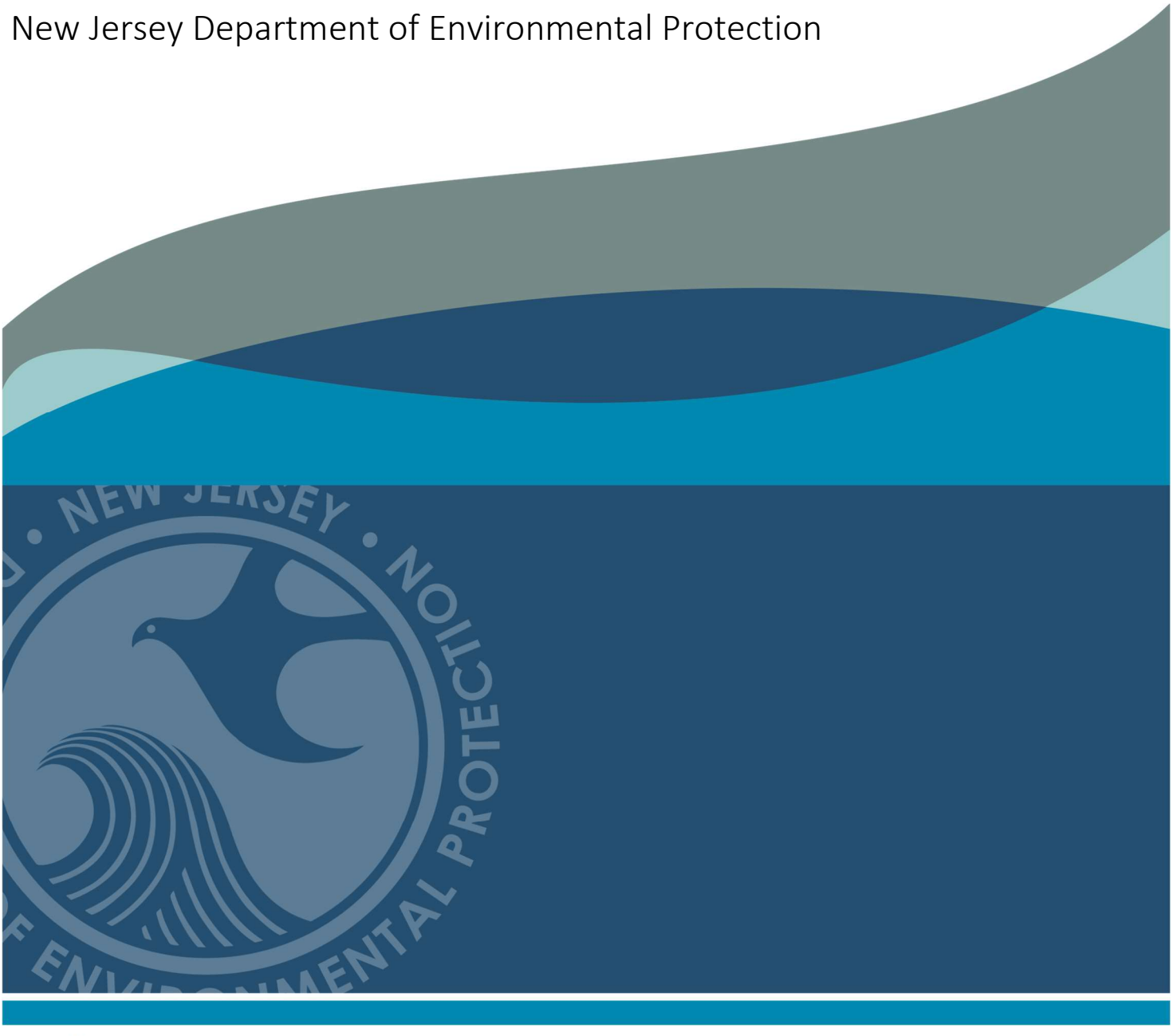
PFAS Interim Soil Remediation Standards Basis & Background

for the Ingestion-Dermal Exposure Pathway for Perfluorononanoic acid (PFNA), Perfluorooctanoic acid (PFOA), Perfluorooctane sulfonate (PFOS), and Hexafluoropropylene oxide dimer acid and Its ammonium salt (GenX)

