

Read :-1. Application dated 23rd June, 2005 of M/s. Inox Air Products Ltd., holder of Certificate of Registration No. 411014/S/471 dt. 1/4/1996.

2. This office letter dt.3rd Jan, 2006 calling the applicant for hearing on 10th Jan, 2006.

Heard :- Shri. P. V. Surte, Advocate attended on behalf of the applicant.

PROCEEDINGS

(Under section 56(1) (e) and (2) of the Maharashtra Value Added Tax Act, 2002)

No.DDQ-11-05/Adm-5/44/B-4

Mumbai,dt. 27/03/2006

The applicant is a registered dealer under the Maharashtra Value Added Tax Act, 2002 and is a manufacturer of industrial gases such as Oxygen, Hydrogen, Acetylene Argon, Nitrogen, Medical Oxygen etc. The applicant is a manufacturer of Nitrous Oxide under the license granted under the Drugs & Cosmetic Act, 1940. In this application, the applicant has sought to know the rate of tax on 'Nitrous Oxide' and hence has enclosed by way of evidence, the bill No. 3267 dated 14th June, 2005. The applicant has charged sales tax @ 4% on the sales of the product considering them as Drugs covered by Schedule Entry C 29 of the Maharashtra Value Added Tax Act, 2002.

EVIDENCES

02. The applicant has enclosed certificates issued by the following Doctors and Hospitals as to the use of 'Nitrous Oxide' :

- a) Dr. Pradeep M. Khopkar (M.D. (Bom.) D.G.O, F.I. C.O.G) : "It is certified that Nitrous Oxide gas is required for treatment and necessary anaesthetic for mitigation in ward and Operation theatres."
- b) Indian Burns Research Society : Dr. Trupti Naidu (M.B.B.S.) has certified that Nitrous Oxide is used in their Operation theatre for anaesthetic purpose.
- c) Dr. Rajiv Chandra (M.S.) : "It is certified that I.P. Gr. Nitrous Oxide is used in their Operation theatre, Intensive Care Unit & Casualty Department for treatment of Trauma patients for anaesthesia purpose."
- d) Indravati Hospital - Dr. Rakesh Chaturvedi (M.S.(Ortho)) : It is certified that I.P. Gr. Nitrous Oxide is used in their Operation theatre, Intensive Care Unit & Casualty Department for treatment of Trauma patients for mitigation.
- e) Criti-Care ICCU & Speciality Centre : Dr. Sundeep G. Mestri (M.D.) has certified that I.P. Gr. Nitrous Oxide is used in their Operation theatre, Intensive Care Unit & Casualty Department for treatment of Trauma patients for mitigation.
- f) Mody Hospital & ICCU : Dr. Praveen Mody has certified that I.P. Gr. Nitrous Oxide is used in their Operation theatre, Intensive Care Unit & Casualty Department for treatment of Trauma patients for mitigation.
- g) Dr. Sanjay N. Doke (M.S.(BOM)) : "It is certified I.P. Gr. Nitrous Oxide is used in their Operation theatre, Intensive Care Unit & Casualty Department for treatment of Trauma patients for anaesthesia purpose."

DETAILS SUBMITTED ALONG WITH THE APPLICATION

03. The following documents are enclosed along with the application.

- (1) License of manufacture for sale (or for distribution) of drugs other than those specified in schedules C, C (1) and X.
- (2) Copy of sale bill.

- (3) Copies of certificates given by the Doctors/hospitals.
- (4) A copy of Undertaking for the manufacture of Medical Oxygen and Nitrous Oxide.
- (5) A copy of the process for the production of Nitrous Oxide along with Flow Diagram.

CONTENTION

04. It is the contention of the applicant that the product qualifies as 'a medicinal formulation or preparation ready for use internally or on the body of human beings, for diagnosis, treatment, mitigation or prevention of any diseases'. Nitrous oxide is a colorless gas used by inhalation as a general anesthetic. It is a drug used in operation theatre as an anesthetic agent. Thus, Nitrous oxide being a drug used for treatment at the time of operation is liable to tax @ 4% under schedule entry C-29 of the Maharashtra Value Added Tax Act, 2002.

