

식약처 설정 니트로사민류 불순물 1일 섭취허용량

기준일 : 2024.10.25.

연번	불순물 명칭	발생 성분	CPCA분류	섭취허용량 (ng/일)	비고	공개일자
1	N-nitrosodi-ethylamine, NDEA	-	-	26.5	-	2018-11-20
2	N-nitrosoethylisopropylamine, EIPNA	-	-	26.5	SAR/read-across, 참조물질 NDEA	2019-11-28
3	N-nitrosodiisopropylamine, DIPNA	-	-	26.5	SAR/read-across, 참조물질 NDEA	2019-11-28
4	N-nitroso-di-n-butylamine, NDBA	-	-	26.5	SAR/read-across, 참조물질 NDEA	2021-11-09
5	N-nitrosodipropylamine, NDPA	-	-	26.5	SAR/read-across, 참조물질 NDEA	2021-11-18
6	N-nitrosodi-methylamine, NDMA	-	-	96	-	2018-08-06
7	N-nitroso-N-methyl-4-aminobutyric acid, NMBA	-	-	96	SAR/read-across, 참조물질 NDMA	2019-11-28
8	1-Methyl-4-nitrosopiperazine, MeNP(MNP)	-	-	96	SAR/read-across, 참조물질 NDMA	2020-10-08
9	N-nitrosomorpholine, NMOR	-	-	127	-	2022-02-17
10	N-nitroso-piperidine, NPIP	-	-	1,300	-	2023-12-13
11	N-nitroso-pyrrolidine, NPYR	-	-	1,700	-	2023-12-13
12	2-nitroso-octahydrocyclopenta(c)pyrrole	글리클라지드(Gliclazide)	-	1,700	SAR/read-across, 참조물질 NPYR ⁴⁾	2023-12-13
13	N-nitroso-nebivolol, NNEB	네비볼롤(Nebivolol)	4	1,500	-	2023-12-13
14	N-nitroso-nortriptyline	노르트립틸린(Nortriptyline)	-	검토중, 추후 확정 예정	-	-
15	N-nitroso-desmethyl-nintedanib	닌테다닙(Nintedanib)	3	400	-	2024-03-20
16	N-nitroso-dabigatran etexilate	다비가트란(Dabigatran)	-	1,500	AMES 음성	2024-06-21
17	N-nitroso-desloratadine	데스로라타딘(Desloratadine)	3	400	-	2023-12-13
18	N-nitroso-N-desmethyl-desvenlafaxine	데스벤라팍신(Desvenlafaxine)	1	26.5	-	2023-12-13
19	N-nitroso-dorzolamide	도르졸라미드(Dorzolamide)	2	100	-	2023-12-13
20	N-nitroso-nordoxepin	독세핀(Doxepin)	1	26.5	-	2023-12-13
21	N-desmethyl-N-nitroso-doxycycline	독시사이클린(Doxycycline)	3	400	-	2023-12-13
22	N-nitroso-N-methyl-2-[1-phenyl-1-(2-pyridinyl)methoxy]ethanamine	독실아민(Doxylamine)	1	26.5	-	2023-12-13
23	N-nitroso-duloxetine	둘록세틴(Duloxetine)	-	100	SAR/read-across, 참조물질 NNK ²⁾	2023-12-13
24	N-nitroso-diclofenac	디클로페낙(Diclofenac)	5	1,500	-	2023-12-13
25	N-nitroso-ranolazine impurity 1	라놀라진(Ranolazine)	3	400	-	2024-03-20
26	N-nitroso-ramipril	라미프릴(Ramipril)	5	1,500	-	2023-12-13
27	N-nitroso-labetalol	라베타롤(Labetalol)	4	1,500	-	2023-12-13
28	N-nitroso-rasagiline	라사길린(Rasagiline)	2	100	-	2023-12-13
29	N-nitroso-levofloxacin	레보플록사신(Levofloxacin)	4	1,500	-	2023-12-13
30	N-nitroso-2,6-pipecoloxilidide	로피바카인(Ropivacaine)	4	1,500	-	2023-12-13
31	N-nitroso-folinic acid: N-[4-[[[(2-amino-5-formyl-3,4,5,6,7,8-hexahydro-4-oxo-6-pteridiny]methyl]nitrosoamino]benzoyl]-L-glutamic acid	류코보린(Leucovorin)	4	1,500	-	2023-12-13
32	N-nitroso-desethylidocaine	리도카인(Lidocaine)	2	100	-	2024-03-20
33	N-nitroso-rivaroxaban amide	리바록사반(Rivaroxaban)	4	1,500	-	2024-03-20
34	N-nitroso-rivaroxaban open-ring acid	리바록사반(Rivaroxaban)	4	1,500	-	2024-03-20
35	N-nitroso-N-desmethyl rivastigmine	리바스티그민(Rivastigmine)	2	100	-	2023-12-13
36	N-nitroso-ribociclib impurity 1	리보시클립(Ribociclib)	3	400	-	2024-03-20
37	N-nitroso-lisinopril	리시노프릴(Lisinopril)	5	1,500	-	2023-12-13
38	N-nitroso-meropenem	메로페넴(Meropenem)	4	1,500	-	2023-12-13
39	N-nitroso-metoprolol	메토프롤롤(Metoprolol)	4	1,500	-	2023-12-13
40	N-nitroso-methylphenidate, NMPH	메틸페니데이트(Methylphenidate)	-	1,300	SAR/read-across, 참조물질 NPIP ³⁾	2023-12-13

