive a predicted no-effect concentration (PNEC). The PNEC was calculated from the standardized NOEC of 12,625 mg/kg DW calculated from the ostracod study, resulting in a PNEC of 252.5 mg/kg DW.

Table 8 below summarizes the resulting risk quotients (RQs), calculated as the ratio of sediment EECs for the South Region (worst-case exposure scenario; Table 6) to the derived PNEC. All RQs are below 1, including under the highly conservative scenario assuming an annual use of (b) (4) metric tons of BEMT. Accordingly, no further refinement of the sediment risk assessment is considered necessary.

	Realistic scenario ((b) (4) tons per year)		**Conservative scenario ((b) (4) tons per year)**	
	Fresh water	*Marine Water*	*Fresh water*	*Marine Water*
RQ	0.0181	0.0018	0.1255	0.0125

Direct release scenario

Based on the refined PT19 exposure estimates, RQs were calculated for all relevant environmental compartments, including surface water and sediment in both freshwater and marine systems. For the sediment compartment, the PNEC derived from the freshwater ostracod study was used as a conservative, worst-case hazard estimate. It is important to note that the EECs and associated RQs for PT19 are derived using conservative exposure assumptions, including continuous daily use over a 91-day seasonal period, representing a high-end use scenario. This approach assumes maximum application rates and uninterrupted use during the peak season and therefore is expected to significantly overestimate actual environmental exposure, resulting in worst-case EEC and RQ estimates.

The detailed exposure calculations, hazard assumptions, and resulting RQs are provided in Appendix 7.

As summarized in ***Table 9*** below, all RQs were below one for all compartments, indicating no environmental risk even under the highly conservative exposure assumptions applied in the PT19 scenario. Consequently, no further risk refinement is needed.

	Freshwater		**Marine**	
	Water	Sediment	*Water*	Sediment
RQ	4.15E-04	0.55	3.65E-05	0.120

6.3. Summary

BEMT exhibits very low water solubility, high hydrophobicity, negligible volatility, and strong adsorption to organic matter in soils and sediments. Experimental data unequivocally demonstrate that BEMT is highly stable and resistant to environmental degradation. No significant biodegradation was observed in water or soil simulation studies, and no degradation products were formed under forced degradation conditions. As a direct consequence of these intrinsic physicochemical properties, BEMT released into the environment rapidly partitions from the aqueous phase to particulate matter and sediments, resulting in limited environmental mobility and low bioavailability.

Environmental exposure was evaluated for both indirect releases via wastewater treatment systems (the "down-the-drain" scenario) and direct releases associated with recreational use. Across all exposure scenarios assessed—including highly conservative assumptions regarding annual usage volumes, biosolids application rates, and long-term accumulation—predicted environmental concentrations in soil, surface water, and sediment remained low. Where appropriate, exposure estimates were further refined using equilibrium partitioning approaches and measured environmental concentrations reported in the literature. These refined assessments consistently identify sediment as the primary environmental sink for BEMT, while concentrations in the water column remain low, transient, and of limited ecological relevance.

A comprehensive and robust ecotoxicological dataset spanning aquatic, sediment, and terrestrial compartments demonstrates that BEMT does not induce acute or chronic adverse effects at the highest concentrations technically achievable in laboratory testing, which substantially exceed both predicted and measured environmental concentrations. Reliable sediment toxicity studies with amphipods showed no adverse effects at concentrations up to 1,000 mg/kg dry weight, and bioaccumulation studies consistently indicate negligible uptake in aquatic and sediment-dwelling organisms. While one freshwater ostracod study reported effects at elevated concentrations, substantial methodological limitations significantly undermine its regulatory reliability. Nevertheless, this study was conservatively incorporated into bounding risk calculations, and the resulting assessment still demonstrated no risk to the sediment compartment.

Based on a comprehensive weight-of-evidence evaluation integrating environmental fate, exposure, bioavailability, and ecotoxicological effects, the proposed use of bemotrizinol at concentrations up to 6% in over-the-counter sunscreen products is not expected to result in significant adverse effects on the quality of the human environment. All risk characterizations, including worst-case exposure scenarios, demonstrate adequate margins of safety.

7. MITIGATION MEASURES

No potential environmental risks associated with the proposed action have been identified; therefore, no mitigation measures are necessary.

8. ALTERNATIVES TO THE PROPOSED ACTION

No potential environmental risks have been identified, making alternatives to the proposed action unnecessary.