Alternatively, the appellant also prays that in case it is held otherwise, the determination order be given prospective effect.

HEARING

05. The case was fixed for hearing on 10th Jan, 2006. Shri. P. V. Surte, Advocate attended. He submitted that the product under consideration, i.e., Nitrous oxide is a drug covered by entry C-29 since it is used for treatment as well as for mitigation of not only diseases but also disorder. It is also manufactured under a license under The Drugs & Cosmetics Act, 1940. They have also produced evidence in the form of certificates from doctors certifying that the product is used for the treatment and mitigation of diseases and disorder.

During the hearing, the applicant's advocate has submitted a copy of the Advance Ruling given under the Karnataka Value Added Tax Act, wherein the said product is treated as medicine.

OBSERVATIONS

06. The basic question for decision here relates to classification of 'Nitrous oxide'. The applicant's contention revolves around the point that as the impugned product is manufactured under the Drugs License given by the Food & Drug Administration under the Drugs & Cosmetics Act, 1940 and is used by the hospitals and dispensaries for treatment at the time of operation, the product qualifies as a drug under schedule entry C-29 of the Maharashtra Value Added Tax Act, 2002.

Similar question is already decided in the case of M/s. Sunny Industrial Gases, No.DDQ-11-2002/Adm-5/18/B-7 Mumbai, dt. 31.01.2003 in which the product was held as covered by residual entry and was not held as a drug covered by the then entry for drugs which was C-II-37 of the Bombay Sales Tax Act, 1959. The schedule entry under consideration in the case of M/s. Sunny Industrial Gases pertained to the classification under the Bombay Sales Tax Act, 1959 and the classification in the present case pertains to the schedule entry under the Maharashtra Value Added Tax Act, 2002. With respect to this reason, it is felt reasonable that the application of the applicant could be re-considered and re-examined in the light of the classification under the new Act and therefore, it escaped from the reach of section 56(3) of the Maharashtra Value Added Tax Act.

In understanding the product one has to look at the characteristics and nature of the product. The Characteristics of the product could be illustrated as under : 1. It is a colorless gas. 2. It is gaseous in form.

The gas is used in hospitals for operations. The question before me is, whether the fact that Nitrous oxide is used in hospitals and dispensaries, would be adequate to vest it with the quality of a drug? The answer is provided by the wording of the schedule entry C-29 itself. The schedule entry C-29 of The Maharashtra Value Added Tax Act, 2002 could be reproduced thus :

Drugs (including Ayurvedic, Siddha, Unani, spirituous Medical Drugs and Homoeopathic Drugs), being formulations or preparations conforming to the following descriptions :-

Any medicinal formulation or preparation ready for use internally or externally on human beings, animals and birds for diagnosis, treatment, mitigation or prevention of any diseases or disorders which is manufactured or imported into India, stocked, distributed or sold

but does not include mosquito repellants in any form.

What should be the characteristics of a drug are sufficiently laid down in schedule entry C-29 and the entry can be broken up into constituents for the sake of understanding. A product, in order to be a drug, should fulfill all the following conditions simultaneously :-

1. It should be a formulation or preparation ready for use internally or externally on the human body.
2. It should be used for diagnosis, treatment, mitigation or prevention of any disease or disorder.
3. It should be manufactured or imported into India, stocked distributed or sold under a license under the Drugs & Cosmetics Act, 1940.

It is contended by the applicant that 'Nitrous oxide' is not a formulation but it is a preparation. I agree with this proposition. It is a preparation which is also ready for use internally as it is inhaled by the patients, thereby satisfying the first condition. The product satisfies the third condition as it carries license under the Drugs & Cosmetics Act.

The crucial aspect is whether it could be said with a degree of confidence that the Nitrous oxide IP is used for either diagnosis or treatment or mitigation or prevention of any disease or disorder? In other words, whether it fulfills the second condition is a crux of the matter, **i.e., whether Nitrous oxide diagnoses or treats or mitigates or prevents disease or disorder?** I would have to examine the question from this angle.