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41	N-nitroso-moxifloxacin	목시플록사신(Moxifloxacin)	4	1,500	-	2023-12-13
42	N-nitroso-mirabegron	미라베그론(Mirabegron)	3	400	-	2023-12-13
43	N-nitroso-mirtazapine	미르타자핀(Mirtazapine)	3	400	-	2024-03-20
44	N-nitroso-varenicline, NNV	바레니클린(Varenicline)	3	400	-	2024-06-21
45	N-nitroso-N-ethyl-valacyclovir	발라시클로비르(Valacyclovir)	3	400	-	2023-12-13
46	N-nitroso-N-methyl-valacyclovir	발라시클로비르(Valacyclovir)	3	400	-	2023-12-13
47	N-nitroso-betahistine	베타히스틴(Betahistine)	1	26.5	-	2023-12-13
48	N-nitroso-betaxolol	베타솔롤(Betaxolol)	4	1,500	-	2024-03-20
49	N-nitroso-vortioxetine	보티옥세틴(Vortioxetine)	3	400	-	2023-12-13
50	N-nitroso-bupropion	부프로피온(Bupropion)	5	1,500	-	2023-12-13
51	N-nitroso-bisoprolol, NBP	비소프로롤(Bisoprolol)	4	1,500	-	2023-12-13
52	N-nitroso-vildagliptin	빌다글립틴(Vildagliptin)	5	1,500	-	2023-12-13
53	N-nitroso-salbutamol	살부타몰(Salbutamol)	5	1,500	-	2023-12-13
54	N-nitroso-sertraline	셀트랄린(Sertraline)	-	검토중, 추후 확정 예정	-	-
55	N-nitroso-celiprolol	셀리프롤롤(Celiprolol)	5	1,500	-	2024-03-20
56	N-nitroso-sotalol	소타롤(Sotalol)	4	1,500	-	2023-12-13
57	3-[2-(N-nitroso-N-methyl)amino]ethyl]-N-methyl-1H-indole-5-methanesulfonamide	수마프립탄(Sumatriptan)	1	26.5	-	2023-12-13
58	N-nitroso-pseudoephedrine	슈도에페드린(Pseudoephedrine)	4	1,500	-	2023-12-13
59	N-nitroso-cinacalcet	시나칼세트(Cinacalcet)	3	400	-	2024-01-18
60	7-nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro[1,2,4]triazolo-[4,3-a]pyrazine, NTPP	시타글립틴(Sitagliptin)	2	100	-	2024-10-25
61	N-nitroso-desmethyl citalopram	시탈로프람(Citalopram)	1	26.5	-	2023-12-13
62	N-nitroso-ciprofloxacin	시프로플록사신(Ciprofloxacin)	4	1,500	-	2024-01-18
63	N-nitroso-desmethyl-sildenafil	실дена필(Sildenafil)	3	400	-	2024-03-20
64	N-nitroso-cilazapril	실라자프릴(Cilazapril)	5	1,500	-	2023-12-13
65	1-(2,3-dichlorophenyl)-4-nitrosopiperazine	아리피프라졸(Aripiprazole)	3	400	-	2024-03-20
66	N-nitroso-desmethyl-azelastine	아젤라스틴(Azelastine)	2	100	-	2024-03-20
67	N-nitroso-azaerythromycin	아지스로마이신(Azithromycin)	-	ICH Q3A/Q3B에 따라 관리	비변이원성 불순물	2023-12-13
68	N-nitroso-desmethy lazithromycin	아지스로마이신(Azithromycin)	-	ICH Q3A/Q3B에 따라 관리	비변이원성 불순물	2023-12-13
69	N-nitroso-atenolol	아테놀롤(Atenolol)	4	1,500	-	2023-12-13
70	N-nitroso-Atomoxetine	아토목세틴(Atomoxetine)	-	100.0	SAR/read-across, 참조물질 NNK ²⁾	2024-03-20
71	3-amino-N-nitrosopiperidine	알로글립틴(Alogliptin)	3	400	-	2024-01-18
72	N-nitroso-ambroxol	암브록솔(Ambroxol)	-	1,500	AMES 음성	2024-03-20
73	N-nitroso-enalapril	에날라프릴(Enalapril)	5	1,500	-	2023-12-13
74	N-nitroso-esmolol	에스몰롤(Esmolol)	4	1,500	-	2024-01-18
75	N-nitroso-folic acid, NFA	엽산/폴산(Folic acid)	4	1,500	-	2023-12-13
76	N-nitroso-N-desmethylo rphenadrine, NMOA	오르페나드린(Orphenadrine)	1	26.5	-	2023-12-13
77	N-nitroso-imatinib	이매티닙(Imatinib)	5	1,500	-	2024-03-20
78	N-nitroso-ethylenediamine-triacetic acid	이소소르비드 모노니트레이트 (Isosorbide mononitrate)	4	1,500	-	2024-03-20
79	N-nitroso-iminodiacetic acid	이소소르비드 모노니트레이트 (Isosorbide mononitrate)	4	1,500	-	2024-03-20
80	Indapamide Impurity A	인다파미드(Indapamide)	5	1,500	-	2024-03-20
81	N-nitroso-ketamine	케타민(Ketamine)	5	1,500	-	2023-12-13
82	N-nitroso-aryl piperazine / N-nitroso-desalkylquetiapine, NDAQ	쿠에티아핀(Quetiapine)	3	400	-	2023-12-13