Contaminated Site Remediation & Redevelopment Program

New Jersey Department of Environmental Protection



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Introduction

Interim Soil Remediation Standards (SRS) for the ingestion-dermal exposure pathway were developed for four poly- and perfluoroalkyl substances (PFAS): perfluorononanoic acid (PFNA), perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), and hexafluoropropylene oxide dimer acid and its ammonium salt (GenX). The methodology used to develop the interim SRS is the same methodology used by the Department to develop SRS for the ingestion-dermal exposure pathway for all other contaminants. The interim SRS were derived using the U.S. Environmental Protection Agency's (USEPA) risk-based equations that combine the ingestion and dermal exposure pathways (USEPA, 2018). This approach acknowledges that concurrent exposure occurs via the two pathways through children's outdoor play; and gardening, landscaping, and excavation by adults. The interim SRS are intended to be protective for chronic (lifetime) exposure to contaminated soil. They are based on a 1 in one million lifetime cancer risk level for carcinogens and a Hazard Quotient of 1 for noncarcinogens, as mandated by the *Brownfield and Contaminated Site Remediation Act* (N.J.S.A. 58:10B-1 et seq.). The interim SRS incorporate default residential and nonresidential exposure parameters consistent with those used by USEPA in the Superfund program (USEPA, 2014 and 2018).

The procedure for calculating residential and nonresidential SRS for the ingestion-dermal exposure pathway is based on USEPA's *Risk Assessment Guidance for Superfund Human Health Evaluation Manual, Part B* (RAGS HHEM, Part B; USEPA, 1991), *Soil Screening Guidance: Technical Background Document* (USEPA, 1996), *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites* (USEPA, 2002), and the *Regional Screening Levels Users Guide* (USEPA, 2018).

Equations and Exposure Parameters

The risk-based equations and input parameters included in N.J.A.C. 7:26D Appendix 2, which are presented below, are used in the development of the residential and nonresidential human health-based criteria for the ingestion-dermal exposure pathway. Carcinogenic and noncarcinogenic human health-based criteria are calculated for contaminants under a residential and nonresidential land use scenario, when applicable toxicity information is available. The default exposure parameters recommended by the USEPA Superfund program (USEPA 2014) are used as input parameters for the calculation of the residential and nonresidential human health-based criteria for the ingestion-dermal exposure pathway. The input parameters reflect reasonable maximum exposure (RME) under the applicable land use scenarios. USEPA defines the RME as the highest exposure that is reasonably expected to occur at a site (USEPA 1989). The exposure parameters, along with the applicable equations, presented below are derived from the *USEPA RSLs, Users Guide* (USEPA 2018). A detailed explanation of the derivation of Equations 1 through 4 is contained in N.J.A.C. 7:26D Appendix 12.

Equation 1
Residential Carcinogenic Ingestion-Dermal Human Health-based Criteria

$$ID_c = \frac{TR * AT * LT}{(10^{-6}\, kg/mg) * [(CFS_o * IFS_{adj}) + (CFS_D * DFS_{adj} * ABS_d)]}$$

Parameter	Definition	Units	Default
ID_c	Carcinogenic ingestion-dermal human health-based criterion	mg/kg	Chemical-specific
TR	Target cancer risk	unitless	1×10^{-6}
AT	Averaging time	days/year	365
LT	Lifetime	years	70
CSF_o	Oral cancer Slope factor	$(mg/kg\text{-}day)^{-1}$	Chemical-specific
IFS_{adj}	Age-adjusted soil ingestion rate	mg/kg	36,750
CSF_D	Dermal cancer slope factor	$(mg/kg\text{-}day)^{-1}$	Chemical-specific
DFS_{adj}	Age-adjusted soil dermal contact factor	mg/kg	103,390
ABS_d	Dermal absorption fraction	unitless	Chemical-specific

Where:

(Equation 1.1)

$$IFS_{adj} = \frac{EF_c * ED_c * IR_c}{BW_c} + \frac{EF_a * ED_a * IR_a}{BW_c}$$

Parameter	Definition	Units	Default
IFS_{adj}	Age-adjusted soil ingestion rate	mg/kg	36,750
EF_c	Exposure frequency – child	days/year	350
EF_a	Exposure frequency – adult	days/year	350
ED_c	Exposure duration – child	years	6
ED_a	Exposure duration – adult	years	20
IR_c	Soil ingestion rate – child	mg/day	200
IR_a	Soil ingestion rate – adult	mg/day	100
BW_c	Body weight – child	kg	15
BW_a	Body weight – adult	kg	80

Where:

(Equation 1.2)

$$DFS_{adj} = \frac{EF_c * ED_c * SA_c * AF_c}{BW_c} + \frac{EF_a * ED_a * SA_a * AF_a}{BW_a}$$

Parameter	Definition	Units	Default
DFS_{adj}	Age-adjusted soil dermal contact factor	mg/kg	103,390
EF_c	Exposure frequency – child	days/year	350
EF_a	Exposure frequency – adult	days/year	350

ED_c	Exposure duration – child	years	6
ED_a	Exposure duration – adult	years	20
SA_c	Skin surface area – child	cm^2/day	2,373
SA_a	Skin surface area – adult	cm^2/day	6,032
AF_c	Soil adherence factor – child	mg/cm^2	0.2
AF_a	Soil adherence factor – adult	mg/cm^2	0.07
BW_c	Body weight – child	kg	15
BW_a	Body weight – adult	kg	80

Where:

(Equation 1.3)

$$CSF_D = \frac{CSF_o}{GIABS}$$

Parameter	Definition	Units	Default
CSF_D	Dermal cancer slope factor	$(mg/kg\text{-}day)^{-1}$	Chemical-specific
CSF_O	Oral cancer slope factor	$(mg/kg\text{-}day)^{-1}$	Chemical-specific
GIABS	Gastro-intestinal absorption fraction	unitless	Chemical-specific

Equation 2
Residential Noncarcinogenic Ingestion-Dermal Human Health-based Criteria

$$ID_{nc} = \frac{THQ * AT * ED * BW}{(EF * ED * 10^{-6}\, kg/mg) * [\left(\frac{1}{RfD_o} * IR\right) + \left(\frac{1}{RfD_D} * SA * AF * ABS_d\right)]}$$

Parameter	Definition	Units	Default
ID_{nc}	Noncarcinogenic ingestion-dermal human health-based criterion	mg/kg	Chemical-specific
THQ	Target hazard quotient	unitless	1
AT	Averaging time	days/year	365
ED	Exposure duration	years	6
BW	Body weight-child	kg	15
EF	Exposure frequency	days/year	350
RfD_O	Oral reference dose	mg/kg-day	Chemical-specific
IR	Soil ingestion rate-child	mg/day	200
RfD_D	Dermal reference dose	mg/kg-day	Chemical-specific
SA	Skin surface area-child	cm^2/day	2,373
AF	Soil adherence factor-child	mg/cm^2	0.2
ABS_d	Dermal absorption fraction	unitless	Chemical-specific

Where:

(Equation 2.1)

$$RfD_D = RfD_o * GIABS$$

Parameter	Definition	Units	Default
RfD$_D$	**Dermal reference dose**	**mg/kg-day**	**Chemical-specific**
RfD$_O$	**Oral reference dose**	**mg/kg-day**	**Chemical-specific**
GIABS	**Gastro-intestinal absorption fraction**	**unitless**	**Chemical-specific**

Equation 3
Nonresidential Carcinogenic Ingestion-Dermal Human Health-based Criteria

$$ID_c = \frac{TR * AT * LT * BW}{(EF * ED * 10^{-6}\, kg/mg) * [(CFS_o * IR) + (CSF_D * SA * AF * ABS_d)]}$$