For obvious reasons, Nitrous oxide is incapable of diagnosing any disease. Normally, when a person undergoes any operation, the entire process involves a dissection of one's body. Therein emerges the need for anaesthesia. That part of a person's body on which it is administered becomes numb and has no sensation of any kind. Is such a use, sufficient to qualify it as a drug? The answer cannot be in the affirmative. It cannot be said that Nitrous oxide is used for treatment of the disease or disorder.

Oxygen is an important element on which the human species live and would die without it. It is like water, a life sustaining element of nature. When any human being fails to draw oxygen from the air on his own or unable to inhale it properly or adequately or does not get sufficient water, such a person would definitely die. This does not mean that oxygen or as the case may be water, is a medicine or drug. They are items of general utility and life sustaining but that does not imply that they can be termed as 'medicine' or 'drugs'.

The fact that Nitrous oxide is IP grade does not make it a pharmaceutical preparation. The IP grade only denotes the purity and its fitness for human inhalation. When oxygen is naturally inhaled from the air or the atmosphere, it need not be of IP grade because the intake is normal and natural with filters provided in the body. But Nitrous oxide is artificially prepared and artificially administered which renders it necessary to be of certain degree of purity making it fit for human consumption. IP grade, therefore, does not make it a drug. It simply declares the fitness of the product for human consumption.

A drug needs to have therapeutic characteristics and Nitrous oxide does not have therapeutic quality or attributes. Is Nitrous oxide used in the treatment of the disease or disorder for which the patient is being operated? Nitrous oxide does not treat diseases.

This brings us to the next question as to **whether Nitrous oxide mitigates disorder or disease?** The answer is again negative. It is true that in operations/surgeries, the use of Nitrous oxide provides relief and comfort to the patients in question. Just because the patient is administered Nitrous oxide due to his inability to bear pain naturally would not make Nitrous oxide a drug. Nitrous oxide does not mitigate or treat diseases. Therefore, I do not agree with the submission of Shri P.V.Surte, Advocate that Nitrous oxide is used for mitigation, prevention or treatment of any diseases or disorder.

Nitrous Oxide does not fall in the category of drugs used for diagnosis, treatment, mitigation or prevention of any disease or disorder.

I have gone through the certificates produced by the applicant. It is stated that IP grade Nitrous Oxide is used in their Operation theatre, Intensive Care Unit & Casualty Department for treatment of Trauma patients for anaesthesia purposes. This only confirms what I have said earlier that Nitrous Oxide only aids in avoiding the pain caused during operation. It has not been recognized as a drug or medicine which, when administered, cures the very disease or disorder for which the patient is being operated. The Certificates have not made any categorical

with respect to the resolution of the issue on hand. These are certificates of interest to the applicant.

The classification of a product under the schedule entry for drugs can be done only with reference to the specific wording of the entry C-29 and the conditionalities provided therein for a product to satisfy. These conditions cannot be ignored or overlooked. The history of the entry shows that products have been considered to be drugs only when they satisfy the primary characteristics as laid down in the entry itself. In the present case, Nitrous Oxide cannot be considered to be a drug as it does not satisfy the essential condition of treatment and mitigation of disease and disorder.

JUDGMENTS

07. Let me also have a look at the determination order in the applicant's own case –

- (a) M/s. Inox Air Products Ltd., [No. DDQ-11-05/Adm-5/19/B-1 Mumbai, dt. 21.07.2005] : It was held that sales of medical oxygen were not covered by Schedule Entry C-29 of the Maharashtra Value Added Tax Act, 2002 on Drugs but are exigible to tax @12.5% in accordance with the residuary schedule entry E-1 of the Maharashtra Value Added Tax Act, 2002. It was held that medical oxygen is not used for mitigation, prevention or treatment of any disease or disorder as understood by the above mentioned entry on drugs.