9. LIST OF PREPARERS

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Ahmed Tlili holds a PhD in Ecology, Ecosystems, Microbiology and Modelling, with a specialization in Environmental Toxicology. With over 15 years of experience, he has extensively studied the environmental fate of chemicals and their impacts on both aquatic and terrestrial ecosystems. Currently, he serves as an Environmental Toxicology Expert at dsm-firmenich, where he deals with the evaluation of the environmental fate, hazards, and risks associated with the company's personal care products. His expertise is particularly focused on UV-filters and active ingredients used in suncare formulations, ensuring that these products are safe for the environment while maintaining their efficacy. He also actively participates in various scientific and industry associations that support regulatory frameworks to mitigate the risks posed by chemicals to the environment.
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Marie Collard has a PhD in Marine Biology and in Chemistry. She is a Diplomate of the International Board of Environmental Risk Assessors (IBERA) and a member of the Society of Environmental Toxicology and Chemistry (SETAC). She currently holds the position of Manager Ecotoxicology and Registration at dsm-firmenich where she handles the hazard and risk assessment of the company's products. Her work concentrates on identifying the hazards (through standardized testing or non-animal alternatives) and the risk of those products for various usage across several regions of the world. Notably, she focuses on general issues related to the fate of chemicals in the environment, including topics such as mobility, POP and PBT chemicals. She further extends her expertise as a member of various workgroups within industry associations tackling scientific and regulatory issues related to environmental risk assessment as well as contributing to the development of guidance.
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11. Appendices

11.1 Nonconfidential Appendices

Appendix 1. Bemotrizinol Data Summary Table

Physical and Chemical Characterization	
Water Solubility (OECD 105)	< 0.014 mg/L 4.5 ng/L
Dissociation Constant	-3 and 9.4 for triazin (3x) and phenol (2x), respectively
Octanol/Water Partition Coefficient (Log K_{ow}) (OECD 107 and 117)	> 5.7
Vapor Pressure (OECD 104)	5.9×10^{-20} Pa
Depletion Mechanisms	
Forced Degradation Study	No Degradation
Aerobic Degradation in Water (OECD 301F)	Not Readily Biodegradable
Simulation Biodegradation Test in Soil (OECD 307)	No Degradation DT_{50} > 120 days
Soil/Biosolids Adsorption Coefficient (Log K_{oc}) (OECD 106)	From 5.7 to 6.8
Environmental Effects	
Microbial Inhibition Activated Sludge (OECD 209)	No effects (≥1000 mg/L)
Earthworm Reproduction Test (OECD 222)	No effects (≥1000 mg/L)
Soil Microorganisms: Nitrogen Transformation (OECD 216)	No effects (≥1000 mg/L)
Zebra Fish (*Danio rerio*) Acute Toxicity Test (OECD 203)	No effects (≥0.81 µg/L)
Japanese medaka (*Oryzias latipes*) Fish Acute Toxicity Test	No effects (≥205 mg/L)
Daphnia magna Acute Toxicity (202)	No effects (≥0.114 mg/L)
Freshwater Green Alga *Scenedesmus subspicatus* Toxicity Test (OECD 201)	No effects (≥17 µg/L)
Daphnia magna Chronic Toxicity (OECD 202)	No effects (≥0.7 mg/L)
Chronic Toxicity to Fish (USEPA ECOSAR v2.2)	No predicted Chronic Toxicity
Bioaacumulation in Carp (*Cyprinus carpio) (MITI Guideline)*	BCF < 19

Appendix 3. Report with STP Fugacity Model predictions on the fate of BEMT in Wastewater Treatment Plants.

Appendix 8. Report with ECOSAR predictions for Chronic Toxicity to Fish.

11.2. Confidential Appendices

Appendix 2. Study report of the OECD 308 with BEMT.

Appendix 4. Detailed calculations of the EIC and EEC in Soil.

Appendix 5. Detailed calculations of the EIC in Water.

Appendix 6. Detailed calculations of the EEC in Ssediment.

Appendix 7. Detailed calculations of the exposure and risk of BEMT through direct release (PT19).

Appendix 9a., 9b. and 9c. Prediction reports with iSafeRat for chronic toxicity of BEMT to fish.

Appendix 10. Study report of the Amphipod test with BEMT.

Appendix 11. Study report of the Ostracods test with BEMT.