Parameter	Definition	Units	Default
ID$_c$	**Carcinogenic ingestion-dermal human health-based criterion**	**mg/kg**	**Chemical-specific**
TR	**Target cancer risk**	**unitless**	**1 x 10^{-6}**
AT	**Averaging time**	**days/year**	**365**
LT	**Lifetime**	**years**	**70**
BW	**Body weight - adult**	**kg**	**80**

EF	**Exposure frequency-outdoor worker**	**days/year**	**225**
ED	**Exposure duration**	**years**	**25**
CSF_o	**Oral cancer Slope factor**	**$(mg/kg\text{-}day)^{-1}$**	**Chemical-specific**
IR	**Soil ingestion rate -outdoor worker**	**mg/day**	**100**
CSF_D	**Dermal cancer slope factor**	**$(mg/kg\text{-}day)^{-1}$**	**Chemical-specific**
SA	**Skin surface area - worker**	**cm^2/day**	**3,527**
AF	**Soil adherence factor-worker**	**mg/cm^2**	**0.12**
ABS_d	**Dermal absorption fraction**	**unitless**	**Chemical-specific**

Where:

(Equation 3.1)

$$CSF_D = \frac{CSF_o}{GIABS}$$

Parameter	Definition	Units	Default
CSF_D	**Dermal cancer slope factor**	**$(mg/kg\text{-}day)^{-1}$**	**Chemical-specific**
CSF_O	**Oral cancer slope factor**	**$(mg/kg\text{-}day)^{-1}$**	**Chemical-specific**
GIABS	**Gastro-intestinal absorption fraction**	**unitless**	**Chemical-specific**

Equation 4
Nonresidential Noncarcinogenic Ingestion-Dermal Human Health-based Criteria

$$ID_{nc} = \frac{THQ * AT * ED * BW}{(EF * ED * 10^{-6}\, kg/mg) * [\left(\frac{1}{RfD_o} * IR\right) + \left(\frac{1}{RfD_D} * SA * AF * ABS_d\right)]}$$

Parameter	Definition	Units	Default
ID_{nc}	Noncarcinogenic ingestion-dermal human health-based criterion	mg/kg	Chemical-specific
THQ	Target hazard quotient	unitless	1
AT	Averaging time	days/year	365
ED	Exposure duration	years	25
BW	Body weight-adult	kg	80
EF	Exposure frequency- outdoor worker	days/year	225
RfD_O	Oral reference dose	mg/kg-day	Chemical-specific
IR	Soil ingestion rate- outdoor worker	mg/day	100
RfD_D	Dermal Reference dose	mg/kg-day	Chemical-specific
SA	Skin surface area - worker	cm^2/day	3,527
AF	Soil adherence factor-worker	mg/cm^2	0.12
ABS_d	Dermal absorption fraction	unitless	Chemical-specific

Where:

(Equation 4.1)

$$RfD_D = RfD_o * GIABS$$

Parameter	Definition	Units	Default
RfD_D	**Dermal reference dose**	**mg/kg-day**	**Chemical-specific**
RfD_O	**Oral reference dose**	**mg/kg-day**	**Chemical-specific**
GIABS	**Gastro-intestinal absorption fraction**	**unitless**	**Chemical-specific**

To ensure consistency with USEPA, the recommended dermal absorption fraction of 0.1 listed in USEPA's Regional Screening Levels (RSL) Tables (USEPA 2022) for PFNA, PFOA, and PFOS was used to develop the ingestion-dermal interim SRS. For GenX, no dermal absorption fraction is recommended because it is classified as a volatile. USEPA has not developed default dermal absorption values for volatile organic compounds because they tend to volatilize from the soil adhered to skin and exposure should be accounted for via the inhalation route of exposure.