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83	N-nitroso Quetiapine HEEP Impurity	쿠에티아핀(Quetiapine)	-	1,500	AMES 음성	2024-03-20
84	N-nitroso-N-desmethyl clarithromycin	클래리트로마이신(Clarithromycin)	4	1,500	-	2023-12-13
85	N-nitroso-clozapine	클로자핀(Clozapine)	5	1,500	-	2023-12-13
86	N-nitroso-tigecycline	타이가사이클린(Tigecycline)	5	1,500	-	2023-12-13
87	N-nitroso-tamsulosin	탐스로신(Tamsulosin)	4	1,500	-	2023-12-13
88	N-nitroso-desmethyl terbinafine	테르비나핀(Terbinafine)	1	26.5	-	2024-03-20
89	N-nitroso-terbinafine impurity A	테르비나핀(Terbinafine)	1	26.5	-	2024-03-20
90	N-nitroso-tetracaine	테트라카인(Tetracaine)	3	400	-	2024-01-18
91	N-nitroso-desmethyl trimebutine	트리메부틴(Trimebutine)	5	1,500	-	2023-12-13
92	N-nitroso-trimetazidine, NTMZ	트리메타지딘(Trimetazidine)	3	400	-	2023-12-13
93	N-nitroso-ticagrelor	티카그렐라(Ticagrelor)	5	1,500	-	2024-01-18
94	N-nitroso-paroxetine	파록세틴(Paroxetine)	-	1,300	SAR/read-across, 참조물질 NPIP ³⁾	2023-12-13
95	N-nitroso-phenylephrine	페닐레프린(Phenylephrine)	2	100	-	2023-12-13
96	N-nitroso-perindopril	페린도프릴(Perindopril)	5	1,500	-	2023-12-13
97	N-nitroso-felodipine	펠로디핀(Felodipine)	5	1,500	-	2023-12-13
98	N-nitroso-calcium folinate	폴리네이트칼슘(Calcium folinate/ Calcium levofolinate)	-	ICH Q3A/Q3B에 따라 관리	비변이원성 불순물	2024-03-20
99	N-nitroso-furosemide	푸로세미드(Furosemide)	4	1,500	-	2023-12-13
100	N-nitroso-pramipexole	프라미펙솔(Pramipexole)	3	400	-	2023-12-13
101	N-nitroso-frovatriptan/(3R)-2,3,4,9-tetrahydro-3-(N-methyl(nitroso)amino)-1H-carbazole-6-carboxamide	프로바트립탄(Frovatriptan)	3	400	-	2023-12-13
102	N-nitroso-propanolol	프로프라놀롤(Propanolol)	4	1,500	-	2023-12-13
103	N-nitroso-flecainide	플레카이니드(Flecainide)	4	1,500	-	2023-12-13
104	N-nitroso-fluoxetine	플루옥세틴(Fluoxetine)	-	100	SAR/read-across, 참조물질 NNK ²⁾	2023-12-13
105	N-nitroso-hydrochlorothiazide	히드로클로로티아지드 (Hydrochlorothiazide)	-	ICH Q3A/Q3B에 따라 관리	비변이원성 불순물	2023-12-13

- 1) NTHP : N-nitroso-1,2,3,6-tetrahydropyridine
2) NNK : 4-(methylnitrosoamino)-1-(3-pyridinyl)-1-butanone
3) NPIP : N-nitroso-piperidine
4) NPYR : N-nitroso-pyrrolidine