PROSPECTIVE EFFECT

08. The applicant has prayed for prospective effect to the order under section 56(2) in case the determination is not held in his favour. In these circumstances, the plea of the applicant could not be entertained as there is no statutory misguidance in the matter. The entry relating to drugs, viz. C-II-37 under the Bombay Sales Tax Act, and C-29 under the Maharashtra Value Added Tax Act, 2002, are parimateria same. There is already a determination in the case of M/s. Sunny Industrial Gases, No. DDQ-11-2002/Adm-5/18/B-7 Mumbai, dt. 31.01.2003, holding medical oxygen as not a drug. The determination in the case of M/s Sunny Industrial Gases had comprehensively and categorically held that medical oxygen is not a medicine. Therefore, there was a statutory precedent as regards a product of a similar nature which should have been made use of for guidance by the applicant. The applicant, therefore, cannot be successful in his request for prospective effect since no reasoning of statutory misguidance of any kind has been established.

AMENDMENT TO SCHEDULE ENTRY C-29 W.E.F 01/02/2006

09. The Schedule entry 29 as it reads w.e.f 01/02/2006 is reproduced hereinbelow.

- " 29. (a) Drugs (including Ayurvedic, Siddha, Unani, Spirituous Medical Drugs and Homoeopathic Drugs), being formulations or preparations conforming to the following description :-

Any medicinal formulation or preparation ready for use internally or on the body of human beings, animals, and birds for diagnosis, treatment, mitigation or prevention of any diseases or disorders, which is manufactured or imported into India, stocked, distributed or sold under licence granted under the Drug and Cosmetic Act, 1940, but does not include mosquito repellants in any form.

- (b) Medical Oxygen and Nitrous Oxide manufactured under licence

granted under the Drug and Cosmetic Act, 1940."

With the above amendment to the Schedule entry C-29, Medical Oxygen & Nitrous Oxide have been inserted in the entry on drugs as a sub-entry. It is to be noted that this addition is by way of a sub-entry. The sub-entry (a) of entry 29 pertains to medicinal formulations or preparations which are used in diagnosis, treatment, mitigation or prevention of any disease or disorder. The sub-entry (b) of entry 29 pertains to Medical Oxygen & Nitrous Oxide manufactured under Drug & Cosmetics Act, 1940.

This insertion of Medical Oxygen & Nitrous Oxide by way of a sub entry to entry C-29 of the Maharashtra Value Added Tax Act, 2002 has made them taxable @ 4%. Thus, the Schedule entry and the rate of tax applicable to Nitrous Oxide under Maharashtra Value Added Tax Act, 2002 is as follows :-

Period	Schedule entry	Rate of Tax
1.4.2005 to 31.1.2006	E-1	12.5%
1.2.2006 onwards	C-2	4%

The Schedule Entry 29 is amended w.e.f. 1.2.2006, and a sub-entry (b) is introduced to include in its ambit medical oxygen and Nitrous oxide. This subsequent amendment to Schedule Entry, confirms my views that Nitrous oxide is not a drug and it is given the benefit of a lower tax regime as a medical product other than a drug with effect from 01/02/2006 only.

10. In the context of the deliberations detailed hereinabove, it is hereby ordered that,-

ORDER

(Under section 56(1) & (2) of the Maharashtra Value Added Tax Act, 2002)

No.DDQ-11-05/Adm-5/44/B-04

Mumbai,dt. 27.03.2006

It is hereby held that the sales of Nitrous Oxide effected through bill No. 3267 dated 14th June, 2005 would be exigible to tax @ 12.5% in accordance with schedule entry E-1 of the Maharashtra Value Added Tax Act, 2002.

The applicant's request of prospective effect is also rejected for the reasons mention in para 8 of the judgment.

In view of the amendment to the Schedule under the Maharashtra Value Added Tax Act,2002, Nitrous Oxide becomes covered by the Schedule entry C-29 w.e.f. 1st February,2006, thereby attracting tax @ 4%.

(B. C. KHATUA)

Commissioner of Sales Tax,

Maharashtra State, Mumbai.

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