Toxicity Information

The toxicity information used to generate interim SRS for the ingestion-dermal exposure pathway is obtained from the New Jersey Drinking Water Quality Institute (NJDWQI) Health Effects Subcommittee Support Documents for PFNA, PFOA, and PFOS (NJDWQI, 2015, 2017 & 2018). This first-tier hierarchy source of toxicity information also forms the basis for New Jersey's drinking water health-based Maximum Contaminant Levels (MCLs) and Ground Water Quality Standards (GWQS) for PFNA, PFOA, and PFOS adopted by the Department. The toxicity information used to generate the interim SRS for the ingestion-dermal exposure pathway for GenX is obtained from USEPA's Office of Water (USEPA 2021). The toxicity information was reviewed by the Department's Division of Science and Research and its use is supported for standard development. The oral reference doses and cancer slope factors are listed below:

- **Oral Reference Doses (RfDs):**
  - PFNA – 7.4E-07 mg/kg-day
  - PFOA – 2E-06 mg/kg-day
  - PFOS – 1.8E-06 mg/kg-day
  - GenX – 3E-06 mg/kg-day
- **Oral Cancer Slope Factors:**
  - PFNA – Not Available
  - PFOA – 2.5 $(mg/kg\text{-}day)^{-1}$
  - PFOS – 9 $(mg/kg\text{-}day)^{-1}$
  - GenX – Not Available

Suggestive Carcinogen and Group C Carcinogen Policy

The Department has a policy for the development of remediation standards for contaminants classified as Group C carcinogens, which are defined as Possible Human Carcinogens by the USEPA under the 1986 guidelines, or as having Suggestive Evidence of Carcinogenic Potential under the 2005 guidelines (USEPA 1986 and 2005). Group C or "Suggestive" carcinogen contaminants are contaminants for which some evidence of human carcinogenicity exists, but for which there is insufficient evidence to classify the contaminants as Known Human Carcinogens (Group A) or Probable Human Carcinogens (Group B) under the 1986 guidelines, or Carcinogenic to Humans or Likely to be Carcinogenic to Humans under the 2005 guidelines. The Department uses this policy to develop Departmental health-based standards including remediation standards, drinking water health-based MCLs, ground water quality criteria, and human health-based surface water quality criteria.

Under this Department policy, remediation standards for contaminants classified as Group C carcinogens under the 1986 guidelines or as having Suggestive Evidence of Carcinogenic Potential under the 2005 guidelines that have a carcinogen toxicity factor (oral slope factor for the ingestion-dermal exposure pathway) are developed based on carcinogenicity using a target cancer risk level of one excess human cancer in one million (1×10^{-6} target cancer risk). For those contaminants for which available data do not support the development of a carcinogen toxicity factor (oral slope factor for the ingestion-dermal pathway), the remediation standards are developed using a noncarcinogen toxicity factor (RfD for the ingestion-dermal exposure pathway), with the application of an additional uncertainty factor of 10 to account for potential carcinogenic effects not addressed by the noncarcinogen toxicity factor.

Using USEPA's 2005 guidelines for carcinogen risk assessment, PFOA and PFOS were classified as having Suggestive Evidence of Carcinogenic Potential by the NJDWQI. GenX was classified as having Suggestive Evidence of Carcinogenic Potential by USEPA's Office of Water. PFOA, PFOS, and GenX all fall under the umbrella of the Department's Group C/Suggestive Carcinogen Policy.

Calculations

In deriving the interim SRS for the ingestion-dermal exposure pathway, the Department applied the rounding rules contained in the American Society for Testing and Materials (ASTM) Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications (ASTM E29-13). This process is consistent with that used to develop the Remediation Standards at N.J.A.C. 7:26D.

The noncarcinogenic and carcinogenic health endpoints were evaluated using the risk-based equations, input parameters, and toxicity information discussed above. The resulting residential and nonresidential interim SRS for PFNA, PFOA, PFOS, and GenX are listed below.

Interim SRS for the Ingestion-Dermal Exposure Pathway (mg/kg)
(All numeric values are rounded to two significant figures)

Contaminant	CAS No.	Interim SRS Ingestion-Dermal Residential	Interim SRS Ingestion-Dermal Nonresidential
Perfluorononanoic acid (PFNA)	375-95-1	0.047	0.67
Perfluorooctanoic acid (PFOA)	335-67-1	0.13	1.8
Perfluorooctane sulfonate (PFOS)	1763-23-1	0.11	1.6
Hexafluoropropylene oxide dimer acid and Its ammonium salt (GenX)	13252-13-6 & 62037-80-3	0.23	3.9

Chemical-Specific Information

A. PFNA

The ingestion-dermal interim SRS for PFNA are based on the noncarcinogenic health endpoint. There is no available information that can be used to evaluate the carcinogenic potential of PFNA because chronic carcinogenicity bioassays have not been conducted.