CONFIDENTIAL APPENDICES WITHHELD IN FULL UNDER (B)(4)

Appendix 3. Report with STP Fugacity Model predictions on the fate of BEMT in Wastewater Treatment Plants

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CAS Number: 187393-00-6
SMILES : OC=1C=C(OCC(CC)CCCC)C=CC1c2nc(nc(n2)C=3C=CC(OCC(CC)CCCC)=CC3O)C=4C=CC(OC)=CC4
CHEM : Bemotrizinol
MOL FOR: C38 H49 N3 O5
MOL WT : 627.83

---------- EPI SUMMARY (v4.11) ----------

Henry LC (atm-m3/mole) :	------
Log Kow (octanol-water):	5.70
Boiling Point (deg C) :	------
Water Solubility (mg/L):	0.014
Physical Property Inputs:	
Vapor Pressure (mm Hg) :	------
Melting Point (deg C) :	80.40

STP Fugacity Model: Predicted Fate in a Wastewater Treatment Facility
==========
(using 10000 hr Bio P,A,S)
PROPERTIES OF: Bemotrizinol

Molecular weight (g/mol)	627.83
Aqueous solubility (mg/l)	0.014
Vapour pressure (Pa)	0
(atm)	0
(mm Hg)	0
Henry 's law constant (Atm-m3/mol)	2.95E-013
Air-water partition coefficient	1.20646E-011
Octanol-water partition coefficient (Kow)	501187
Log Kow	5.7
Biomass to water partition coefficient	100238
Temperature [deg C]	25

Biodeg rate constants (h^-1),half life in biomass (h) and in 2000 mg/L MLSS (h):

-Primary tank	0.00	9950.37	10000.00
-Aeration tank	0.00	9950.37	10000.00
-Settling tank	0.00	9950.37	10000.00

STP Overall Chemical Mass Balance:
---

	g/h	mol/h	percent
Influent	1.00E+001	1.6E-002	100.00
Primary sludge	5.71E+000	9.1E-003	57.06
Waste sludge	3.25E+000	5.2E-003	32.52
Primary volatilization	7.63E-012	1.2E-014	0.00
Settling volatilization	1.72E-011	2.7E-014	0.00
Aeration off gas	4.25E-011	6.8E-014	0.00

Primary biodegradation	1.68E-002	2.7E-005	0.17
Settling biodegradation	4.16E-003	6.6E-006	0.04
Aeration biodegradation	5.48E-002	8.7E-005	0.55
Final water effluent	9.66E-001	1.5E-003	9.66
Total removal	9.03E+000	1.4E-002	90.34
Total biodegradation	7.58E-002	1.2E-004	0.76

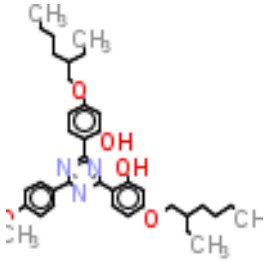
Appendix 8. Report with ECOSAR predictions for Chronic Toxicity to Fish

Organic Module Report

Results of Organic Module Evaluation

CAS	Name	SMILES
		CCC(CCCC)COc4ccc(c1nc(nc(n1)c2ccc(cc2O)OCC(CC)CCCC)c3ccc(OC)cc3)c(O)c4

Structure



Details	
Mol Wt	627.83
Selected LogKow	
Selected Water Solubility (mg/L)	
Selected Melting Point (°C)	
Estimated LogKow	9.29
Estimated Water Solubility (mg/L)	0
Measured LogKow	
Measured Water Solubility (mg/L)	
Measured Melting Point (°C)	

Class Results:	

Neutral Organics

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Fish	96h	LC50	1.46E-04	5	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Daphnid	48h	LC50	1.63E-04	5	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Green Algae	96h	EC50	1.96E-03	6.4	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Fish		ChV	3.17E-05	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Daphnid		ChV	1.03E-04	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Green Algae		ChV	2.30E-03	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Fish (SW)	96h	LC50	1.93E-04	5	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Mysid	96h	LC50	1.03E-06	5	• If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Fish (SW)		ChV	1.79E-03	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Mysid (SW)		ChV	1.02E-08	8	• If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Earthworm	14d	LC50	1.91E02	6	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Triazines, Aromatic

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Fish	96h	LC50	2.36E-04	5	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Daphnid	48h	LC50	4.87E-03	5	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Green Algae	96h	EC50	9.18E-05	6.4	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Fish		ChV	1.66E-05	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Daphnid		ChV	8.81E-05	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Green Algae		ChV	7.07E-04	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Fish (SW)	96h	LC50	1.74E-03	5	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Mysid (SW)	96h	LC50	6.15E-05	5	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Fish (SW)		ChV	2.65E-03	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Mysid (SW)		ChV	2.00E-08	8	• If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Phenols, Poly

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Fish	96h	LC50	1.53E-03	7	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Daphnid	48h	LC50	6.61E-04	5	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Green Algae	96h	EC50	4.51E-02	6.4	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Fish		ChV	2.77E-04	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints

Class Results:	

Organism	Duration	End Point	Concentration (mg/L)	Max Log Kow	Flags
Daphnid		ChV	1.59E-04	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints
Green Algae		ChV	1.77E-02	8	• Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported , • If the Log Kow of the chemical is greater than the endpoint specific cut-offs presented, then no effects at saturation are expected for those endpoints