

Chemical Information Sheet Version 2.0 | March 2021

NITROSAMINES

Other Names	N-Nitrosamines	
CAS Number	Substance	
62-75-9	N-nitrosodimethylamine (NDMA)	
55-18-5	N-nitrosodiethylamine (NDEA)	
621-64-7	N-nitrosodipropylamine (NDPA)	
List continued in "Additional Information"		
May Be Found In	 Agricultural chemicals (pesticides) Rubber Plastics Solvents Tanned leather (if amines are used to accelerate liming process) Textiles 	

Detergents²

Nitrosamines are a class of chemicals that are inadvertently produced under specific conditions, and which can be avoided with proper chemicals management and reaction conditions. Nitrosamines are commonly found in some cooked meats and tobacco smoke and may be present in materials used in apparel and footwear such as rubber or plastic.

Uses in the Supply Chain

Nitrosamines are produced when nitrites react with nitrosatable substances (secondary or tertiary amines) under certain conditions, such as exposure to acidic pH values, high temperatures, and presence of certain reducing agents. Nitrosamines are avoidable by paying close attention to the chemical reaction conditions during production.

There is no publicly documented case of intentional addition or functional use of nitrosamines in consumer food or non-food products. Nitrosamines have been detected as contaminants in a number of products including rubber products, foods, beer, tobacco products, and cosmetics.¹

Why Nitrosamines are Restricted

- Legislation in major markets around the world restricts the presence of nitrosamines in finished products.
- Nitrosamines are a large group of chemicals and each specific chemical may have slightly different toxicity classifications.
- Nitrosamines are suspected carcinogens and are typically classified in the GHS system as Class 1 or 2 carcinogens.
- Other hazards including acute toxicity and specific target organ effects may also be listed and are specific to each chemical in the nitrosamine class.
- Chemical hazard information for many chemicals can be found at the following external databases:
 - o GESTIS Substance Database: Here (external link)
 - US National Library of Medicine: <u>Here (external link)</u>
 - o US OSHA Occupational Chemical Database: Here (external link)

Sourcing Compliant Materials from Your Suppliers

- Contact your suppliers and explain that you require their manufactured materials to be compliant with the current AFIRM RSL limits.³
- Require suppliers to submit a confirmation of material compliance or a test report from a third-party laboratory.
- When materials are received, consider performing risk-based testing to ensure the current AFIRM RSL limits are met.



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- Share this information sheet with your material suppliers so they have full visibility and understand your sourcing requirements.
- There is a potential for rubber and plastic materials to contain nitrosamines when produced under specific conditions.
- Pay special attention to suppliers of plastics and rubbers.

Sourcing Compliant Formulations from Your Chemical Suppliers

- For all formulations, request SDS documentation that meets current GHS requirements.
- Contact your suppliers and explain that you require formulations to be compliant with the current ZDHC MRSL limits whenever applicable.⁴
- Prior to procuring any formulation, the chemical properties must be reviewed to ensure that proper protective
 equipment, chemical storage facilities, facility engineering controls, and associated treatment/disposal facilities are
 appropriate for the chemical(s).
- Pay special attention to suppliers of polymer starting materials and the accelerants used for polymerization or vulcanization.
- Some vulcanizing agents and accelerators for rubber and plastics are associated with the creation of nitrosamines in the finished material. The following accelerators should be avoided as they have been reported to have the potential to create nitrosamines:
 - Dithiocarbamates
 - Sulfenamides
 - Sulfur donors
 - o Thiurams

Safer Alternatives

Safer alternatives are simply materials that are produced in high quality production environments with suitable controls in place to avoid creation of nitrosamine substances. These chemicals are not intentionally added to any material but are byproducts from other processing.

Additional Information

Visit ECHA's Candidate List of substances of very high concern to view dossiers for many restricted substances https://echa.europa.eu/candidate-list-table.

In some cases, the use of specific chemicals in wastewater treatment plants can cause the formation of nitrosamines in the effluent. The use of organic coagulants (e.g., polydiallyldimethylammonium chloride or PolyDADMAC) and polyamine chemistries may accelerate the formation of nitrosamines in the treatment process, which could impact production if recycled water is used.⁵

Continued list of CAS numbers and substance names from first page:

CAS Number	Substance
924-16-3	N-nitrosodibutylamine (NDBA)
100-75-4	N-nitrosopiperidine (NPIP)
930-55-2	N-nitrosopyrrolidine (NPYR)
59-89-2	N-nitrosomorpholine (NMOR)
614-00-6	N-nitroso N-methyl N-phenylamine (NMPhA)
612-64-6	N-nitroso N-ethyl N-phenylamine (NEPhA)



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References

¹ European Union Scientific Committee on Consumer Products. Presence and Release of Nitrosamines and Nitrosatable Compounds from Rubber Balloons. (2007) http://ec.europa.eu/health/ph-risk/committees/04-sccp/docs/sccp-o-121.pdf

² National Toxicology Program. (2016). Report on Carcinogens, Fourteenth Edition. Retrieved December 18, 2017 from https://ntp.niehs.nih.gov/ntp/roc/content/profiles/nitrosamines.pdf

³ Apparel and Footwear International RSL Management Group Restricted Substances List (AFIRM RSL) http://afirm-group.com/afirm-rsl/

⁴ ZDHC Manufacturing Restricted Substances List (ZDHC MRSL) https://www.roadmaptozero.com/mrsl online/

⁵ Water Research Foundation (2015). Controlling the Formation of Nitrosamines During Water Treatment. Retrieved on April 4, 2017, from https://www.waterrf.org/research/projects/controlling-formation-nitrosamines-during-water-treatment