B. PFOA

The ingestion-dermal interim SRS for PFOA are based on the noncarcinogenic health endpoint. The NJDWQI cancer slope factor was also used to evaluate whether the calculated noncarcinogenic ingestion-dermal human health-based criteria were protective of carcinogenic effects. The residential noncarcinogenic ingestion-dermal human health-based criterion (0.13 mg/kg) results in an estimated cancer risk less than 1 in one million and the nonresidential noncarcinogenic ingestion-dermal human health-based criterion (1.8 mg/kg) results in an estimated cancer risk of 1.8 in one million. The estimated cancer risk of 1.8 in one million for the nonresidential land use exposure scenario is slightly above the cancer risk target for New Jersey remediation standards/screening levels of 1 in one million. However, since the estimated cancer risk at the health-based criterion based on a sensitive noncarcinogenic effect is close to the New Jersey cancer risk target of 1 in one million, the noncarcinogenic health endpoint is considered sufficiently protective when the uncertainties in the cancer risk assessment for PFOA are considered.

C. PFOS

Carcinogenic ingestion-dermal human health-based criteria were not used as the basis for the interim SRS for PFOS due to uncertainties associated with the study used to derive the cancer slope factor. Instead, a quantitative estimate of cancer risk was used to provide context, and for informational purposes, to assess whether the noncarcinogenic human health-based criteria were protective of potential carcinogenic effects. The residential noncarcinogenic ingestion-dermal human health-based criterion (0.11 mg/kg) results in an

estimated cancer risk of 1.8 in one million and the nonresidential noncarcinogenic ingestion-dermal human health-based criterion (1.6 mg/kg) results in an estimated cancer risk of 5.6 in one million. The estimated cancer risks of 1.8 in one million and 5.6 in one million for the residential and nonresidential exposure scenarios, respectively, are slightly above the cancer risk target for New Jersey remediation standards/screening levels of 1 in one million. It is the general policy of the NJDWQI, NJDEP, and USEPA Office of Water to apply an additional uncertainty factor of 10 to an RfD for a noncancer endpoint to account for potential cancer risk of Group C Carcinogens when a cancer slope factor is not available or is considered uninformative. However, since the estimated cancer risk at the health-based SSL based on a sensitive noncarcinogenic effect is close to the New Jersey cancer risk target of 1 in one million, application of this uncertainty factor is not necessary. This approach is consistent with that used to develop the drinking water health-based MCL and GWQS for PFOS.

D. **GenX**

The ingestion-dermal interim SRS for GenX are based on the noncarcinogenic health endpoint. Currently the data are not adequate to derive a quantitative risk estimate for carcinogenic potential. Based on the evaluation of the limited (i.e., one chronic carcinogenicity bioassay in rats) data relevant to carcinogenicity of GenX chemicals, USEPA concluded that there is Suggestive Evidence of Carcinogenic Potential of oral exposure to GenX chemicals in humans. It is the general policy of the NJDWQI, NJDEP, and USEPA Office of Water to apply an additional uncertainty factor of 10 to an RfD for a noncancer endpoint to account for potential cancer risk of Group C Carcinogens when a cancer slope factor is not available or is considered uninformative. However, screening level estimates of cancer risk performed by the Department's Division of Science and Research, based on the tumor data from the chronic rat study, indicate that the residential and non-residential noncarcinogenic ingestion-dermal human health-based criteria are protective of lifetime cancer risk at the one-in-one million risk level for GenX. Therefore, application of the additional uncertainty factor is not necessary.

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62037-80-3), Also Known as “GenX Chemicals”. Office of Water, Washington, DC. EPA Document Number 822R-21-010.

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